1 IDENTIFICAZIONE DELLA SOSTANZA / MISCELA E DELLA SOCIETÀ / IMPRESA

1.1 Identificatore del prodotto
Nomi commerciali / sinonimi: : SANYMAYER.
PRESIDIO MEDICO CHIRURGICO
Registrazione del Ministero della Sanità N°19.523

1.2 Usi pertinenti identificati della sostanza o miscela e usi sconsigliati : AEROSOL DISINFETTANTE GERMICIDA CON AZIONE BATTERICIDA, FUNGICIDA E VIRUCIDA.
Ogni altro uso non è consentito.

1.3 Informazioni sul fornitore della scheda di dati di sicurezza : MAYER BRAUN DEUTSCHLAND Srl.
Via Brigata Marche n. 129
31030 CARBONERA (TV)
Tel. 0422 445455
Fax 0422 398244
http://www.mayerbraun.com

Email persona competente : question@mayerbraun.com

1.4 Numero telefonico di emergenza : Mayer Braun Deutschland Tel. 0422 445455 (8.00 am - 18 pm lun-ven)
pCAV Osp. Pediatrico Bambino Gesù" - Roma - Tel. 0668593726
Az. Osp. Univ. Foggia - Foggia - Tel. 0881-732326
Az. Osp. "A. Cardarelli" - Napoli - Tel. 081-7472870
CAV Policlinico "Umberto I" - Roma - Tel. 06-49978000
CAV Policlinico "A. Gemelli" - Roma - Tel. 06-3054343
Az. Osp. "Careggi" U.O. Tossicologia Medica - Firenze Tel. 055-7947819
CAV Centro Naz. di Informazione Tossicologica - Pavia - Tel. 038224444
Osp. Niguarda Ca' Granda - Milano Tel. 02-66101029
Azienda Ospedaliera Papa Giovanni XXIII - Bergamo - Tel. 800883300

2 IDENTIFICAZIONE DEI PERICOLI

2.1 Classificazione della sostanza o della miscela

Il prodotto è classificato pericoloso ai sensi delle disposizioni di cui al Regolamento (CE) 1272/2008 (CLP) (e successive modifiche ed adeguamenti). Il prodotto pertanto richiede una scheda dati di sicurezza conforme alle disposizioni del Regolamento (CE) 1907/2006 e successive modifiche.

Classificazione secondo il regolamento 1272/2008/CE: : Aerosol, categoria di pericolo 1
Irritazione oculare, categoria 2
Irritazione cutanea, categoria 2
Sensibilizzazione della pelle, categoria 1
Tossicità cronica per l'ambiente acquatico, categoria di pericolo 3

2.2 Elementi dell'etichetta

Etichettatura di pericolo ai sensi del Regolamento (CE) 1272/2008 (CLP) e successive modifiche ed adeguamenti.

Pittogrammi di pericolo:

Avvertenze : PERICOLO

Indicazioni di pericolo : PERICOLI FISICI:
H222 Aerosol estremamente infiammabile.
H229 Contenitore pressurizzato: può scoppiare se riscaldato.
PERICOLI PER LA SALUTE:
H315 Provoca irritazione cutanea.
H319 Provoca grave irritazione oculare.

H317 Può provocare una reazione allergica cutanea.

PERICOLI PER L'AMBIENTE:
H412 Nocivo per gli organismi acquatici con effetti di lunga durata.

Consigli di prudenza : P102 Tenere fuori dalla portata dei bambini.
P210 Tenere lontano da fonti di calore, superfici calde, scintille, fiamme libere o altre fonti di accensione. Non fumare.
P211 Non vaporizzare su una fiamma libera o altra fonte di accensione.
P251 Non perforare né bruciare, neppure dopo l'uso.
P280 Indossare guanti/Proteggere gli occhi/il viso.
P302+P352 IN CASO DI CONTATTO CON LA PELLE: lavare abbondantemente con acqua e sapone.
PP305+P351+P338 IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare.
P313 Consultare un medico.
P403 Conservare in luogo ben ventilato.
P410+P412 Proteggere dai raggi solari. Non esporre a temperature superiori a 50 °C/122 °F.
P501 Smaltire il contenuto/recipiente in conformità alla regolamentazione nazionale.

Informazioni supplementari : EUH 208 Contiene: alfa-Pinene; Eucaliptolo; Pin-2(3)-ene. Può provocare una reazione allergica.

EUH 401 Per evitare rischi per la salute umana e per l'ambiente, seguire le istruzioni per l'uso.

Contiene : Olio da foglie di EUCALYPTUS GLOBULUS (Spagna).

2.3 Altri pericoli

Proprietà PBT o vPvB : Questa miscela non contiene componenti considerati sia persistenti, bioaccumulabili che tossici (PBT), oppure molto persistenti e molto bioaccumulabili (vPvB) a concentrazioni di 0.1% o superiori.

Altri pericoli : Contenitore pressurizzato. Proteggere dai raggi solari e non esporre a temperature superiori a 50 °C. Non perforare né bruciare neppure dopo l'uso. Non spruzzare su una fiamma o su corpo incandescente - NON FUMARE. Il riscaldamento del contenitore aumenta la pressione con rischio di scoppio.

3 COMPOSIZIONE/INFORMAZIONI SUGLI INGREDIENTI.

3.1 Sostanza : Non applicabile. Questo prodotto è regolato come miscela.

3.2 Miscela : Miscela delle sostanze sotto indicate pericolose per la salute ai sensi del Regolamento 1272/2008/CE (e successivi adeguamenti) o per le quali esistono limiti di esposizione riconosciuti:

N°. CAS	REGISTRAZIONE	N°. CE	N°. INDICE	Classificazione	Concentrazione
ETANOLO					
64-17-5	01-2119457610-43	200-578-6	603-002-00-5	Flam. Liq. 2 H225, Eye Irrit. 2 H319	50 ≤ x < 100
BUTANO					
106-97-8	01-2119474691-32	203-448-7	601-004-00-0	Flam. Gas 1 H220, Nota K	9 ≤ x < 30 %
PROPANO					
74-98-6	01-2119486944- 21	200-827-9	200-827-9	Flam. Gas 1 H220 Nota K	9 ≤ x < 30 %
ISOBUTANO					
75-28-5	01-2119485395-27	200-857-2	601-004-00-0	Flam. Gas 1 H220, Nota K	5 ≤ x < 9 %

2-PROPANOLO					
67-63-0	01-2119457558-25	200-661-7	603-117-00-0	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336	2 ≤ x < 3 %
Propionato di N,N-didecil-N-metil- poli (ossietil) ammonio (bardap 26)					
94667-33-1	01-2119950327-36	619-057-3	---	Acute Tox. 4 H302, Skin Corr. 1A H314, Aquatic Acute 1 H400 M = 10 Aquatic Chronic 1 H410 M=1	0,5 ≤ x < 1 %
OLIO DA FOGLIE DI EUCALYPTUS GLOBULUS (Spagna)					
8000-48-4	01-2119978250-37	283-406-2	---	Flam. Liq. 3 H226 Asp. Tox. 1 H304 Skin Irrit. 2 H315 Skin Sens. 1 H317 Aquatic Chronic 2 H411	0,1 ≤ x < 1 %
EUCALIPTOLO					
470-82-6	01-2119967772-24	207-431-5	---	Flam. Liq. 3 H226 Skin Sens. 1 H317	0,1 ≤ x < 0,4 %
ETAN-1,2 DIOLO SOSTANZA CON LIMITE DI ESPOSIZIONE COMUNITARIO					
107-21-1	01-2119456816-28	203-473-3	603-027-00-1	Acute Tox. 4 H302, STOT RE 2 H373	0,1 ≤ x < 0,3 %
METILETILCHETONE SOSTANZA CON LIMITE DI ESPOSIZIONE COMUNITARIO					
78-93-3	01-2119457290-43	201-159-0	606-002-00-3	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336, EUH066	0,25 ≤ x < 0,3 %
alfa-PINENE					
7785-26-4	01-2119979519-16	232-077-3	---	Flam. Liq. 3 H226 Asp. Tox. 1 H304 Skin Irrit. 2 H315 Skin Sens. 1 H317 Aquatic Chronic 1 H410	0,1 ≤ x < 0,3 %
PIN-2(3)-ENE					
80-56-8	---	201-291-9	---	Skin Irrit. 2 H315 Flam. Liq. 3 H226 3.10/1 Asp. Tox. 1 H304 Skin Sens. 1B H317 Aquatic Acute 1 H400 M=1 Aquatic Chronic 1 H410 M=1	0,1 ≤ x < 0,3 %

Il testo completo delle indicazioni di pericolo H è riportato al paragrafo 16.

Il prodotto è un aerosol contenente propellenti. Ai fini del calcolo dei pericoli per la salute, i propellenti non sono considerati (salvo che presentino pericoli per la salute). Le percentuali indicate sono comprensive dei propellenti. Percentuale propellenti: 40%.

Questa miscela contiene < 0,1 %/p di 1.3 butadiene (CAS 106-99-0 / EINECS 203-450-8)

Applicabile nota K. La classificazione come cancerogeno non è necessaria se si può dimostrare che LA MISCELA CONTIENE 1,3-BUTADIENE IN PERCENTUALE INFERIORE ALLO 0,1% DI PESO/PESO (EINECS n. 203-450-8). Se la sostanza non è classificata cancerogena o mutagena dovrebbero almeno figurare i consigli di prudenza (P102-) P210-403.

4 MISURE DI PRIMO SOCCORSO

4.1 Descrizione delle misure di primo soccorso

Indicazioni generali	:	In caso di malessere consultare un medico mostrandogli questa scheda di sicurezza.
Inalazione	:	Allontanare il paziente dal luogo d'esposizione e esporlo ad aria fresca. Se non respira attuare respirazione artificiale. Se la respirazione è difficoltosa fornire ossigeno. Consultare il medico.
Contatto con la pelle	:	Lavare con sapone e acqua. Togliersi di dosso gli indumenti contaminati e lavarli prima di riutilizzarli. Consultare un medico se i disturbi persistono.
Contatto con gli occhi	:	Lavare con acqua tiepida per almeno 15 minuti tenendo le palpebre ben aperte e consultare il medico.
Ingestione	:	Non somministrare nulla tramite bocca se il paziente è incosciente. Consultare immediatamente il medico.

4.2. Principali sintomi ed effetti, sia acuti che ritardati : Provoca irritazione cutanea. Provoca grave irritazione oculare. Può provocare una reazione allergica cutanea.

4.3. Indicazione dell'eventuale necessità di consultare immediatamente un medico oppure di trattamenti speciali : Trattare sintomaticamente.

5 MISURE ANTINCENDIO

5.1 Mezzi di estinzione

Mezzi di estinzione idonei : Utilizzare sistemi estinguenti compatibili con la situazione locale e con l'ambiente circostante.

Mezzi di estinzione idonei: acqua nebulizzata, CO_2, schiume, sostanze chimiche asciutte.

Mezzi di estinzione non idonei : Getto d'acqua ad alta potenza.

5.2 Pericoli speciali derivanti dalla sostanza o dalla miscela : Aerosol estremamente infiammabile. In caso di surriscaldamento i contenitori aerosol possono deformarsi, scoppiare e possono essere proiettati a notevole distanza. Indossare un casco di protezione prima di avvicinarsi all'incendio. Evitare di respirare i prodotti di combustione.

In caso di incendio può liberare vapori pericolosi: ossidi di carbonio (CO, CO_2), ossidi di azoto e altri composti organici non definiti potenzialmente tossici.

5.3 Raccomandazioni per gli addetti all'estinzione degli incendi : Indossare indumenti di protezione adatti (maschera, guanti, elmetto), giacca e pantaloni ignifughi e apparato respiratorio autonomo (secondo NIOSH).

Se necessario, indossare in caso di incendio, dispositivi di protezione delle vie respiratorie con apporto d'aria indipendente.

EQUIPAGGIAMENTO Indumenti normali per la lotta al fuoco, come un autorespiratore ad aria compressa a circuito aperto (EN 137), completo antifiamma (EN469), guanti antifiamma (EN 659) e stivali per Vigili del Fuoco (HO A29 oppure A30).

Ulteriori informazioni : Smaltire i residui dell'incendio e l'acqua di spegnimento contaminata secondo le disposizioni della legislazione locale vigente. Fare evacuare il personale dalla zona interessata dall'incendio.

6 MISURE IN CASO DI RILASCIO ACCIDENTALE

6.1 Precauzioni personali, dispositivi di protezione e procedure in caso di emergenza

Per chi non interviene direttamente : Eliminare ogni sorgente di ignizione (sigarette, fiamme, scintille, ecc.) o di calore dall'area in cui si è verificata la perdita. Allontanare le persone non equipaggiate. Indossare guanti / indumenti protettivi / proteggere gli occhi / il viso.

Evacuare il personale in aree di sicurezza. Garantire una ventilazione sufficiente.

Per chi interviene direttamente : Indossare adeguati dispositivi di protezione.

6.2 Precauzioni ambientali : Evitare sversamenti o perdite supplementari, se questo può essere fatto senza pericolo. Non lasciar penetrare il prodotto negli scarichi o nei corsi d'acqua.

6.3 Metodi e materiali per il contenimento e per la bonifica : Per piccole fuoriuscite, pulire con una salvietta di carta e porre in un contenitore per la successiva eliminazione.

Per fuoriuscite abbondanti: impregnare con materiale assorbente inerte (es. sabbia, torba, segatura, etc.) e smaltire come rifiuto. Smaltimento del materiale contaminato conformemente al punto 13.

Lavare accuratamente il luogo in cui è avvenuta la fuoriuscita con acqua e sapone o con una soluzione detergente.

6.4 Riferimenti ad altre sezioni : Consultare la sezione 8 per i dispositivi di protezione individuale. Per lo smaltimento riferirsi alla sezione 13.

7. MANIPOLAZIONE E IMMAGAZZINAMENTO

7.1 Precauzioni per la manipolazione sicura : Evitare l'accumulo di cariche elettrostatiche. Non vaporizzare su fiamme o corpi incandescenti. Non respirare gli aerosol. Conservare lontano da fiamme e scintille - Non fumare.

Evitare ingestione e contatto con pelle ed occhi. Per una manipolazione sicura della sostanza è necessario rispettare le misure generali di igiene occupazionali. Tali misure comprendono buone pratiche personali e gestionali (es. pulizia regolare con detergenti adatti), di non fumare, bere o mangiare nel luogo di lavoro. Non indossare gli abiti contaminati a casa.

7.2 Condizioni per l'immagazzinamento sicuro, comprese eventuali incompatibilità : Conservare ad una temperatura ambiente, al di sotto dei 40°C. Conservare lontano da fonti di calore e luce diretta in un luogo ventilato. Mantenere i contenitori chiusi quando non si utilizza il prodotto. Evitare l'esposizione diretta al sole. Tenere lontano da fiamme libere, scintille ed altre fonti di ignizione. Evitare l'accumulo di cariche elettrostatiche.

Contenitore pressurizzato. Proteggere dai raggi solari e non esporre a temperature superiori a 50 °C. Non perforare né bruciare neppure dopo l'uso. Non spruzzare su una fiamma o su corpo incandescente - NON FUMARE. Il riscaldamento del contenitore aumenta la pressione con rischio di scoppio.

7.3 Usi finali specifici : Informazioni non disponibili.

8 CONTROLLO DELL'ESPOSIZIONE/PROTEZIONE INDIVIDUALE

8.1 Parametri di controllo

Componenti con limiti di esposizione :

Riferimenti Normativi:

ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
EU	OEL EU	Direttiva 2009/161/UE; Direttiva 2006/15/CE; Direttiva 2004/37/CE; Direttiva 2000/39/CE.
	TLV-ACGIH	ACGIH 2016

METILETILCHETONE

Valore limite di soglia.

Tipo	Stato	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV	IT	600	200	900	300
OEL	EU	600	200	900	300
TLV- ACGIH		590	200	885	300

ETAN-1,2-DIOLO

Valore limite di soglia.

Tipo	Stato	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV	IT	52	20	104	40
OEL	EU	52	20	104	40

Monitoraggio : Fare riferimento al D.Lgs 81/2008 e alle buone pratiche di igiene industriale.

DNEL Propionato di N,N- didecil-N-metil- poli(ossietil)ammonio
Uso finale: Lavoratori
Via di esposizione: Inalazione
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 0,5 mg/m3
Uso finale: Lavoratori
Via di esposizione: Contatto con la pelle
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 0,7 mg/kg bw/day
Uso finale: Consumatori
Via di esposizione: Inalazione
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 0,12 mg/m3
Via di esposizione: Contatto con la pelle
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 0,35 mg/kg bw/day
Uso finale: Consumatori
Via di esposizione: Ingestione
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 0,35 mg/kg bw/day

PNEC Propionato di N,N- didecil-N-metil- poli(ossietil)ammonio
Valore di riferimento in acqua dolce 0,001 mg/l
Valore di riferimento in acqua marina nessun dato disponibile
Valore di riferimento STP 0,118 mg/l
Valore di riferimento per sedimenti in acqua dolce 5,3 mg/kg
Valore di riferimento per sedimenti in acqua marina nessuna esposizione attesa
Valore di riferimento per il compartimento terrestre 2,83 mg/kg

DNEL ETANOLO
Uso finale: Lavoratori
Via di esposizione: Inalazione
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 950 mg/m3
Uso finale: Lavoratori
Via di esposizione: Contatto con la pelle
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 343mg/Kg bw/day
Uso finale: Consumatori
Via di esposizione: Inalazione
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 114 mg/m3
Via di esposizione: Contatto con la pelle
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 206 mg/kg bw/day
Uso finale: Consumatori
Via di esposizione: Ingestione
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 87 mg/kg bw/day

PNEC ETANOLO

Valore di riferimento in acqua dolce 0,96 mg/l
Valore di riferimento in acqua marina 0,79 mg/l
Valore di riferimento per sedimenti in acqua dolce 3,6 mg/kg
Valore di riferimento per sedimenti in acqua marina 2,9 mg/kg
Valore di riferimento per i microorganismi STP 580 mg/l
Valore di riferimento per la catena alimentare (avvelenamento secondario) 0,38 g/kg
Valore di riferimento per il compartimento terrestre 0,63 mg/kg

DNEL 2-PROPANOLO
Uso finale: Lavoratori
Via di esposizione: Inalazione
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 500 mg/m3
Uso finale: Lavoratori
Via di esposizione: Contatto con la pelle
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 888 mg/Kg bw/day
Uso finale: Consumatori
Via di esposizione: Inalazione
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 89 mg/m3
Via di esposizione: Contatto con la pelle
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 319 mg/kg bw/day
Uso finale: Consumatori
Via di esposizione: Ingestione
Potenziali conseguenze sulla salute: Lungo-termine - effetti sistemici Valore: 26 mg/kg bw/day

PNEC 2-PROPANOLO
Valore di riferimento in acqua dolce 140,9 mg/l
Valore di riferimento in acqua marina 140,9 mg/l
Valore di riferimento per i microorganismi STP 2251 mg/l
Valore di riferimento per sedimenti in acqua dolce 552 mg/kg
Valore di riferimento per sedimenti in acqua marina 552 mg/kg
Valore di riferimento per il compartimento terrestre 28 mg/kg
Valore di riferimento per la catena alimentare (avvelenamento secondario) 160 mg/kg

8.2 Controlli dell'esposizione

Controlli tecnici idonei	:	Usare solo con ventilazione adeguata. Eseguire il processo in condizioni di contenimento, usare sistemi di aspirazione localizzata o altri dispositivi di controllo per mantenere l'esposizione degli operatori a inquinanti nell'aria al di sotto di qualsiasi limite consigliato o prescritto dalla legge.
Protezione per gli occhi e per il volto	:	Occhiali di sicurezza conformi alla norma EN166. Non indossare lenti a contatto. Si consiglia anche la presenza di un dispositivo lavaocchi individuale.
Protezione della pelle	:	Utilizzare i guanti. Materiali adeguati: gomma butilica; nitrile. Tempo di permeazione: ≥ 4h; spessore: 0,5 mm. Osservare le istruzioni riguardo la permeabilità e il tempo di penetrazione che sono fornite dal fornitore di guanti.
Protezione del corpo	:	Non necessaria per l'utilizzo normale.
Protezione respiratoria	:	In caso di superamento del valore di soglia (es. TLV-TWA) della sostanza o di una o più delle sostanze presenti nel prodotto, si consiglia di indossare una maschera con filtro di tipo AX (rif. norma EN 14387). L'utilizzo di mezzi di protezione delle vie respiratorie è necessario in caso le misure tecniche adottate non siano sufficienti per limitare l'esposizione del lavoratore ai valori di soglia presi in considerazione. La protezione offerta dalle maschere è comunque limitata.
Controlli dell'esposizione ambientale	:	Le emissioni da processi produttivi, comprese quelle da apparecchiature di ventilazione dovrebbero essere controllate ai fini del rispetto della normativa di tutela ambientale. Non gettare i residui nelle fognature.

9 PROPRIETÀ FISICHE E CHIMICHE

9.1 Informazioni sulle proprietà fisiche e chimiche fondamentali

Aspetto	:	aerosol incolore
Odore	:	Tipico
Soglia olfattiva	:	Nessun dato disponibile.
pH	:	Nessun dato disponibile.
Punto di fusione / punto di congelamento	:	Nessun dato disponibile.
Punto di ebollizione iniziale e intervallo di ebollizione.	:	Nessun dato disponibile.
Punto di infiammabilità	:	Non determinato.
Velocità di evaporazione	:	Nessun dato disponibile.
Infiammabilità (solidi, gas)	:	Nessun dato disponibile.
Limiti superiore/inferiore di infiammabilità	:	inferiore: 1,8 % (V/V).
	:	superiore: 9,5 % (V/V).
Tensione di vapore	:	Nessun dato disponibile.
Densità di vapore	:	Nessun dato disponibile.
Densità relativa	:	Nessun dato disponibile.
Solubilità (acqua)	:	Parzialmente solubile.
Coefficiente di ripartizione n-ottanolo/acqua	:	Nessun dato disponibile.
Temperatura di autoaccensione	:	Nessun dato disponibile.
Temperatura di decomposizione	:	Nessun dato disponibile.
Proprietà esplosive	:	Non disponibile.
Proprietà ossidanti	:	Non disponibile.

9.2 Altre Informazioni

VOC (Direttiva 2010/75/CE) : 98 %
VOC (carbonio volatile) : 0
PRESSIONE (Bar) : 3-4 bar
Punto di infiammabilità/Flash point: < -60°C (rif. propellente)

10 STABILITÀ E REATTIVITÀ

10.1 Reattività : Non reattivo.

10.2 Stabilità chimica : Il prodotto è stabile nelle normali condizioni di utilizzo e di stoccaggio.

10.3 Possibilità di reazioni pericolose : Non sono previste reazioni pericolose.

ETANOLO
Rischio di esplosione a contatto con: metalli alcalini, ossidi alcalini, ipoclorito di calcio, monofluoruro di zolfo, anidride acetica, acidi, perossido di idrogeno concentrato, perclorati, acido perclorico, percloronitrile, nitrato di mercurio, acido nitrico, argento, nitrato di argento, ammoniaca, ossido di argento, ammoniaca, agenti ossidanti forti, diossido di azoto. Può reagire pericolosamente con: bromo acetilene, cloro acetilene, trifluoruro di bromo, triossido di cromo, cromil cloruro, fluoro, potassio ter-butossido, idruro di litio, triossido di fosforo, platino nero, cloruro di zirconio (IV), ioduro di zirconio (IV). Forma miscele esplosive con: aria.

10.4 Condizioni da evitare : Evitare il calore e le fiamme libere.

ETANOLO
Evitare l'esposizione a: fonti di calore, fiamme libere.

10.5 Materiali incompatibili : Forti riducenti e ossidanti, basi e acidi forti, materiali ad elevata temperatura.

10.6 Prodotti di decomposizione pericolosi : In caso di incendio si possono sviluppare: NO_x, CO, CO_2 e sostanze organiche non definite.

11 INFORMAZIONI TOSSICOLOGICHE

In mancanza di dati tossicologici sperimentali sul prodotto stesso, gli eventuali pericoli del prodotto per la salute sono stati valutati in base alle proprietà delle sostanze contenute, secondo i criteri previsti dalla normativa di riferimento per la classificazione.
Considerare perciò la concentrazione delle singole sostanze pericolose eventualmente citate in sez. 3, per valutare gli effetti tossicologici derivanti dall'esposizione al prodotto.

11.1 Informazioni sugli effetti tossicologici :

Tossicità acuta

MISCELA
LC50 (Inalazione - vapori) della miscela:
Non classificato (nessun componente rilevante).
LC50 (Inalazione - nebbie / polveri) della miscela:
Non classificato (nessun componente rilevante).
LD50 (Orale) della miscela:
Non classificato.
LD50 (Cutanea) della miscela:
Non classificato (nessun componente rilevante).

Propionato di N,N-didecil-N-metil-poli(ossietil)ammonio
LD50 (Orale) 1157 mg/kg ratto OECD 401

2-PROPANOLO
LD50 (Orale) 4710 mg/kg ratto
LD50 (Cutanea) 12800 mg/kg ratto
LC50 (Inalazione) 72,6 mg/l ratto

METILETILCHETONE
LD50 (Orale) 2737 mg/kg bw ratto
LD50 (Cutanea) 6480 mg/kg 14g coniglio
LC50 (Inalazione – aerosol) 23,5 mg/l 8h ratto

ETANOLO
LD50 (Orale) > 5000 mg/kg ratto

CORROSIONE CUTANEA / IRRITAZIONE CUTANEA.
Provoca irritazione cutanea.
GRAVI DANNI OCULARI / IRRITAZIONE OCULARE.
Provoca grave irritazione oculare.
SENSIBILIZZAZIONE RESPIRATORIA O CUTANEA.
Può provocare reazione allergica cutanea.
MUTAGENICITÀ SULLE CELLULE GERMINALI.
Non risponde ai criteri di classificazione per questa classe di pericolo.
CANCEROGENICITÀ.
Non risponde ai criteri di classificazione per questa classe di pericolo.

TOSSICITÀ PER LA RIPRODUZIONE.
Non risponde ai criteri di classificazione per questa classe di pericolo.
TOSSICITÀ SPECIFICA PER ORGANI BERSAGLIO (STOT) - ESPOSIZIONE SINGOLA.
Non risponde ai criteri di classificazione per questa classe di pericolo.
TOSSICITÀ SPECIFICA PER ORGANI BERSAGLIO (STOT) - ESPOSIZIONE RIPETUTA.
Non risponde ai criteri di classificazione per questa classe di pericolo.
PERICOLO IN CASO DI ASPIRAZIONE.
Non risponde ai criteri di classificazione per questa classe di pericolo.

12 INFORMAZIONI ECOLOGICHE

12.1 Tossicità : La miscela è classificata sulla base delle informazioni di pericolosità per gli ingredienti come definito dai criteri di classificazione per le miscele per ogni classe di pericolo o in base alle differenziazioni presenti in Allegato I della 1272/2008/CE. Il prodotto è altamente tossico per gli organismi acquatici e può causare effetti avversi a lungo termine nell'ambiente acquatico.

Propionato di N,N-didecil-N-metil-poli(ossietil)ammonio
LC50 - Pesci. >0,78 mg/96h Danio Rerio OECD 203
EC50 - Crostacei. 0,07 mg/l/48h Dafnia magna OECD 202
NOEC – Crostacei 0,18 mg/l 21g Dafnia magna OECD TG 211
EC50 - Alghe / Piante Acquatiche. 0,15 mg/l /72h Desmodesmus subspicatus
NOEC - Alghe / Piante Acquatiche. 0,044 mg/l 72h Scenedesmus subspicatus

12.2 Persistenza e degradabilità : ETANOLO
Rapidamente biodegradabile.

2-PROPANOLO
Rapidamente biodegradabile

METILETILCHETONE
Rapidamente biodegradabile

Propionato di N,N-didecil-N-metil-poli(ossietil)ammonio
Non immediatamente biodegradabile.

12.3 Potenziale di bioaccumulo : Propionato di N,N-didecil-N-metil-poli(ossietil)ammonio
BCF: 81

ETANOLO
d-Coefficiente di ripartizione: n-ottanolo/acqua. -0,35
Non bioccumulabile.

2-PROPANOLO
Coefficiente di ripartizione: n-ottanolo/acqua. 0,05

METILETILCHETONE
Coefficiente di ripartizione: n-ottanolo/acqua. 0,3

12.4 Mobilità nel suolo : nessun datro disponibile.

12.5 Risultati della valutazione PBT e vPvB : il prodotto non contiene sostanze PBT o vPvB in percentuale superiore a 0,1%.

12.6 Altri effetti avversi : Nessun dato disponibile.

13 CONSIDERAZIONI SULLO SMALTIMENTO

13.1 Metodi di trattamento dei rifiuti

Prodotto : Il materiale dovrebbe essere recuperato per essere riciclato laddove possibile. Scarti e residui di questo materiale devono essere smaltiti secondo la legislazione vigente e le competenti Autorità per la Regolamentazione dei Rifiuti (DLgs 152/2006 e norm. collegata).

Contenitori contaminati : Svuotare completamente l'imballaggio dopo l'uso e smaltire i contenitori contaminati come prodotto inutilizzato.

SEZIONE 14. INFORMAZIONI SUL TRASPORTO

14.1 Numero ONU : UN1950

14.2 Nome di spedizione dell'ONU : ADR/RID: AEROSOL
IMDG: AEROSOLS
IATA: AEROSOLS, flammable

14.3 Classi di pericolo connesso al trasporto : 2

14.4 Gruppo d'imballaggio : -

14.5 Pericoli per l'ambiente : NO

14.6 Precauzioni speciali per gli utilizzatori : Attenzione: Gas

14.7 Trasporto di rinfuse secondo l'allegato II di MARPOL 73/78 e il codice IBC : Non applicabile.

Trasporto/ulteriori indicazioni:

ADR / RID:	Kemler: --	Quantità Limitate: 1 L	Codice di restrizione in galleria: (D)
	Disposizione Speciale: -		
IMDG:	EMS: F-D, S-U	Quantità Limitate: 1 L	
IATA:	Cargo:	Quantità massima: 100 Kg	Istruzioni Imballo: 130
	Pass.:	Quantità massima: 25 Kg	Istruzioni Imballo: 130
	Istruzioni Particolari	A802	

15 INFORMAZIONI SULLA REGOLAMENTAZIONE

15.1 Norme e legislazione su salute, sicurezza e ambiente specifiche per la sostanza o la miscela

Legislazione specifica

Sostanze soggette ad autorizzazione (Allegato XIV REACH): Nessuna.

Lista SVHC : Il prodotto NON contiene sostanze presenti nell'elenco delle sostanze estremamente preoccupanti (SVHC) .

Restrizioni relative al prodotto o alle sostanze contenute secondo l'Allegato XVII Regolamento (CE) 1907/2006: punto 40.

Categoria Seveso III : P3a AEROSOL INFIAMMABILI
Dir. 2012/18/EU

Sostanze soggette ad obbligo di notifica di esportazione Reg. (CE) 649/2012: nessuna.

Altri Regolamenti EU : il prodotto NON contiene una sostanza dannosa per l'ozono, né una sostanza POP (Persistent Organic Pollutant).

Controlli Sanitari : I lavoratori esposti a questo agente chimico pericoloso per la salute devono essere sottoposti alla sorveglianza sanitaria effettuata secondo le disposizioni dell'art. 41 del D.Lgs. 81 del 9 aprile 2008 salvo che il rischio per la sicurezza e la salute del lavoratore sia stato valutato irrilevante, secondo quanto previsto dall'art. 224 comma 2.

Legislazione generale

1. Regolamento n.1272/2008/CE o CLP;
2. Regolamento n.1907/2006/CE denominato REACH e Regolamento n. 830/2015/CE.
3. Direttive 89/391/CE, 89/654/CE, 89/655/CE, 89/656/CE, 90/269/CE, 90/270/CE, 90/394/CE, 90/679/CE, 93/88/CE, 95/63/CE, 97/42/CE, 98/24/CE, 99/38/CE, 99/92/CE, 2001/45/CE, 2003/10/CE, 2003/18/CE e 2004/40/CE riguardanti il miglioramento della sicurezza e della salute dei lavoratori durante il lavoro;
4. Direttive n. 80/1107/CE, n. 82/605/CE, n. 83/477/CE, n. 86/188/CE e n. 88/642/CE, in materia di protezione dei lavoratori contro i rischi derivanti da esposizione ad agenti chimici, fisici e biologici durante il lavoro;
5. Direttive 96/61/CE ,2000/60/CE, 91/156/CE, 91/689/CE, 94/62/CE, 84/360/CE, 94/63/CE, 1999/13/CE, 1999/32/CE, 93/12/CE, 2001/80/CE, 2004/35/CE in materia ambientale;
6. ADR ed. 2019
7. European Agreement concerning the International Carriage of Dangerous Goods by Rail – RID (UNECE)
8. IMDG Code - 2018 Edition (Amdt.38) (IMO)
9. Dangerous Goods Regulation 60th edition (IATA)

15.2 Valutazione della sicurezza chimica

: è stata condotta una valutazione della sicurezza chimica per le seguenti sostanze contenute nella miscela:
Propionato di N,N-didecil-N-metil- poli (ossietil) ammonio; GPL (miscela di propano + butano +isobutano liquefatti).

16 ALTRE INFORMAZIONI

Revisione del 01/03/2020

: sostituisce la rev. 3 del 01/02/2017.
Sono state apportate variazioni alle seguenti sezioni:
01 / 02 / 03 / 04 / 05 / 06 / 07 / 08 / 09 / 10 / 11 / 12 / 13 / 14 / 15 / 16.

Legenda

- ADR: Accordo europeo per il trasporto delle merci pericolose su strada
- CAS NUMBER: Numero del Chemical Abstract Service

- CE50: Concentrazione che dà effetto al 50% della popolazione soggetta a test
- CE NUMBER: Numero identificativo in ESIS (archivio europeo delle sostanze esistenti)
- CLP: Regolamento CE 1272/2008
- DNEL: Livello derivato senza effetto
- EmS: Emergency Schedule
- GHS: Sistema armonizzato globale per la classificazione e la etichettatura dei prodotti chimici
- IATA DGR: Regolamento per il trasporto di merci pericolose della Associazione internazionale del trasporto aereo
- IC50: Concentrazione di immobilizzazione del 50% della popolazione soggetta a test
- IMDG: Codice marittimo internazionale per il trasporto delle merci pericolose
- IMO: International Maritime Organization
- INDEX NUMBER: Numero identificativo nell'Allegato VI del CLP
- LC50: Concentrazione letale 50%
- LD50: Dose letale 50%
- OEL: Livello di esposizione occupazionale
- PBT: Persistente, bioaccumulante e tossico secondo il REACH
- PEC: Concentrazione ambientale prevedibile
- PEL: Livello prevedibile di esposizione
- PNEC: Concentrazione prevedibile priva di effetti
- REACH: Regolamento CE 1907/2006
- RID: Regolamento per il trasporto internazionale di merci pericolose su treno
- TLV: Valore limite di soglia
- TLV CEILING: Concentrazione che non deve essere superata durante qualsiasi momento dell'esposizione lavorativa.
- TWA STEL: Limite di esposizione a breve termine
- TWA: Limite di esposizione medio pesato
- VOC: Composto organico volatile
- vPvB: Molto persistente e molto bioaccumulante secondo il REACH
- WGK: Classe di pericolosità acquatica (Germania).

Fonti di dati

ECDIN	Environmental Chem. Data and Information Network
IUCLID	International Uniform Chemical Information Database
NIOSH	National Institute for Occupational Safety and Health
ACGIH	American Conference of Governmental Industrial Hygienists.

Procedura utilizzata per derivare la classificazione a norma del regolamento (CE) N. 1272/2008 [CLP/GHS)]

:

Classificazione	**Giustificazione**
Aerosol 1 H222, H229	dati sperimentali
Skin Irrit. 2, H315	metodo di calcolo
Eye Irrit., 2 H319	metodo di calcolo
Skin Sens. 1 H317	metodo di calcolo
Aquatic Chronic 3, H412	metodo di calcolo

Elenco indicazioni di pericolo H citate in sezione 3

H220 Gas altamente infiammabile
H222 Aerosol estremamente infiammabile.
H225 Liquido e vapori facilmente infiammabili.
H229 Recipiente sotto pressione: può scoppiare se riscaldato.
H226 Liquido e vapori infiammabili.
H302 Nocivo se ingerito.
H304 Può essere letale in caso di ingestione e di penetrazione nelle vie respiratorie.
H314 Provoca gravi ustioni cutanee e gravi lesioni oculari.
H319 Provoca grave irritazione oculare.
H336 Può provocare sonnolenza o vertigini.
H373 Può provocare danni agli organi in caso di esposizione prolungata o ripetuta.
H400 Molto tossico per gli organismi acquatici.

H410 Molto tossico per gli organismi acquatici con effetti di lunga durata.
EUH066 L'esposizione ripetuta può provocare secchezza e screpolature della pelle.

Avvertenze generali relative alla redazione del documento

Questo documento è stato redatto da un tecnico competente in materia di SDS e che ha ricevuto formazione adeguata.

Le informazioni contenute nella presente scheda sono basate sulle migliori conoscenze a disposizione della nostra Società. I riferimenti ai rischi connessi all'impiego del prodotto ed alle sue caratteristiche intrinseche, così come a norme legislative ed a fonti bibliografiche, non possono essere ritenuti di tipo esaustivo. L'utilizzatore deve valutare ogni ulteriore rischio che possa derivare dalle modalità e dalle condizioni d'uso del prodotto.

ALLEGATI:

SCENARI ESPOSITIVI

Propionato di N,N-didecil-N-metil- poli (ossietil) ammonio

Overview of exposure scenarios and contributing scenarios

Bardap 26 is a biocidal substance used in disinfectants for medical devices, cleaning and maintenance products, and surface active agents. N,N-Didecyl-N-methylpoly(oxyethyl)ammonium Propionate (technical material) always exists in process solvents; ethylene glycol and water. For professional and consumer uses, the substance is always used in formulation at concentrations of less than 1%. Bardap 26 is formulated in both open and closed processes including batch processes, mixing/blending and preparation transfer. The formulation is used industrially as cleaning products and as metal treatment products; uses include transfer of the preparation, industrial spraying and roller/brush application. The substance is also used as a cleaner/disinfectant and as a laboratory agent by professionals. The formulation is used by consumers as a cleaner/disinfectant and in furniture, floor and leather care products.

Tonnage information:

Assessed tonnage: 250 tonnes/year based on:

- 250 tonnes/year imported

The following table list all the exposure scenarios (ES) assessed in this CSR.

Table 1. Overview of exposure scenarios and contributing scenarios

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
ES1 - F1		ES1 Formulation of preparations - Formulation (ERC 2) - Use in closed process (PROC 1) - Use in closed, continuous process (PROC 2) - Use in closed batch process (PROC 3) - Use in batch process (PROC 4) - Mixing or blending (PROC 5) - Transfer at non-dedicated facilities (PROC 8a) - Transfer at dedicated facilities (PROC 8b) - Transfer into small containers (PROC 9) - Laboratory reagent (PROC 15)	250
ES2 - IW1		ES2 Industrial use as Cleaning Products - Industrial use of processing aids (ERC 4) - Industrial closed process (PROC 2) - Industrial batch process (PROC 4)	10

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
		- Industrial spraying - indoors (PROC 7) - Industrial spraying - outdoors (PROC 7) - Transfer at non-dedicated facilities - indoors (PROC 8a) - Transfer at non-dedicated facilities - outdoors (PROC 8a) - Transfer at dedicated facilities (PROC 8b) - Transfer into small containers (PROC 9) - Roller application or brushing (PROC 10)	
ES3 - IW2		ES3 Industrial use of Metal Treatment Products - Industrial use of processing aids (ERC 4) - Industrial closed process (PROC 2) - Industrial batch process (PROC 4) - Transfer at dedicated facilities (PROC 8b) - Industrial spraying (PROC 7) - Roller application or brushing (PROC 10)	10

ES4 - PW1		ES4 Professional use of Cleaning Products Wide dispersive indoor use of reactive substances (ERC 8a) - Professional closed process (PROC 2) - Professional batch process (PROC 4) - Transfer at non-dedicated facilities (PROC 8a) - Transfer into small containers (PROC 9) - Roller application or brushing (PROC 10) - Spraying (PROC 11) - Dipping and pouring (PROC 13) - Professional closed process - 15% (PROC 2) - Professional batch process - 15% (PROC 4) - Transfer at non-dedicated facilities - 15% (PROC 8a) - Transfer into small containers - 15% (PROC 9)	10
ES5 - PW2		ES5 Professional use of Medical Devices - processing aids - Wide dispersive indoor use of reactive substances (ERC	150

Identifiers	**Market Sector**	**Titles of exposure scenarios and the related contributing scenarios**	**Tonnage (tonnes per year)**
		8a) - Professional batch process (PROC 4) - Transfer at non-dedicated facilities (PROC 8a) - Spraying (PROC 11) - Dipping and pouring (PROC 13) - Professional batch process - 15% (PROC 4) - Transfer at non-dedicated facilities - 15% (PROC 8a)	
ES6 - PW3		ES6 Professional use of Medical Devices - reactive substances Wide dispersive indoor use of reactive substances (ERC 8b) - Professional batch process (PROC 4) - Transfer at non-dedicated facilities (PROC 8a) - Spraying (PROC 11) - Dipping and pouring (PROC 13) - Professional batch process - 15% (PROC 4) - Transfer at non-dedicated facilities - 15% (PROC 8a)	150
ES7 - PW4		ES7 Professional Laboratory Use - Wide dispersive indoor use of processing aids (ERC 8a) - Laboratory reagent (PROC 15)	1
ES8 - C1		Consumer Use - Wide dispersive indoor use of processing aids (ERC 8a) - Washing and cleaning products (PC 35) - Furniture floor and leather care (PC 31)	1
Manufacture: M-#, Formulation: F-#, Industrial end use at site: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial site): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.)			

9.0.2. Introduction to the assessment

9.0.2.1. Environment

Scope and type of assessment

The scope of exposure assessment and type of risk characterisation required for the environment are described in the following table based on the hazard conclusions presented in section 7.

Table 2. Type of risk characterisation required for the environment

Protection target	Type of risk characterisation	Hazard conclusion (see section 7)
Freshwater	Quantitative	PNEC aqua (freshwater) = 0.001 mg/L
Sediment (freshwater)	Quantitative	PNEC sediment (freshwater) = 5.3 mg/kg sediment dw
Marine water	Qualitative	No data available: testing technically not feasible
Sediment (marine water)	Qualitative	No exposure of sediment expected
Sewage treatment plant	Quantitative	PNEC STP = 0.118 mg/L
Air	Not needed	No hazard identified
Agricultural soil	Quantitative	PNEC soil = 2.83 mg/kg soil dw
Predator	Not needed	No potential for bioaccumulation

Comments on assessment approach:

The regional concentrations are reported in section 10.2.1.2 (see Table 80, “Predicted regional exposure concentrations (Regional PEC)”). The local Predicted Exposure Concentrations (PECs) reported for each contributing scenario correspond to the sum of the local concentrations (Clocal) and the regional concentrations (PEC regional).
A default quantitative assessment was carried out in CHESAR 2.0.1 using any ERCs applicable to a given exposure scenario. The risk assessment characterised the risk to freshwater, sediment (freshwater), sewage treatment plants and agricultural soil. Safe use was not demonstrated in the tier 1 assessment so further refinements were considered necessary.
In the tier 2 risk assessment various methods and sources of information were used to refine the assessment depending on what was most applicable to a given exposure scenario. Relevant SPERCs from the CEFIC SPERC library were used for exposure scenarios where safe use could be demonstrated with an appropriate SPERC. Certain exposure scenarios were refined using information from the Bardap 26 PT2 biocide dossier. Information from the Doc IIB of the PT2 biocide dossier is considered to give a more accurate estimation of environmental emissions and can be seen in full in appendix 1. Further to this, maximum permitted emissions were set in exposure scenarios where safe use could not be demonstrated by other refinements.
Safe use was demonstrated in the tier 2 assessment.

9.0.2.2. Man via environment Scope and type of assessment

The scope of exposure assessment and type of risk characterisation required for man via the environment are described in the following table based on the hazard conclusions reported and justified in section 5.11.

Table 3. Type of risk characterisation required for man via the environment

Route of exposure and type of effects	Type of risk characterisation	Hazard conclusion (see section 5.11)
Inhalation: Systemic Long Term	Quantitative	DNEL (Derived No Effect Level) = 0.12 mg/m³
Oral: Systemic Long Term	Quantitative	DNEL (Derived No Effect Level) = 0.35 mg/kg bw/day

9.0.2.3. Workers

Scope and type of assessment

The scope of exposure assessment and type of risk characterisation required for workers are described in the following table based on the hazard conclusions presented in section 5.11.

Table 4. Type of risk characterisation required for workers

Route	Type of effect	Type of risk characterisation	Hazard conclusion (see section 5.11)
Inhalation	Systemic Long Term	Quantitative	DNEL (Derived No Effect Level) = 0.5 mg/m³
	Systemic Acute	Qualitative	Low hazard (no threshold derived)
	Local Long Term	Qualitative	Medium hazard (no threshold derived)
	Local Acute	Qualitative	Medium hazard (no threshold derived)
Dermal	Systemic Long Term	Quantitative	DNEL (Derived No Effect Level) = 0.7 mg/kg bw/day
	Systemic Acute	Qualitative	Low hazard (no threshold derived)
	Local Long Term	Qualitative	Medium hazard (no threshold derived)
	Local Long Term	Qualitative	Medium hazard (no threshold derived)
Eye	Local	Qualitative	Medium hazard (no threshold derived)

Comments on assessment approach:

The potential risks of systemic toxicity in workers associated with long-term dermal and inhalation exposures to N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate arising from the use of this substance in industrial and professional settings were characterised using a quantitative approach based on DNELs derived respectively for these routes.

In a quantitative exposure assessment, the potential long-term systemic dermal exposures and inhalation exposures to vapours associated with professional and industrial uses were assessed for workers using the Tier 1 model: ECETOC TRA Workers version 3 (April 2012) integrated in CHESAR 2.0.1. The ECETOC TRA workers model is a screening level model which does not assess exposures to aerosols. Long-term inhalation exposures associated with processes which can potentially generate aerosols (e.g. PROC 7 – industrial spraying, PROC 11 – professional spraying and PROC 10 – brush and roller applications) were therefore assessed using the Advanced REACH Tool (ART) v. 1.0.

In the characterisation of risks of systemic effects associated with long-term dermal and inhalation exposures to N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate in workers, the predicted dermal and inhalation exposures were compared with the respective DNEL values to determine the risk characterisation ratio (RCR) for each respective route. The RCR for combined routes relevant to workers (i.e. inhalation and dermal) for each process were determined by RCR (dermal) + RCR (inhalation).

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye). In the absence of adequate dose-response data, it is not possible to derive DNELs for acute systemic effects, and local dermal and inhalation effects. Therefore, a qualitative risk assessment

is required for acute systemic exposures, and local inhalation and local dermal exposures. Acute systemic toxicity as a result of acute exposure to the substance is not likely. Systemic absorption is limited; no systemic toxicity is predicted following a single (acute) exposure, the most sensitive endpoint is local irritation. Also, peak exposures are not expected.

Common risk management measured related to toxicological hazard:

Due to the corrosive properties of the substance, workers formulating and using Bardap 26 are trained in the procedures and protective equipment is designed to cope with the worst case scenario, in order to minimise exposure and risks.
Formulation, industrial and professional uses involves some activities which may result in potential exposure for workers. Local exhaust ventilation (LEV) is used for all processes during formulation with the exception of PROC 1 (used in closed process) to minimise exposures. LEV is also used during industrial spraying of metal treatment products, professional spraying of cleaning products, during transfer at dedicated facilities (industrial uses) and during transfer of the 15% solution at non-dedicated facilities (professional uses) and during dipping and pouring tasks (professional users), to minimise exposures during these processes. The product is supplied to formulators and down-stream users as a 15% concentration, which is further diluted prior to use. The in-use concentration for industrial workers is below 3%, and the use concentration for professional workers is below 1%, reducing the hazard associated with exposure.
Following the “Guidance on information requirements and chemical safety assessment Part E: Risk Characterisation” document, the health hazard presented by corrosive substances is allocated to the moderate hazard category on the basis that exposure to such corrosive substances should be well-controlled.
Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). The RMMs and PPE recommended for corrosive substances are Risk management measures (RMMs):

- Containment as appropriate;
- Minimise number of staff exposed;
- Segregation of the emitting process;
- Effective contaminant extraction;
- Good standard of general ventilation;
- Minimisation of manual phases;
- Avoidance of contact with contaminated tools and objects;
- Regular cleaning of equipment and work area;
- Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed;
- Training for staff on good practice;
- Good standard of personal hygiene.

Personal protective equipment (PPE):

- Substance / task appropriate gloves (nitrile rubber gloves with a breakthrough time of > 480 minutes);
- Skin coverage with appropriate barrier material based on potential for contact with the chemicals (rubber or plastic apron, rubber or plastic boots);
- Substance/task appropriate respirator (respiratory vapour filter (EN 141) and a respirator with ABEK filter);
- Optional face shield;
- Eye protection (tight fitting safety goggles);
- Chemical goggles (tight fitting safety goggles).

9.0.2.4. Consumers

Scope and type of assessment

The scope of exposure assessment and type of risk characterisation required for consumers are described in the following table based on the hazard conclusions presented in section 5.11.

Table 5. Type of risk characterisation required for consumers

Route	Type of effect	Type of risk characterisation	Hazard conclusion (see section 5.11)
Inhalation	Systemic Long Term	Quantitative	DNEL (Derived No Effect Level) = 0.12 mg/m³
	Systemic Acute	Qualitative	Low hazard (no threshold derived)
	Local Long Term	Qualitative	Medium hazard (no threshold derived)
	Local Acute	Qualitative	Medium hazard (no threshold derived)
Dermal	Systemic Long Term	Quantitative	DNEL (Derived No Effect Level) = 0.35 mg/kg bw/day
	Systemic Acute	Qualitative	Low hazard (no threshold derived)
	Local Long Term	Qualitative	Medium hazard (no threshold derived)
	Local Long Term	Qualitative	Medium hazard (no threshold derived)
Eye	Local	Qualitative	Medium hazard (no threshold derived)
Oral	Systemic Long Term	Quantitative	DNEL (Derived No Effect Level) = 0.35 mg/kg bw/day

Comments on assessment approach:

The potential risks of systemic toxicity in consumers associated with long-term dermal, inhalation and oral exposures to N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate arising from the uses of consumer products containing this substance were characterised using a quantitative approach based on DNELs derived respectively for these routes.

In a quantitative exposure assessment, the potential long-term systemic dermal, inhalation and oral exposures associated with the use of consumer products containing N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate were assessed using the AISE REACT Consumer Tool. A detailed discussion on the model and assumptions used to determine exposures is provided in Section 9.8: Exposure scenario 8: Consumer use.
In the characterisation of risks of systemic effects associated with long-term dermal, inhalation and oral exposures to N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate in consumers, the predicted dermal, inhalation and oral exposures were compared with the respective DNEL values to determine the risk characterisation ratio (RCR) for each respective route. The RCR for combined routes of exposures in consumers (i.e. inhalation, dermal and oral) for each use were determined by adding the respective RCR for the relevant routes.
N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye). In the absence of adequate dose-response data, it is not possible to derive DNELs for acute systemic effects, and local dermal and inhalation effects. Therefore, a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Acute systemic toxicity as a result of acute exposure to the substance is not likely. Systemic absorption is limited; no systemic toxicity is predicted following a single (acute) exposure, the most sensitive endpoint is local irritation. Also, peak exposures are not expected.

9.1. Exposure scenario 1 : ES1 Formulation of preparations

Environment contributing scenario(s):

Formulation	ERC 2

Worker contributing scenario(s):

Use in closed process	PROC 1
Use in closed, continuous process	PROC 2
Use in closed batch process	PROC 3
Use in batch process	PROC 4
Mixing or blending	PROC 5
Transfer at non-dedicated facilities	PROC 8a
Transfer at dedicated facilities	PROC 8b
Transfer into small containers	PROC 9
Laboratory reagent	PROC 15

Explanation on the approach taken for the ES

Formulation of the technical material is carried out to prepare mixtures containing N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate for downstream users in a closed batch process and/or continuous process, or open batch process. Formulation encompasses a wide range of activities such as transfer, mixing and loading, sampling and dilution steps during which exposure can occur. Workers will be exposed to in-use concentrations of 5-25% (maximum actual concentration 15%). It has been assumed that workers will wear gloves and goggles during all processes, and that all activities (with the exception of PROC 1) will take place indoors with LEV. The duration of activity is between 4 and 8 hours, except for transfer where the duration of activity is 1 hour.

Releases to the environment were initially based on the default release factors for ERC2. However, the assessment was refined using information on from AISE SPERC 2.1.k.v1 (number of emission days set to 220) and by setting maximum emission limits for release to air and water. Substance losses to waste water are generally restricted to equipment cleaning as processes operate with limited or without contact with water. Such uses and substances properties result in limited to no discharge to waste water or to soil from the industrial site. Releases to air are also likely to be minimal due to the low Henry's law constant of the substance.

9.1.1. Environmental contributing scenario 1: Formulation

9.1.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use at site: <= 1.136 tonnes/day *Based on a worst-case on-site value of 250 tonnes per annum and 220 emission days from AISE SPERC 2.1.k.v1*
• Annual use at a site: <= 250 tonnes/year
Manufacturer information
• Percentage of tonnage used at regional scale: = 100 %
Conditions and measures related to sewage treatment plant
• Municipal STP: Yes (Wat: 87.79 %;)
• Discharge rate of STP: <= 2E3 m3/d
• Application of the STP sludge on agricultural soil: Yes
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d

9.1.1.2. Releases

The local releases to the environment are reported in the following table.

Table 6. Local releases to the environment

Release	**Release factor estimation method**	**Explanation / Justification**
Water	Measured release (Maximum permitted release to water)	**Final release factor:** 0.005% **Local release rate:** 0.06 kg/day **Explanation / Justification:** The maximum amount of the substance that can be emitted to waste water from formulation sites is 0.06 kg/day.
Air	Measured release (Maximum permitted release to air)	**Final release factor:** 0.088% **Local release rate:** 1 kg/day **Explanation / Justification:** The maximum amount of the substance that can be emitted to air from formulation sites is 1 kg/day.
Soil	ERC based	**Final release factor:** 0.01%

Releases to waste
No further releases to waste which are relevant for the environmental risk assessment are foreseen and emissions relevant to establishment of environmental PECs are stated above.

Any emission to solid waste (landfill) or to specialized waste disposal companies or processes are not considered to be under the scope of REACH as these are regulated under dedicated waste and local regulatory statutes.

9.1.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 7. Exposure concentrations and risks for the environment

Protection target	**Exposure concentration**	**Risk characterisation**
Freshwater	**Local PEC:** 3.233E-4 mg/L	RCR = 0.323
Sediment (freshwater)	**Local PEC:** 4.894 mg/kg dw	RCR = 0.923
Marine water		Qualitative risk characterisation (see below)
Sediment (marine water)		Qualitative risk characterisation (see below)
Protection target	**Exposure concentration**	**Risk characterisation**
Sewage treatment plant	**Local PEC:** 0.004 mg/L	RCR = 0.031
Air		
Agricultural soil	**Local PEC:** 1.27 mg/kg dw	RCR = 0.449
Man via Environment - Inhalation	**Local PEC:** 1.676E-4 mg/m³	RCR = 0.001
Man via Environment - Oral	**Exposure via food consumption:** 1.311 mg/kg bw/day	RCR = 3.747 >>>**CAUTION:** Risk <u>not</u> controlled <<<
Man via environment - combined routes		RCR = 3.748

Table 8. Contribution to oral intake for man via the environment from local contribution

Type of food	**Estimated daily dose**	**Concentration in food**
Drinking water	1.2E-5 mg/kg bw/day	4.2E-4 mg/L
Fish	2.725E-5 mg/kg bw/day	0.017 mg/kg ww
Leaf crops	2.593E-4 mg/kg bw/day	0.015 mg/kg ww
Root crops	1.31 mg/kg bw/day	238.9 mg/kg ww
Meat	4.558E-4 mg/kg bw/day	0.106 mg/kg ww
Milk	2.686E-4 mg/kg bw/day	0.034 mg/kg ww

<u>Conclusion on risk characterisation</u>

No significant exposure expected for marine environments, and as such no risk characterisation is conducted for these compartments.

Risk characterisation ratios (RCRs) were derived for freshwater, freshwater sediment, STP and soil compartments. Following a tier 2 risk assessment with refinements for releases to air and water (specified maximum permitted releases), all RCRs were found to be less than 1. As such it should be considered that safe use has been demonstrated. The maximum permitted release to wastewater from a formulation site is 0.06 kg/day, and the maximum permitted release to air is 1 kg/day.

9.1.2. Worker contributing scenario 1: Use in closed process (PROC 1)

9.1.2.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25% *The end-use concentration is 15%.*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Closed system (minimal contact during routine operations)	TRA Workers
	Method
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Workers

9.1.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.109 mg/m³** (TRA Workers)	RCR = 0.219
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.002 mg/kg bw/day** (TRA Workers)	RCR = 0.003
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.222

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management

measures (RMMs), predicted long-term inhalation and dermal exposures arising during the formulation of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate do not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.1.3. Worker contributing scenario 2: Use in closed, continuous process (PROC 2)

9.1.3.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25% *The end-use concentration is 15%.*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
Containment: Closed continuous process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: yes (Inh: 90 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 90 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.1.3.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 10. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.109 mg/m³** (TRA Workers)	RCR = 0.219
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)

Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.008 mg/kg bw/day** (TRA Workers)	RCR = 0.012
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.231

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the formulation of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate do not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.1.4. Worker contributing scenario 3: Use in closed batch process (PROC 3)

9.1.4.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25% *The end-use concentration is 15%.*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Closed batch process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: yes (Inh: 90 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 90 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Workers

9.1.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 11. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.109 mg/m³** (TRA Workers)	RCR = 0.219
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.004 mg/kg bw/day** (TRA Workers)	RCR = 0.006
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.225

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the formulation of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate do not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.1.5. Worker contributing scenario 4: Use in batch process (PROC 4)

9.1.5.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25% *The end-use concentration is 15%.*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers

• Local exhaust ventilation: yes (Inh: 90 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 90 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.1.5.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 12. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.109 mg/m³** (TRA Workers)	RCR = 0.219
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.041 mg/kg bw/day** (TRA Workers)	RCR = 0.059
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.278

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the formulation of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate do not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.1.6. Worker contributing scenario 5: Mixing or blending (PROC 5)

9.1.6.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25% *The end-use concentration is 15%.*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation: yes (Inh: 90 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 90 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
	Method
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.1.6.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 13. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.066 mg/m³** (TRA Workers)	RCR = 0.131
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.082 mg/kg bw/day** (TRA Workers)	RCR = 0.118
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.249

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management

measures (RMMs), predicted long-term inhalation and dermal exposures arising during the formulation of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate do not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.1.7. Worker contributing scenario 6: Transfer at non-dedicated facilities (PROC 8a)

9.1.7.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25% *The end-use concentration is 15%.*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
	Method
• Containment: No	TRA Workers
• Local exhaust ventilation: yes (Inh: 90 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 90 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

9.1.7.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 14. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.022 mg/m³** (TRA Workers)	RCR = 0.044
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)

Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.082 mg/kg bw/day** (TRA Workers)	RCR = 0.118
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.161

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the formulation of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate do not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.1.8. Worker contributing scenario 7: Transfer at dedicated facilities (PROC 8b)

9.1.8.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25% *The end-use concentration is 15%.*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: yes (Inh: 95 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 95 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

9.1.8.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 15. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.011 mg/m³** (TRA Workers)	RCR = 0.022
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.041 mg/kg bw/day** (TRA Workers)	RCR = 0.059
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.081

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the formulation of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate do not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.1.9. Worker contributing scenario 8: Transfer into small containers (PROC 9)

9.1.9.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25% *The end-use concentration is 15%.*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: yes (Inh: 90 %;)	TRA Workers

• Local exhaust ventilation (for dermal): yes (Der: 90 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.1.9.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 16. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.022 mg/m³** (TRA Workers)	RCR = 0.044
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.041 mg/kg bw/day** (TRA Workers)	RCR = 0.059
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.103

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the formulation of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate do not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.1.10. Worker contributing scenario 9: Laboratory reagent (PROC 15)

9.1.10.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25% *The end-use concentration is 15%.*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation: yes (Inh: 90 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 90 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Workers

9.1.10.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 17. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.066 mg/m³** (TRA Workers)	RCR = 0.131
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.002 mg/kg bw/day** (TRA Workers)	RCR = 0.003
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.134

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the formulation of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate do not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.2. Exposure scenario 2 : ES2 Industrial use as Cleaning Products

Environment contributing scenario(s):

Industrial use of processing aids	ERC 4

Worker contributing scenario(s):

Industrial closed process	PROC 2
Industrial batch process	PROC 4
Industrial spraying - indoors	PROC 7
Industrial spraying - outdoors	PROC 7
Transfer at non-dedicated facilities - indoors	PROC 8a
Transfer at non-dedicated facilities - outdoors	PROC 8a
Transfer at dedicated facilities	PROC 8b
Transfer into small containers	PROC 9
Roller application or brushing	PROC 10

Explanation on the approach taken for the ES

Bardap 26 is used as a cleaning/disinfectant product for hard surfaces such as floors, walls and ceilings. The formulation is used in closed continuous processes and open batch processes where exposure can occur. Exposure is also possible during spraying of the cleaning products, transfer to/from large containers, transfer into small containers and roller/brush application of the product onto hard surfaces. All activities take place indoors with the exception of spraying (PROC 7) and transfer to/from large containers (PROC 8a) which can also occur outdoors. Transfer at dedicated facilities will take place with LEV. The end-use concentration of the formulation is 0.01 – 1%. The duration is task dependent. Workers will use gloves and goggles in all cases, and also respiratory protection when spraying (indoors and outdoors).

Releases to the environment were initially based on the default release factors for ERC4. However, the assessment was refined using information on from the Bardap 26 PT2 biocides dossier. Releases to wastewater were based on the calculated daily releases in the Doc IIB of the PT2 dossier. The calculated releases were based on an annual EU usage of 400 tonnes per year. As such, it is considered conservative to use this value here. For further information

see appendix 1.

Releases to air are likely to be minimal due to the low Henry's law constant of the substance.

9.2.1. Environmental contributing scenario 1: Industrial use of processing aids

9.2.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use at site: <= 0.045 tonnes/day *Based on a worst-case on-site use of 10 tonnes per annum and 220 emission days based on information from AISE SPERC 4.1.v1.*
• Annual use at a site: <= 10 tonnes/year

Manufacturer information
• Percentage of tonnage used at regional scale: = 100 %
Conditions and measures related to sewage treatment plant
• Municipal STP: Yes (Wat: 87.79 %;)
• Discharge rate of STP: <= 2E3 m3/d
• Application of the STP sludge on agricultural soil: Yes
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d

9.2.1.2. Releases

The local releases to the environment are reported in the following table.

Table 18. Local releases to the environment

Release	**Release factor estimation method**	**Explanation / Justification**
Water	Measured release	**Final release factor:** 0.005% **Local release rate:** 0.002 kg/day **Explanation / Justification:** Based on the refined predicted daily release for PT 2.01a(i) in the Bardap 26 PT2 biocide dossier. PT2.01 covers the use of biocidal products for accommodation for man or in industrial areas. More specifically, 2.01a(i) covers the release of disinfectants used for sanitary purposes based on annual tonnage. As such is considered to be directly applicable to this exposure scenario. As the calculated daily release is taking into account an annual EU tonnage of 400 tonnes per annum, it is considered to be sufficiently conservative for use in this assessment. For further information see appendix 1.

Air	Measured release	**Final release factor:** 0% **Local release rate:** 0 kg/day **Explanation / Justification:** In the PT2 biocide dossier for Bardap 26, no PEC is calculated for air. Bardap 26 has a low Henry's law constant (3.03E-11 Pa m3/mol) and is expected to be quickly degraded in air. The photochemical oxidative degradation half-life of Bardap 26 in is expected to be approximately 2.8 hours based on the structurally related DDAC. For further information see appendix 1.
Soil	ERC based	**Final release factor:** 5%

Releases to waste
No further releases to waste which are relevant for the environmental risk assessment are foreseen and emissions relevant to establishment of environmental PECs are stated above.

Any emission to solid waste (landfill) or to specialized waste disposal companies or processes are not considered to be under the scope of REACH as these are regulated under dedicated waste and local regulatory statutes.

9.2.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 19. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 3.572E-5 mg/L	RCR = 0.036
Sediment (freshwater)	**Local PEC:** 0.541 mg/kg dw	RCR = 0.102
Marine water		Qualitative risk characterisation (see below)
Sediment (marine water)		Qualitative risk characterisation (see below)
Sewage treatment plant	**Local PEC:** 1.343E-4 mg/L	RCR = 0.001
Air		
Agricultural soil	**Local PEC:** 0.129 mg/kg dw	RCR = 0.046
Man via Environment - Inhalation	**Local PEC:** 4.737E-12 mg/m³	RCR = 3.948E-11
Man via Environment - Oral	**Exposure via food consumption:** 0.133 mg/kg bw/day	RCR = 0.38
Man via environment - combined routes		RCR = 0.38

Table 20. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	1.216E-6 mg/kg bw/day	4.256E-5 mg/L
Fish	4.176E-6 mg/kg bw/day	0.003 mg/kg ww
Leaf crops	5.628E-7 mg/kg bw/day	3.283E-5 mg/kg ww
Root crops	0.133 mg/kg bw/day	24.21 mg/kg ww
Meat	1.604E-5 mg/kg bw/day	0.004 mg/kg ww

Milk	9.452E-6 mg/kg bw/day	0.001 mg/kg ww

Conclusion on risk characterisation

No significant exposure expected for marine environments, and as such no risk characterisation is conducted for these compartments.

Risk characterisation ratios (RCRs) were derived for freshwater, freshwater sediment, STP and soil compartments. Following a tier 2 risk assessment with refinements for releases to air and water based on information in the Bardap 26 PT2 biocide dossier, all RCRs were found to be less than 1. As such it should be considered that safe use has been demonstrated.

9.2.2. Worker contributing scenario 1: Industrial closed process (PROC 2)

9.2.2.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
	Method
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
Containment: Closed continuous process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.2.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 21. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.182 mg/m³** (TRA Workers)	RCR = 0.365
Inhalation, systemic, acute		Qualitative (see below)

Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.014 mg/kg bw/day** (TRA Workers)	RCR = 0.02
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.384

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.2.3. Worker contributing scenario 2: Industrial batch process (PROC 4)

9.2.3.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.2.3.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 22. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.182 mg/m³** (TRA Workers)	RCR = 0.365
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.069 mg/kg bw/day** (TRA Workers)	RCR = 0.098
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.463

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.2.4. Worker contributing scenario 3: Industrial spraying - indoors (PROC 7)

9.2.4.1. Conditions of use (contributing scenario)

Dermal exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers

• Local exhaust ventilation (for dermal): no (Der: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands and upper wrists (1500 cm2)	TRA Workers

Inhalation exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	ART 1.0
• Vapour pressure : 1.8 x 10^{-6} Pa at 20°C	ART 1.0
• Viscosity : Liquids with low viscosity	ART 1.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: *Exposure period = 240 mins (240 mins non-exposure period)*	ART 1.0
Primary emission source	
	Method
• Primary emission source: near field	ART 1.0
• Proximity: Located in breathing zone of worker	ART 1.0
Activity class: Spray application of liquids, surface spraying e.g. spraying cleaning agents onto surfaces (spraying in any direction including upwards, with no or low compressed air use)	ART 1.0
• Application rate: 0.03- 3 L/min	ART 1.0
• Primary localised controls: none	ART 1.0
• Secondary localised controls: none	ART 1.0
Surface contamination/fugative emission sources: Process not fully enclosed, but demonstrable and effective housekeeping practices in place (e.g. daily cleaning using appropriate methods (e.g. vacuum), preventive maintenance of machinery and control measures, and use of protective clothing that will repel spills and reduce personal cloud)	ART 1.0
• Dispersion: Room size = 300 m^3; Air Changes per Hour (ACH) = 1	ART 1.0
Secondary emission source	
• None	ART 1.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	Manual calculation
Other conditions affecting workers exposure	
• Place of use: Indoor	ART 1.0

• Process temperature (for liquid): Room temperature (15-25°C)	ART 1.0

9.2.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 23. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.051 mg/m³** (External exposure estimation tool (ART 1.0))	RCR = 0.102
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.429 mg/kg bw/day** (TRA Workers)	RCR = 0.612
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.714

Remarks on exposure data

External exposure estimation tool (ART 1.0)

Long-term systemic inhalation exposures (in mg/m³) were determined using ART 1.0 as the upper value of the inter-quartile confidence interval of the predicted 75th percentile full-shift (8 hour) inhalation exposure value. It has been assumed that workers will wear RPE (90% efficiency) during this task (the ART model does not include RPE – the exposure values were adjusted manually for RPE).

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.2.5. Worker contributing scenario 4: Industrial spraying - outdoors (PROC 7)

9.2.5.1. Conditions of use (contributing scenario)

Dermal exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hours	TRA Workers
Technical and organisational conditions and measures	
• Containment: No	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Outdoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands and upper wrists (1500 cm2)	TRA Workers

Inhalation exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	ART 1.0
• Vapour pressure : 1.8 x 10^{-6} Pa at 20°C	ART 1.0
	Method
• Viscosity : Liquids with low viscosity	ART 1.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: *Exposure period = 240 mins (240 mins non-exposure period)*	ART 1.0
Primary emission source	
• Primary emission source: near field	ART 1.0
• Proximity: Located in breathing zone of worker	ART 1.0
Activity class: Spray application of liquids, surface spraying e.g. spraying cleaning agents onto surfaces (only horizonal or downward spraying, with no or low compressed air use)	ART 1.0
• Application rate: 0.03- 3 L/min	ART 1.0
• Primary localised controls: none	ART 1.0
• Secondary localised controls: none	ART 1.0
Surface contamination/fugative emission sources: Process not fully enclosed, but demonstrable and effective housekeeping practices in place (e.g. daily cleaning using appropriate methods (e.g. vacuum), preventive maintenance of machinery and control measures, and use of protective clothing that will repel spills and reduce personal cloud)	ART 1.0

• Dispersion: Outdoors, close to buildings	ART 1.0
Secondary emission source	
• None	ART 1.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	Manual calculation
Other conditions affecting workers exposure	
• Place of use: Indoor	ART 1.0
• Process temperature (for liquid): Room temperature (15-25°C)	ART 1.0

9.2.5.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 24. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.017 mg/m³** (External exposure estimation tool (ART 1.0))	RCR = 0.034
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.429 mg/kg bw/day** (TRA Workers)	RCR = 0.612
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.646

Remarks on exposure data

External exposure estimation tool (ART 1.0)

Long-term systemic inhalation exposures (in mg/m³) were determined using ART 1.0 as the upper value of the inter-quartile confidence interval of the predicted 75th percentile full-shift (8 hour) inhalation exposure value. It has been assumed that workers will wear RPE (90% efficiency) during this task (the ART model does not include RPE – the exposure values were adjusted manually for RPE).

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed

information on PPE and RMMs refer to Section 9.0.2.3.

9.2.6. Worker contributing scenario 5: Transfer at non-dedicated facilities - indoors (PROC 8a)

9.2.6.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

9.2.6.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 25. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.182 mg/m³** (TRA Workers)	RCR = 0.365
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.137 mg/kg bw/day** (TRA Workers)	RCR = 0.196
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.561

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.2.7. Worker contributing scenario 6: Transfer at non-dedicated facilities - outdoors (PROC 8a)

9.2.7.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Workers
Technical and organisational conditions and measures	
• Containment: No	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Outdoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

9.2.7.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 26. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.026 mg/m³** (TRA Workers)	RCR = 0.051
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.137 mg/kg bw/day** (TRA Workers)	RCR = 0.196

Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.247

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.2.8. Worker contributing scenario 7: Transfer at dedicated facilities (PROC 8b)

9.2.8.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: yes (Inh: 95 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 95 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

9.2.8.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 27. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.002 mg/m³** (TRA Workers)	RCR = 0.004
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.007 mg/kg bw/day** (TRA Workers)	RCR = 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.013

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.2.9. Worker contributing scenario 8: Transfer into small containers (PROC 9)

9.2.9.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1%	TRA Workers
	Method
The end-use concentration is 0.01-1%	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers

Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.2.9.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 28. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.182 mg/m³** (TRA Workers)	RCR = 0.365
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.069 mg/kg bw/day** (TRA Workers)	RCR = 0.098
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.463

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.2.10. Worker contributing scenario 9: Roller application or brushing (PROC 10)

9.2.10.1. Conditions of use (contributing scenario)

Dermal exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

Inhalation exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	ART 1.0
• Vapour pressure : 1.8 x 10^{-6} Pa at 20°C	ART 1.0
• Viscosity : Liquids with low viscosity	ART 1.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: *Exposure period = 240 mins (240 mins non-exposure period)*	ART 1.0
Primary emission source	
• Primary emission source: near field	ART 1.0
• Proximity: Located in breathing zone of worker	ART 1.0
• Activity class: Spreading of liquid products	ART 1.0
• Application rate: 3 m²/hour	ART 1.0
• Primary localised controls: none	ART 1.0
• Secondary localised controls: none	ART 1.0

Surface contamination/fugative emission sources: Process not fully enclosed, but demonstrable and effective housekeeping practices in place (e.g. daily cleaning using appropriate methods (e.g. vacuum), preventive	ART 1.0
	Method
maintenance of machinery and control measures, and use of protective clothing that will repel spills and reduce personal cloud)	
• Dispersion: Room size = 300 m^3; Air Changes per Hour (ACH) = 1	ART 1.0
Secondary emission source	
• None	ART 1.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	Manual calculation
Other conditions affecting workers exposure	
• Place of use: Indoor	ART 1.0
• Process temperature (for liquid): Room temperature (15-25°C)	ART 1.0

9.2.10.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 29. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.002 mg/m³** (External exposure estimation tool (ART 1.0))	RCR = 0.003
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.274 mg/kg bw/day** (TRA Workers)	RCR = 0.392
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.395

Remarks on exposure data

External exposure estimation tool (ART 1.0)

Long-term systemic inhalation exposures (in mg/m^3) were determined using ART 1.0 as the upper value of the inter-quartile confidence interval of the predicted 75th percentile full-shift (8 hour) inhalation exposure value. It has been assumed that workers will wear RPE (90% efficiency) during this task (the ART model does not include RPE – the exposure values were adjusted manually for RPE).

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial cleaning product does not exceed the respective DNEL

for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided

through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.3. Exposure scenario 3 : ES3 Industrial use of Metal Treatment Products

Environment contributing scenario(s):

Industrial use of processing aids	ERC 4

Worker contributing scenario(s):

Industrial closed process	PROC 2
Industrial batch process	PROC 4
Transfer at dedicated facilities	PROC 8b
Industrial spraying	PROC 7
Roller application or brushing	PROC 10

Explanation on the approach taken for the ES

Bardap 26 is used as a metal treatment. The activities involved include closed continuous processes, batch processes, spraying, transfer to/from large containers and roller/brush application. All activities take place indoors. It has been assumed that spraying and transfer of the substance take place with LEV. The duration of activity is task dependent. Workers will use gloves in all cases. Workers will use respiratory protection when spraying and during roller/brush application. The maximum end-use concentration is 3%.

Releases to the environment were initially based on the default release factors for ERC4. However, the assessment was refined using information on from AISE SPERC 4.1.v1 (number of emission days set to 220) and by setting maximum emission limits for release to air and water. Substance losses to waste water and soil are generally limited from the industrial site. Releases to air are also likely to be minimal due to the low Henry's law constant of the substance.

9.3.1. Environmental contributing scenario 1: Industrial use of processing aids

9.3.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use at site: <= 0.046 tonnes/day *Based on a worst-case on-site use of 10 tonnes per annum and 220 emission days based on information from AISE SPERC 4.1.v1.*

• Annual use at a site: <= 10 tonnes/year *Manufacturer information.*
• Percentage of tonnage used at regional scale: = 100 %
Conditions and measures related to sewage treatment plant
• Municipal STP: Yes (Wat: 87.79 %;)
• Discharge rate of STP: <= 2E3 m3/d
• Application of the STP sludge on agricultural soil: Yes
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d

9.3.1.2. Releases

The local releases to the environment are reported in the following table.

Table 30. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	Measured release (Maximum permitted release)	**Final release factor:** 0.132% **Local release rate:** 0.06 kg/day **Explanation / Justification:** The maximum amount of the substance that can be emitted to waste water from sites using Bardap 26 in metal treatment products is 0.06 kg/day.
Air	Measured release (Maximum permitted release to air)	**Final release factor:** 2.198% **Local release rate:** 1 kg/day **Explanation / Justification:** The maximum amount of the substance that can be emitted to air from sites using Bardap 26 in metal treatment products is 1 kg/day.
Soil	ERC based	**Final release factor:** 5%

Releases to waste
No further releases to waste which are relevant for the environmental risk assessment are foreseen and emissions relevant to establishment of environmental PECs are stated above.

Any emission to solid waste (landfill) or to specialized waste disposal companies or processes are not considered to be under the scope of REACH as these are regulated under dedicated waste and local regulatory statutes.

9.3.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 31. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 3.233E-4 mg/L	RCR = 0.323
Sediment (freshwater)	**Local PEC:** 4.894 mg/kg dw	RCR = 0.923

Marine water		Qualitative risk characterisation (see below)
Sediment (marine water)		Qualitative risk characterisation (see below)
Sewage treatment plant	**Local PEC:** 0.004 mg/L	RCR = 0.031
Air		
Agricultural soil	**Local PEC:** 1.27 mg/kg dw	RCR = 0.449
Man via Environment - Inhalation	**Local PEC:** 1.674E-4 mg/m³	RCR = 0.001
Man via Environment - Oral	**Exposure via food consumption:** 1.311 mg/kg bw/day	RCR = 3.747 >>>**CAUTION:** Risk not controlled <<<
Man via environment -		RCR = 3.748
Protection target	**Exposure concentration**	**Risk characterisation**
combined routes		

Table 32. Contribution to oral intake for man via the environment from local contribution

Type of food	**Estimated daily dose**	**Concentration in food**
Drinking water	1.2E-5 mg/kg bw/day	4.2E-4 mg/L
Fish	2.722E-5 mg/kg bw/day	0.017 mg/kg ww
Leaf crops	2.589E-4 mg/kg bw/day	0.015 mg/kg ww
Root crops	1.31 mg/kg bw/day	238.9 mg/kg ww
Meat	4.553E-4 mg/kg bw/day	0.106 mg/kg ww
Milk	2.684E-4 mg/kg bw/day	0.033 mg/kg ww

Conclusion on risk characterisation

No significant exposure expected for marine environments, and as such no risk characterisation is conducted for these compartments.

Risk characterisation ratios (RCRs) were derived for freshwater, freshwater sediment, STP and soil compartments. Following a tier 2 risk assessment with refinements for releases to air and water (specified maximum permitted releases), all RCRs were found to be less than 1. As such it should be considered that safe use has been demonstrated. The maximum permitted release to wastewater from a formulation site is 0.06 kg/day, and the maximum permitted release to air is 1kg/day.

9.3.2. Worker contributing scenario 1: Industrial closed process (PROC 2)

9.3.2.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1-5% *The end-use concentration is 3%.*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	

• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
Containment: Closed continuous process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.3.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 33. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.365 mg/m³** (TRA Workers)	RCR = 0.73
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.027 mg/kg bw/day** (TRA Workers)	RCR = 0.039
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.769

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial metal treatment does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.3.3. Worker contributing scenario 2: Industrial batch process (PROC 4)

9.3.3.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1-5% *The end-use concentration is 3%.*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
	Method
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.3.3.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 34. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.365 mg/m³** (TRA Workers)	RCR = 0.73
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.137 mg/kg bw/day** (TRA Workers)	RCR = 0.196
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.926

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial metal treatment does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.3.4. Worker contributing scenario 3: Transfer at dedicated facilities (PROC 8b)

9.3.4.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1-5% *The end-use concentration is 3%.*	TRA Workers
	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: yes (Inh: 95 %;)	TRA Workers
• Local exhaust ventilation (for dermal): no (Der: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

9.3.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 35. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.018 mg/m³** (TRA Workers)	RCR = 0.036

Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.274 mg/kg bw/day** (TRA Workers)	RCR = 0.392
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.428

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial metal treatment does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.3.5. Worker contributing scenario 4: Industrial spraying (PROC 7)

9.3.5.1. Conditions of use (contributing scenario)

Dermal exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1-5% *The end-use concentration is 3%.*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 95 %;)	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with specific activity training) (Der: 95 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers

• Skin surface potentially exposed: Two hands and upper wrists (1500 cm2)	TRA Workers

Inhalation exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	ART 1.0
• Vapour pressure : 1.8 x 10^{-6} Pa at 20°C	ART 1.0
• Viscosity : Liquids with low viscosity	ART 1.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: *Exposure period = 180 mins (300 mins non-exposure period)*	ART 1.0
Primary emission source	
• Primary emission source: near field	ART 1.0
• Proximity: Located in breathing zone of worker	ART 1.0
Activity class: Spray application of liquids, surface spraying e.g. spraying cleaning agents onto surfaces (only horizonal or downward spraying, with no or low compressed air use)	ART 1.0
• Application rate: 0.03- 3 L/min	ART 1.0
• Primary localised controls: LEV (unspecified type)	ART 1.0
	Method
• Secondary localised controls: none	ART 1.0
Surface contamination/fugative emission sources: Process not fully enclosed, but demonstrable and effective housekeeping practices in place (e.g. daily cleaning using appropriate methods (e.g. vacuum), preventive maintenance of machinery and control measures, and use of protective clothing that will repel spills and reduce personal cloud)	ART 1.0
• Dispersion: Room size = 300 m^3; Air Changes per Hour (ACH) = 1	ART 1.0
Secondary emission source	
• None	ART 1.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	Manual calculation
Other conditions affecting workers exposure	
• Place of use: Indoor	ART 1.0
• Process temperature (for liquid): Room temperature (15-25°C)	ART 1.0

9.3.5.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 36. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.026 mg/m³** (External exposure estimation tool (ART 1.0))	RCR = 0.052

Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.021 mg/kg bw/day** (TRA Workers)	RCR = 0.031
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.083

Remarks on exposure data

External exposure estimation tool (ART 1.0)

Long-term systemic inhalation exposures (in mg/m^3) were determined using ART 1.0 as the upper value of the inter-quartile confidence interval of the predicted 75th percentile full-shift (8 hour) inhalation exposure value. It has been assumed that workers will wear RPE (90% efficiency) during this task (the ART model does not include RPE – the exposure values were adjusted manually for RPE).

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial metal treatment does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity. N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.3.6. Worker contributing scenario 5: Roller application or brushing (PROC 10)

9.3.6.1. Conditions of use (contributing scenario)

Dermal exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1-5% *The end-use concentration is 3%.*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Occupational Health and Safety Management System: Advanced	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	

Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

Inhalation exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	ART 1.0
• Vapour pressure : 1.8 x 10^{-6} Pa at 20°C	ART 1.0
• Viscosity : Liquids with low viscosity	ART 1.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: *Exposure period = 240 mins (240 mins non-exposure period)*	ART 1.0
Primary emission source	
• Primary emission source: near field	ART 1.0
• Proximity: Located in breathing zone of worker	ART 1.0
• Activity class: Spreading of liquid products	ART 1.0
• Application rate: 3 m²/hour	ART 1.0
• Primary localised controls: none	ART 1.0
• Secondary localised controls: none	ART 1.0
	Method
Surface contamination/fugative emission sources: Process not fully enclosed, but demonstrable and effective housekeeping practices in place (e.g. daily cleaning using appropriate methods (e.g. vacuum), preventive maintenance of machinery and control measures, and use of protective clothing that will repel spills and reduce personal cloud)	ART 1.0
• Dispersion: Room size = 300 m^3; Air Changes per Hour (ACH) = 1	ART 1.0
Secondary emission source	
• None	ART 1.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	Manual calculation
Other conditions affecting workers exposure	
• Place of use: Indoor	ART 1.0
• Process temperature (for liquid): Room temperature (15-25°C)	ART 1.0

9.3.6.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 37. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.002 mg/m³** (External exposure estimation tool (ART 1.0))	RCR = 0.003
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.549 mg/kg bw/day** (TRA Workers)	RCR = 0.784
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.787

Remarks on exposure data

External exposure estimation tool (ART 1.0)

Long-term systemic inhalation exposures (in mg/m^3) were determined using ART 1.0 as the upper value of the inter-quartile confidence interval of the predicted 75th percentile full-shift (8 hour) inhalation exposure value. It has been assumed that workers will wear RPE (90% efficiency) during this task (the ART model does not include RPE – the exposure values were adjusted manually for RPE).

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during the use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as an industrial metal treatment does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.4. Exposure scenario 4 : ES4 Professional use of Cleaning Products

Environment contributing scenario(s):

Wide dispersive indoor use of reactive substances	ERC 8a

Worker contributing scenario(s):

Professional closed process	PROC 2
Professional batch process	PROC 4
Transfer at non-dedicated facilities	PROC 8a
Transfer into small containers	PROC 9
Roller application or brushing	PROC 10
Spraying	PROC 11
Dipping and pouring	PROC 13
Professional closed process - 15%	PROC 2
Professional batch process - 15%	PROC 4
Transfer at non-dedicated facilities - 15%	PROC 8a
Transfer into small containers - 15%	PROC 9

Environment contributing scenario:

Wide dispersive use in 'down the drain' cleaning and maintenance products (consumers and professionals)

Explanation on the approach taken for the ES

Bardap 26 is used by professionals as a cleaner/disinfectant. The activities involved include batch processes, transfer to/from large containers, spraying and dipping/pouring. Professionals will be required to dilute a 15% concentration prior to use; end-use concentrations are below 1% (typically 0.1-0.3%). It has been assumed that all activities take place indoors, and that LEV is used during spraying, dipping and pouring, and transfer of the 15% solution (at non-dedicated facilities). The duration of activity is less than 8 hours for batch processes, less than 1 hour for transfer, and less than 4 hours for spraying and roller/brush application. Workers will wear gloves in all cases. Workers will wear also wear respiratory protection when spraying, during roller/brush application, and when transferring the 15% solution at non-dedicated facilities.

Releases to the environment were initially based on the default release factors for ERC8A. However, the assessment was refined using AISE SPERC 8a.1.a.v1.

9.4.1. Environmental contributing scenario 1: Wide dispersive indoor use of reactive substances

9.4.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily wide dispersive use: <= 5.5E-6 tonnes/day
Default calculated value
• Percentage of tonnage used at regional scale: = 10 %
Conditions and measures related to sewage treatment plant
• Municipal STP: Yes (Wat: 87.79 %;)
• Discharge rate of STP: <= 2E3 m3/d
• Application of the STP sludge on agricultural soil: Yes
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d

9.4.1.2. Releases

The local releases to the environment are reported in the following table.

Table 38. Local releases to the environment

Release	**Release factor estimation method**	**Explanation / Justification**
Water	SpERC based AISE SPERC 8a.1.a.v1 (ERC 8a) Bardap26 - AISE SPERC 8a.1.a.v1 AISE SPERC 8a.1.a.v1 (ERC 8a) Bardap26 - AISE 16	**Initial release factor:** 100% **Final release factor:** 100% **Local release rate:** 0.006 kg/day **Explanation / Justification:** From AISE SPERC 8a.1.a.v1
Air	SpERC based same as above	**Initial release factor:** 0% **Final release factor:** 0% **Explanation / Justification:** From AISE SPERC 8a.1.a.v1
Soil	SpERC based same as above	**Final release factor:** 0% **Explanation / Justification:** From AISE SPERC 8a.1.a.v1

Releases to waste
No further releases to waste which are relevant for the environmental risk assessment are foreseen and emissions relevant to establishment of environmental PECs are stated above.

Any emission to solid waste (landfill) or to specialized waste disposal companies or processes are not considered to be under the scope of REACH as these are regulated under dedicated waste and local regulatory statutes.

9.4.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 39. Exposure concentrations and risks for the environment

Protection target	**Exposure concentration**	**Risk characterisation**
Freshwater	**Local PEC:** 5.214E-5 mg/L	RCR = 0.052
Sediment (freshwater)	**Local PEC:** 0.789 mg/kg dw	RCR = 0.149

Marine water		Qualitative risk characterisation (see below)
Sediment (marine water)		Qualitative risk
Protection target	**Exposure concentration**	**Risk characterisation**
		characterisation (see below)
Sewage treatment plant	**Local PEC:** 3.358E-4 mg/L	RCR = 0.003
Air		
Agricultural soil	**Local PEC:** 0.19 mg/kg dw	RCR = 0.067
Man via Environment - Inhalation	**Local PEC:** 4.737E-12 mg/m³	RCR = 3.948E-11
Man via Environment - Oral	**Exposure via food consumption:** 0.196 mg/kg bw/day	RCR = 0.559
Man via environment - combined routes		RCR = 0.559

Table 40. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	1.792E-6 mg/kg bw/day	6.271E-5 mg/L
Fish	6.938E-6 mg/kg bw/day	0.004 mg/kg ww
Leaf crops	8.293E-7 mg/kg bw/day	4.838E-5 mg/kg ww
Root crops	0.196 mg/kg bw/day	35.67 mg/kg ww
Meat	1.997E-5 mg/kg bw/day	0.005 mg/kg ww
Milk	1.177E-5 mg/kg bw/day	0.001 mg/kg ww

Conclusion on risk characterisation

No significant exposure expected for marine environments, and as such no risk characterisation is conducted for these compartments.

Risk characterisation ratios (RCRs) were derived for freshwater, freshwater sediment, STP and soil compartments. Following a tier 2 risk assessment with the addition of an appropriate SPERC, all RCRs were found to be less than 1. As such it should be considered that safe use has been demonstrated.

9.4.2. Worker contributing scenario 1: Professional closed process (PROC 2)

9.4.2.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers

Containment: Closed continuous process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.4.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 41. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.182 mg/m³** (TRA Workers)	RCR = 0.365
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.014 mg/kg bw/day** (TRA Workers)	RCR = 0.02
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.384

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a professional cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.4.3. Worker contributing scenario 2: Professional batch process (PROC 4)

9.4.3.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1%	TRA Workers
	Method
The end-use concentration is 0.01-1%	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.4.3.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 42. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.182 mg/m³** (TRA Workers)	RCR = 0.365
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.069 mg/kg bw/day** (TRA Workers)	RCR = 0.098
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.463

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management

measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a professional cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.4.4. Worker contributing scenario 3: Transfer at non-dedicated facilities (PROC 8a)

9.4.4.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

9.4.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 43. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.036 mg/m³** (TRA Workers)	RCR = 0.073
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.137 mg/kg bw/day** (TRA Workers)	RCR = 0.196

Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.269

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a professional cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.4.5. Worker contributing scenario 4: Transfer into small containers (PROC 9)

9.4.5.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.4.5.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 44. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.036 mg/m³** (TRA Workers)	RCR = 0.073
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.069 mg/kg bw/day** (TRA Workers)	RCR = 0.098
Dermal, systemic, acute		Qualitative (see below)
Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.171

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a professional cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.4.6. Worker contributing scenario 5: Roller application or brushing (PROC 10)

9.4.6.1. Conditions of use (contributing scenario)

Dermal exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

Inhalation exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	ART 1.0
	Method
• Vapour pressure : 1.8 x 10^{-6} Pa at 20°C	ART 1.0
• Viscosity : Liquids with low viscosity	ART 1.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: *Exposure period = 240 mins (240 mins non-exposure period)*	ART 1.0
Primary emission source	
• Primary emission source: near field	ART 1.0
• Proximity: Located in breathing zone of worker	ART 1.0
• Activity class: Spreading of liquid products	ART 1.0
• Application rate: 3 m²/hour	ART 1.0
• Primary localised controls: none	ART 1.0
• Secondary localised controls: none	ART 1.0
Surface contamination/fugative emission sources: Process not fully enclosed, but demonstrable and effective housekeeping practices in place (e.g. daily cleaning using appropriate methods (e.g. vacuum), preventive maintenance of machinery and control measures, and use of protective clothing that will repel spills and reduce personal cloud)	ART 1.0

• Dispersion: Room size = 300 m^3; Air Changes per Hour (ACH) = 1	ART 1.0
Secondary emission source	
• None	ART 1.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	Manual calculation
Other conditions affecting workers exposure	
• Place of use: Indoor	ART 1.0
• Process temperature (for liquid): Room temperature (15-25°C)	ART 1.0

9.4.6.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 45. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.002 mg/m³** (External exposure estimation tool (ART 1.0))	RCR = 0.003
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.274 mg/kg bw/day** (TRA Workers)	RCR = 0.392
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.395

Remarks on exposure data

External exposure estimation tool (ART 1.0)

Long-term systemic inhalation exposures (in mg/m^3) were determined using ART 1.0 as the upper value of the inter-quartile confidence interval of the predicted 75th percentile full-shift (8 hour) inhalation exposure value. It has been assumed that workers will wear RPE (90% efficiency) during this task (the ART model does not include RPE – the exposure values were adjusted manually for RPE).

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a professional cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.4.7. Worker contributing scenario 6: Spraying (PROC 11)

9.4.7.1. Conditions of use (contributing scenario)

Dermal exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 80 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands and upper wrists (1500 cm2)	TRA Workers

Inhalation exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	ART 1.0
• Vapour pressure : 1.8 x 10^{-6} Pa at 20°C	ART 1.0
	Method
• Viscosity : Liquids with low viscosity	ART 1.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: *Exposure period = 240 mins (240 mins non-exposure period)*	ART 1.0
Primary emission source	
• Primary emission source: near field	ART 1.0
• Proximity: Located in breathing zone of worker	ART 1.0
Activity class: Spray application of liquids, surface spraying e.g. spraying cleaning agents onto surfaces (spraying in any direction including upwards, with no or low compressed air use)	ART 1.0
• Application rate: 0.03- 3 L/min	ART 1.0
• Primary localised controls: LEV (unspecified type)	ART 1.0
• Secondary localised controls: none	ART 1.0

Surface contamination/fugative emission sources: Process not fully enclosed, but demonstrable and effective housekeeping practices in place (e.g. daily cleaning using appropriate methods (e.g. vacuum), preventive maintenance of machinery and control measures, and use of protective clothing that will repel spills and reduce personal cloud)	ART 1.0
• Dispersion: Room size = 300 m^3; Air Changes per Hour (ACH) = 1	ART 1.0
Secondary emission source	
• None	ART 1.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	Manual calculation
Other conditions affecting workers exposure	
• Place of use: Indoor	ART 1.0
• Process temperature (for liquid): Room temperature (15-25°C)	ART 1.0

9.4.7.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 46. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.026 mg/m³** (External exposure estimation tool (ART 1.0))	RCR = 0.052
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.214 mg/kg bw/day** (TRA Workers)	RCR = 0.306
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.378

Remarks on exposure data

External exposure estimation tool (ART 1.0)

Long-term systemic inhalation exposures (in mg/m^3) were determined using ART 1.0 as the upper value of the inter-quartile confidence interval of the predicted 75^{th} percentile full-shift (8 hours) inhalation exposure value. It has been assumed that workers will wear RPE (90% efficiency) during this task (the ART model does not include RPE – the exposure values were adjusted manually for RPE).

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a professional cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.4.8. Worker contributing scenario 7: Dipping and pouring (PROC 13)

9.4.8.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation: yes (Inh: 80 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 80 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.4.8.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 47. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.036 mg/m³** (TRA Workers)	RCR = 0.073
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.027 mg/kg bw/day** (TRA Workers)	RCR = 0.039
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)

Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.112

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a professional cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.4.9. Worker contributing scenario 8: Professional closed process - 15% (PROC 2)

9.4.9.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25% *The concentration is 15%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
Containment: Closed continuous process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	TRA Workers
Other conditions affecting workers exposure	
	Method
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.4.9.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 48. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.109 mg/m³** (TRA Workers)	RCR = 0.219
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.082 mg/kg bw/day** (TRA Workers)	RCR = 0.117
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.336

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a professional cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.4.10. Worker contributing scenario 9: Professional batch process - 15% (PROC 4)

9.4.10.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25% *The concentration is 15%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers

	Method
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.4.10.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 49. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.109 mg/m³** (TRA Workers)	RCR = 0.219
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.412 mg/kg bw/day** (TRA Workers)	RCR = 0.588
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.807

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a professional cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.4.11. Worker contributing scenario 10: Transfer at non-dedicated facilities - 15% (PROC 8a)

9.4.11.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25% *The concentration is 15%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation: yes (Inh: 80 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 80 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

9.4.11.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 50. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.044 mg/m³** (TRA Workers)	RCR = 0.088
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.164 mg/kg bw/day** (TRA Workers)	RCR = 0.235
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.323

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a professional cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.4.12. Worker contributing scenario 11: Transfer into small containers - 15% (PROC 9)

9.4.12.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25% *The concentration is 15%*	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.4.12.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 51. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.022 mg/m³** (TRA Workers)	RCR = 0.044
Inhalation, systemic, acute		Qualitative (see below)

Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.412 mg/kg bw/day** (TRA Workers)	RCR = 0.588
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.632

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a professional cleaning product does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.5. Exposure scenario 5 : ES5 Professional use of Medical Devices - processing aids

Environment contributing scenario(s):

Wide dispersive indoor use of reactive substances	ERC 8a

Worker contributing scenario(s):

Professional batch process	PROC 4
Transfer at non-dedicated facilities	PROC 8a
Spraying	PROC 11
Dipping and pouring	PROC 13
Professional batch process - 15%	PROC 4
Transfer at non-dedicated facilities - 15%	PROC 8a

Explanation on the approach taken for the ES

Bardap 26 is used by professionals as a disinfectant for medical devices (e.g. hospital equipment, utensils and instruments). Typical use of the product involves soaking pre-washed equipment prior to rinsing. The activities involved include batch processes, transfer to/from large containers, spraying and dipping/pouring. Professionals will be required to dilute a 15% concentration prior to use; end-use concentrations are below 1% (typically 0.1- 0.3%). It

has been assumed that all activities take place indoors, and that LEV is used during spraying, dipping and pouring, and transfer of the 15% solution (at non-dedicated facilities). The duration of activity is less than 8 hours for batch processes, less than 1 hour for transfer, and less than 4 hours for spraying and roller/brush application. Workers will wear gloves during all tasks. Works will also wear respiratory protection during spraying and professional batch processes carried out with the 15% solution.

Releases to the environment were initially based on the default release factors for ERC8a. However, the assessment was refined using information on from the Bardap 26 PT2 biocides dossier. Releases to wastewater were based on the calculated daily releases in the Doc IIB of the PT2 dossier. For further information see appendix 1.

Releases to air are likely to be minimal due to the low Henry's law constant of the substance.

9.5.1. Environmental contributing scenario 1: Wide dispersive indoor use of reactive substances

9.5.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily wide dispersive use: <= 8.25E-5 tonnes/day *Default calculated value*
• Percentage of tonnage used at regional scale: = 10 %
Conditions and measures related to sewage treatment plant
• Municipal STP: Yes (Wat: 87.79 %;)
• Discharge rate of STP: <= 2E3 m3/d
• Application of the STP sludge on agricultural soil: Yes
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d

9.5.1.2. Releases

The local releases to the environment are reported in the following table.

Table 52. Local releases to the environment

Release	**Release factor estimation method**	**Explanation / Justification**
Water	Measured release	**Final release factor:** 2.909E-4% **Local release rate:** 2.4E-7 kg/day **Explanation / Justification:** Based on the predicted daily release for PT 2.01b in the Bardap 26 PT2 biocide dossier. PT2.01b covers the disinfection of medical instruments by soaking, and as such is considered to be directly applicable to this exposure scenario. For further information see appendix 1.

Air	Release factor	**Initial release factor:** 0% **Final release factor:** 0% **Explanation / Justification:** In the PT2 biocide dossier for Bardap 26, no PEC is calculated for air. Bardap 26 has a low Henry's law constant (3.03E-11 Pa m3/mol) and is expected to be quickly degraded in air. The photochemical oxidative degradation half-life of Bardap 26 in is expected to be approximately 2.8 hours based on the structurally related DDAC. For further information see appendix 1.
Soil	ERC based	**Final release factor:** 0%

Releases to waste
No further releases to waste which are relevant for the environmental risk assessment are foreseen and emissions relevant to establishment of environmental PECs are stated above.

Any emission to solid waste (landfill) or to specialized waste disposal companies or processes are not considered to be under the scope of REACH as these are regulated under dedicated waste and local regulatory statutes.

9.5.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 53. Exposure concentrations and risks for the environment

Protection target	**Exposure concentration**	**Risk characterisation**
Freshwater	**Local PEC:** 2.477E-5 mg/L	RCR = 0.025
Sediment (freshwater)	**Local PEC:** 0.375 mg/kg dw	RCR = 0.071
Marine water		Qualitative risk characterisation (see below)
Sediment (marine water)		Qualitative risk characterisation (see below)
Sewage treatment plant	**Local PEC:** 1.465E-8 mg/L	RCR = 1.242E-7
Air		
Agricultural soil	**Local PEC:** 0.088 mg/kg dw	RCR = 0.031
Protection target	**Exposure concentration**	**Risk characterisation**
Man via Environment - Inhalation	**Local PEC:** 4.737E-12 mg/m³	RCR = 3.948E-11
Man via Environment - Oral	**Exposure via food consumption:** 0.091 mg/kg bw/day	RCR = 0.26
Man via environment - combined routes		RCR = 0.26

Table 54. Contribution to oral intake for man via the environment from local contribution

Type of food	**Estimated daily dose**	**Concentration in food**
Drinking water	8.323E-7 mg/kg bw/day	2.913E-5 mg/L
Fish	3.297E-6 mg/kg bw/day	0.002 mg/kg ww
Leaf crops	3.852E-7 mg/kg bw/day	2.247E-5 mg/kg ww
Root crops	0.091 mg/kg bw/day	16.57 mg/kg ww

Meat	1.341E-5 mg/kg bw/day	0.003 mg/kg ww
Milk	7.906E-6 mg/kg bw/day	9.864E-4 mg/kg ww

Conclusion on risk characterisation

No significant exposure expected for marine environments, and as such no risk characterisation is conducted for these compartments.

Risk characterisation ratios (RCRs) were derived for freshwater, freshwater sediment, STP and soil compartments. Following a tier 2 risk assessment with refinements for releases to air and water based on information in the Bardap 26 PT2 biocide dossier, all RCRs were found to be less than 1. As such it should be considered that safe use has been demonstrated.

9.5.2. Worker contributing scenario 1: Professional batch process (PROC 4)

9.5.2.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1%	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.5.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 55. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.182 mg/m³** (TRA Workers)	RCR = 0.365
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.069 mg/kg bw/day** (TRA Workers)	RCR = 0.098
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.463

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a disinfectant for medical devices does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.5.3. Worker contributing scenario 2: Transfer at non-dedicated facilities (PROC 8a)

9.5.3.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1%	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	

Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
	Method
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

9.5.3.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 56. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.036 mg/m³** (TRA Workers)	RCR = 0.073
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.137 mg/kg bw/day** (TRA Workers)	RCR = 0.196
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.269

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a disinfectant for medical devices does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.5.4. Worker contributing scenario 3: Spraying (PROC 11)

9.5.4.1. Conditions of use (contributing scenario)

Dermal exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1%	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hours	TRA Workers

	Method
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 80 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands and upper wrists (1500 cm2)	TRA Workers

Inhalation exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	ART 1.0
• Vapour pressure : 1.8 x 10^{-6} Pa at 20°C	ART 1.0
• Viscosity : Liquids with low viscosity	ART 1.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: *Exposure period = 240 mins (240 mins non-exposure period)*	ART 1.0
Primary emission source	
• Primary emission source: near field	ART 1.0
• Proximity: Located in breathing zone of worker	ART 1.0
Activity class: Spray application of liquids, surface spraying e.g. spraying cleaning agents onto surfaces (spraying in any direction including upwards, with no or low compressed air use)	ART 1.0
• Application rate: 0.03- 3 L/min	ART 1.0
• Primary localised controls: LEV (unspecified type)	ART 1.0
• Secondary localised controls: none	ART 1.0
Surface contamination/fugative emission sources: Process not fully enclosed, but demonstrable and effective housekeeping practices in place (e.g. daily cleaning using appropriate methods (e.g. vacuum), preventive maintenance of machinery and control measures, and use of protective clothing that will repel spills and reduce personal cloud)	ART 1.0
• Dispersion: Room size = 300 m^3; Air Changes per Hour (ACH) = 1	ART 1.0
Secondary emission source	
• None	ART 1.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	Manual calculation
Other conditions affecting workers exposure	

• Place of use: Indoor	ART 1.0
• Process temperature (for liquid): Room temperature (15-25°C)	ART 1.0

9.5.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 57. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.026 mg/m³** (External exposure estimation tool (ART 1.0))	RCR = 0.052
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.214 mg/kg bw/day** (TRA Workers)	RCR = 0.306
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.378

Remarks on exposure data

External exposure estimation tool (ART 1.0)

Long-term systemic inhalation exposures (in mg/m^3) were determined using ART 1.0 as the upper value of the inter-quartile confidence interval of the predicted 75th percentile full-shift (8 hour) inhalation exposure value. It has been assumed that workers will wear RPE (90% efficiency) during this task (the ART model does not include RPE – the exposure values were adjusted manually for RPE).

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a disinfectant for medical devices does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.5.5. Worker contributing scenario 4: Dipping and pouring (PROC 13)

9.5.5.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	

• Concentration of substance in mixture: <1%	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
	Method
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation: yes (Inh: 80 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 80 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.5.5.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 58. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.036 mg/m³** (TRA Workers)	RCR = 0.073
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.027 mg/kg bw/day** (TRA Workers)	RCR = 0.039
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.112

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a disinfectant for medical devices does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.
N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures,

and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.5.6. Worker contributing scenario 5: Professional batch process - 15% (PROC 4)

9.5.6.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25%	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.5.6.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 59. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.109 mg/m³** (TRA Workers)	RCR = 0.219
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.412 mg/kg bw/day** (TRA Workers)	RCR = 0.588
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.807

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a disinfectant for medical devices does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.5.7. Worker contributing scenario 6: Transfer at non-dedicated facilities - 15% (PROC 8a)

9.5.7.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25%	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation: yes (Inh: 80 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 80 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

9.5.7.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 60. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.044 mg/m³** (TRA Workers)	RCR = 0.088
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)

Dermal, systemic, long-term	**0.164 mg/kg bw/day** (TRA Workers)	RCR = 0.235
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.323

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a disinfectant for medical devices does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.6. Exposure scenario 6 : ES6 Professional use of Medical Devices - reactive substances

Environment contributing scenario(s):

Wide dispersive indoor use of reactive substances	ERC 8b

Worker contributing scenario(s):

Professional batch process	PROC 4
Transfer at non-dedicated facilities	PROC 8a
Spraying	PROC 11
Dipping and pouring	PROC 13
Professional batch process - 15%	PROC 4
Transfer at non-dedicated facilities - 15%	PROC 8a

Explanation on the approach taken for the ES

Bardap 26 is used by professionals as a disinfectant for medical devices (e.g. hospital equipment, utensils and instruments). Typical use of the product involves soaking pre-washed equipment prior to rinsing. The activities involved include batch processes, transfer to/from large containers, spraying and dipping/pouring. Professionals will be required to dilute a 15% concentration prior to use; end-use concentrations are below 1% (typically 0.1- 0.3%). It has been assumed that all activities take place indoors, and that LEV is used during spraying, dipping and pouring, and transfer of the 15% solution (at non-dedicated facilities). The duration of activity is less than 8 hours for batch processes, less than 1 hour for transfer, and less than 4 hours for spraying and roller/brush application. Workers will

wear gloves during all tasks. Works will also wear respiratory protection during spraying and professional batch processes carried out with the 15% solution.

Releases to the environment were initially based on the default release factors for ERC8b. However, the assessment was refined using information on from the Bardap 26 PT2 biocides dossier. Releases to wastewater were based on the calculated daily releases in the Doc IIB of the PT2 dossier. For further information see appendix 1.

Releases to air are likely to be minimal due to the low Henry's law constant of the substance.

9.6.1. Environmental contributing scenario 1: Wide dispersive indoor use of reactive substances

9.6.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily wide dispersive use: <= 8.25E-5 tonnes/day *Default calculated value*
• Percentage of tonnage used at regional scale: = 10 %
Conditions and measures related to sewage treatment plant
• Municipal STP: Yes (Wat: 87.79 %;)
• Discharge rate of STP: <= 2E3 m3/d
• Application of the STP sludge on agricultural soil: Yes
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d

9.6.1.2. Releases

The local releases to the environment are reported in the following table.

Table 61. Local releases to the environment

Release	**Release factor estimation method**	**Explanation / Justification**
Water	Measured release	**Final release factor:** 2.909E-4% **Local release rate:** 2.4E-7 kg/day **Explanation / Justification:** Based on the predicted daily release for PT 2.01b in the Bardap 26 PT2 biocide dossier. PT2.01b covers the disinfection of medical instruments by soaking, and as such is considered to be directly applicable to this exposure scenario. For further information see appendix 1.
Air	Release factor	**Initial release factor:** 0% **Final release factor:** 0% **Explanation / Justification:** In the PT2 biocide dossier for Bardap 26, no PEC is calculated for air. Bardap 26 has a low Henry's law constant (3.03E-11 Pa m3/mol) and is expected to be quickly degraded in air. The photochemical oxidative degradation half-life of Bardap 26 in is expected to be approximately 2.8 hours based on the structurally related DDAC. For further information see appendix 1.

Soil	ERC based	**Final release factor:** 0%

Releases to waste
No further releases to waste which are relevant for the environmental risk assessment are foreseen and emissions relevant to establishment of environmental PECs are stated above.

Any emission to solid waste (landfill) or to specialized waste disposal companies or processes are not considered to be under the scope of REACH as these are regulated under dedicated waste and local regulatory statutes.

9.6.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 62. Exposure concentrations and risks for the environment

Protection target	**Exposure concentration**	**Risk characterisation**
Freshwater	**Local PEC:** 2.477E-5 mg/L	RCR = 0.025
Sediment (freshwater)	**Local PEC:** 0.375 mg/kg dw	RCR = 0.071
Marine water		Qualitative risk characterisation (see below)
Sediment (marine water)		Qualitative risk characterisation (see below)
Sewage treatment plant	**Local PEC:** 1.465E-8 mg/L	RCR = 1.242E-7
Air		
Agricultural soil	**Local PEC:** 0.088 mg/kg dw	RCR = 0.031
Protection target	**Exposure concentration**	**Risk characterisation**
Man via Environment - Inhalation	**Local PEC:** 4.737E-12 mg/m³	RCR = 3.948E-11
Man via Environment - Oral	**Exposure via food consumption:** 0.091 mg/kg bw/day	RCR = 0.26
Man via environment - combined routes		RCR = 0.26

Table 63. Contribution to oral intake for man via the environment from local contribution

Type of food	**Estimated daily dose**	**Concentration in food**
Drinking water	8.323E-7 mg/kg bw/day	2.913E-5 mg/L
Fish	3.297E-6 mg/kg bw/day	0.002 mg/kg ww
Leaf crops	3.852E-7 mg/kg bw/day	2.247E-5 mg/kg ww
Root crops	0.091 mg/kg bw/day	16.57 mg/kg ww
Meat	1.341E-5 mg/kg bw/day	0.003 mg/kg ww
Milk	7.906E-6 mg/kg bw/day	9.864E-4 mg/kg ww

Conclusion on risk characterisation

No significant exposure expected for marine environments, and as such no risk characterisation is conducted for these compartments.

Risk characterisation ratios (RCRs) were derived for freshwater, freshwater sediment, STP and soil compartments. Following a tier 2 risk assessment with refinements for releases to air and water based on information in the Bardap 26 PT2 biocide dossier, all RCRs were found to be less than 1. As such it should be considered that safe use has been demonstrated.

9.6.2. Worker contributing scenario 1: Professional batch process (PROC 4)

9.6.2.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1%	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.6.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 64. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.182 mg/m³** (TRA Workers)	RCR = 0.365
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.069 mg/kg bw/day** (TRA Workers)	RCR = 0.098
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.463

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a disinfectant for medical devices does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.6.3. Worker contributing scenario 2: Transfer at non-dedicated facilities (PROC 8a)

9.6.3.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1%	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	

Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
	Method
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

9.6.3.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 65. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.036 mg/m³** (TRA Workers)	RCR = 0.073
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.137 mg/kg bw/day** (TRA Workers)	RCR = 0.196
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.269

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a disinfectant for medical devices does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.6.4. Worker contributing scenario 3: Spraying (PROC 11)

9.6.4.1. Conditions of use (contributing scenario)

Dermal exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1%	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 80 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands and upper wrists (1500 cm2)	TRA Workers

Inhalation exposure assessment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1% *The end-use concentration is 0.01-1%*	ART 1.0
• Vapour pressure : 1.8 x 10^{-6} Pa at 20°C	ART 1.0
• Viscosity : Liquids with low viscosity	ART 1.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: *Exposure period = 240 mins (240 mins non-exposure period)*	ART 1.0
Primary emission source	
• Primary emission source: near field	ART 1.0
• Proximity: Located in breathing zone of worker	ART 1.0
Activity class: Spray application of liquids, surface spraying e.g. spraying cleaning agents onto surfaces (spraying in any direction including upwards, with no or low compressed air use)	ART 1.0
• Application rate: 0.03- 3 L/min	ART 1.0
• Primary localised controls: LEV (unspecified type)	ART 1.0
• Secondary localised controls: none	ART 1.0
Surface contamination/fugative emission sources: Process not fully enclosed, but demonstrable and effective housekeeping practices in place (e.g. daily cleaning using appropriate methods (e.g. vacuum), preventive maintenance of machinery and control measures, and use of protective clothing that will repel spills and reduce personal cloud)	ART 1.0
• Dispersion: Room size = 300 m^3; Air Changes per Hour (ACH) = 1	ART 1.0
Secondary emission source	

• None	ART 1.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	Manual calculation
Other conditions affecting workers exposure	
• Place of use: Indoor	ART 1.0
• Process temperature (for liquid): Room temperature (15-25°C)	ART 1.0

9.6.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 66. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.026 mg/m³** (External exposure estimation tool (ART 1.0))	RCR = 0.052
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.214 mg/kg bw/day** (TRA Workers)	RCR = 0.306
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.378

Remarks on exposure data

External exposure estimation tool (ART 1.0)

Long-term systemic inhalation exposures (in mg/m³) were determined using ART 1.0 as the upper value of the inter-quartile confidence interval of the predicted 75th percentile full-shift (8 hour) inhalation exposure value. It has been assumed that workers will wear RPE (90% efficiency) during this task (the ART model does not include RPE – the exposure values were adjusted manually for RPE).

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a disinfectant for medical devices does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.6.5. Worker contributing scenario 4: Dipping and pouring (PROC 13)

9.6.5.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1%	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
	Method
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation: yes (Inh: 80 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 80 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.6.5.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 67. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.036 mg/m³** (TRA Workers)	RCR = 0.073
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.027 mg/kg bw/day** (TRA Workers)	RCR = 0.039
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.112

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a disinfectant for medical devices does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.6.6. Worker contributing scenario 5: Professional batch process - 15% (PROC 4)

9.6.6.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25%	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: Yes (Respirator with APF of 10) (Inh: 90 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers

9.6.6.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 68. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.109 mg/m³** (TRA Workers)	RCR = 0.219
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)

Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.412 mg/kg bw/day** (TRA Workers)	RCR = 0.588
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.807

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a disinfectant for medical devices does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.6.7. Worker contributing scenario 6: Transfer at non-dedicated facilities - 15% (PROC 8a)

9.6.7.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 5-25%	TRA Workers
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation: yes (Inh: 80 %;)	TRA Workers
• Local exhaust ventilation (for dermal): yes (Der: 80 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Workers

9.6.7.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 69. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.044 mg/m³** (TRA Workers)	RCR = 0.088
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.164 mg/kg bw/day** (TRA Workers)	RCR = 0.235
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.323

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a disinfectant for medical devices does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.7. Exposure scenario 7 : ES7 Professional Laboratory Use

Environment contributing scenario(s):

Wide dispersive indoor use of processing aids — ERC 8a

Worker contributing scenario(s):

Laboratory reagent — PROC 15

Explanation on the approach taken for the ES

Bardap 26 is used by professionals in the laboratory at concentrations of below 1%. Basic general ventilation is expected as a minimum, and the duration of activity is up to 8 hours. Workers will wear gloves.

A tier 1 assessment was conducted using the default release factors for ERC 8a. Safe use was demonstrated on tier 1 and no further refinements were necessary.

9.7.1. Environmental contributing scenario 1: Wide dispersive indoor use of processing aids

9.7.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily wide dispersive use: <= 5.5E-7 tonnes/day *Default calculated value*
• Percentage of tonnage used at regional scale: = 10 %
Conditions and measures related to sewage treatment plant
• Municipal STP: Yes (Wat: 87.79 %;)
• Discharge rate of STP: <= 2E3 m3/d
• Application of the STP sludge on agricultural soil: Yes
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d

9.7.1.2. Releases

The local releases to the environment are reported in the following table.

Table 70. Local releases to the environment

Release	**Release factor estimation method**	**Explanation / Justification**
Water	ERC based	**Initial release factor:** 100% **Final release factor:** 100% **Local release rate:** 5.5E-4 kg/day
Air	ERC based	**Initial release factor:** 100% **Final release factor:** 100%
Soil	ERC based	**Final release factor:** 0%

Releases to waste
No further releases to waste which are relevant for the environmental risk assessment are foreseen and emissions relevant to establishment of environmental PECs are stated above.

Any emission to solid waste (landfill) or to specialized waste disposal companies or processes are not considered to be under the scope of REACH as these are regulated under dedicated waste and local regulatory statutes.

9.7.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 71. Exposure concentrations and risks for the environment

Protection target	**Exposure concentration**	**Risk characterisation**
Freshwater	**Local PEC:** 2.751E-5 mg/L	RCR = 0.028
Sediment (freshwater)	**Local PEC:** 0.416 mg/kg dw	RCR = 0.079
Marine water		Qualitative risk characterisation (see below)
Sediment (marine water)		Qualitative risk characterisation (see below)

Sewage treatment plant	**Local PEC:** 3.358E-5 mg/L	RCR = 2.846E-4
Air		
Agricultural soil	**Local PEC:** 0.098 mg/kg dw	RCR = 0.035
Man via Environment - Inhalation	**Local PEC:** 4.737E-12 mg/m³	RCR = 3.948E-11
Man via Environment - Oral	**Exposure via food consumption:** 0.101 mg/kg bw/day	RCR = 0.29
Man via environment - combined routes		RCR = 0.29

Table 72. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	9.282E-7 mg/kg bw/day	3.249E-5 mg/L
Fish	3.661E-6 mg/kg bw/day	0.002 mg/kg ww
Leaf crops	4.296E-7 mg/kg bw/day	2.506E-5 mg/kg ww
Root crops	0.101 mg/kg bw/day	18.48 mg/kg ww
Meat	1.407E-5 mg/kg bw/day	0.003 mg/kg ww
Milk	8.292E-6 mg/kg bw/day	0.001 mg/kg ww

Conclusion on risk characterisation

No significant exposure expected for marine environments, and as such no risk characterisation is conducted for these compartments.

Risk characterisation ratios (RCRs) were derived for freshwater, freshwater sediment, STP and soil compartments. In a tier 1 assessment using default release factors from the appropriate ERC, all RCRs were found to be less than 1. As such it should be considered that safe use has been demonstrated.

9.7.2. Worker contributing scenario 1: Laboratory reagent (PROC 15)

9.7.2.1. Conditions of use (contributing scenario)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: <1%	TRA Workers
	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers
• Containment: No	TRA Workers
• Local exhaust ventilation: no (Inh: 0 %;)	TRA Workers
• Occupational Health and Safety Management System: Basic	TRA Workers
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Der: 90 %;)	TRA Workers
• Respiratory Protection: No (Inh: 0 %;)	TRA Workers
Other conditions affecting workers exposure	

• Place of use: Indoor	TRA Workers
• Process temperature (for liquid): <= 40 °C	TRA Workers
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Workers

9.7.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 73. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.182 mg/m³** (TRA Workers)	RCR = 0.365
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.003 mg/kg bw/day** (TRA Workers)	RCR = 0.005
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.37

Conclusion on risk characterisation

Based on the exposure assessment and assumptions regarding the operational conditions and risk management measures (RMMs), predicted long-term inhalation and dermal exposures arising during use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate as a laboratory reagent does not exceed the respective DNEL for systemic effects. Potential exposures arising from this process do not therefore pose an unacceptable health risk to workers with respect to systemic toxicity.

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye), therefore a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures. Dermal and inhalation contact should be avoided through the use of personal protective equipment (PPE) and appropriate risk management measures (RMMs). For more detailed information on PPE and RMMs refer to Section 9.0.2.3.

9.8. Exposure scenario 8 : Consumer Use

Environment contributing scenario(s):

Wide dispersive indoor use of processing aids	ERC 8a

Consumer contributing scenario(s):

Washing and cleaning products	PC 35
Furniture floor and leather care	PC 31

Explanation on the approach taken for the ES

Environmental assessment
A tier 1 assessment was conducted using the default release factors for ERC 8a. Safe use was demonstrated on tier 1 and no further refinements were necessary.
Consumer use
N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is used as a disinfectant and surface active agent in cleaning and washing products (PC 35) and as a biocide in furniture, floor and leather care maintenance products (e.g. spray or liquid products; PC 31 – polishes and wax blends) used by consumers. The in-use concentration of the substance in these products is 0.1 – 0.3 % w/w.
When using disinfectant, cleaning, washing products (PC 35) and furniture, floor and leather care products (PC 31), consumers can potentially be exposed to N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate via the dermal, oral or inhalation routes. Due to the low volatility of the substance, inhalation exposures to vapours through the use of these products are unlikely. Inhalation exposures to N,N-Didecyl-N-methyl- poly(oxyethyl)ammonium Propionate in the aerosolised form can however occur when products are sprayed or discharged into air (e.g. from the use of spray-based cleaning products). Skin contact can arise when cleaning products (e.g. laundry or dishwashing detergents) are used directly or indirectly, for example when wearing washed clothes. Indirect ingestion of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate can arise when residues remain on surfaces (e.g. residues of dishwashing products remaining on dishes after washing).
Consumers would not be expected to use gloves or other protective clothing or equipment when using common household products. Exposures have therefore been assessed assuming no personal or respiratory equipment is worn.
Potential scenarios for consumer exposure to a range of products and the associated assessment models and default parameters have been identified by the International Association for Soaps, Detergents and Maintenance Products (AISE) as part of the Human and Environmental Risk Assessment (HERA) Project: a voluntary industry programme to carry out risk assessments on ingredients of household cleaning products (http://www.heraproject.com). Taking this into account, the AISE REACT Consumer Tool developed by AISE allows the quantitative estimation of systemic exposures to substances present in preparations used by consumers. The model incorporates default data from the habits and practices for consumer products in Western Europe developed by AISE within the HERA project in 2002 (AISE, 2002) and amended with additional categories in 2009.
In a Tier 1.5 assessment, potential inhalation, dermal and oral exposures to N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate arising from the consumer use of cleaning and washing products (PC 35) and furniture, floor and leather care maintenance products (PC 31) which contain this substance at concentrations up to 0.3% w/w were assessed using the AISE REACT Consumer Tool, modified to align with the risk characterisation approach required by REACH. Since the model presents systemic doses following inhalation exposures only, modified algorithms were used to derive the external airborne concentrations (expressed in mg/m^3) for consumer use scenarios, for the purposes of comparison with inhalation DNELs in the risk characterisation. Algorithms used to derive estimated exposures are discussed further below. Parameters from the AISE REACT Consumer Tool and modified parameters used to predict inhalation, dermal and oral exposures are presented in the respective sections for contributing scenarios for PC 35 and PC 31.

Inhalation, systemic long-term exposure
N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is of low volatility. Inhalation exposures to aerosols generated by the use of consumer products (e.g. by using products in a container generating sprays or

aerosols) were therefore assessed. Inhalation exposures arising from the consumer use of cleaning and washing products (PC35) and furniture, floor and leather care maintenance products were assessed for products applied by spraying. The following algorithm was used to predict the inhalation exposure concentrations. For comparison with the long-term systemic inhalation DNEL, daily inhalation exposure concentrations in mg/m^3 were determined as 24 hour time-weighted averages.

Inh_{ext}	=	(F1 x C' x DF x n) /C" x (T/24)
Inh_{ext}	=	External inhalation concentration (mg/m^3)
F1	=	Ingredient fraction by weight (fraction)
DF	=	Dilution factor
C'	=	Total mass sprayed per use (mg/task)
C"	=	Room volume (m^3)
T	=	Duration of exposure (hours)

The model includes a factor to account for basic ventilation in domestic premises. Even in homes with closed doors and no active ventilation, a certain low level of air exchange occurs. In line with the default approach taken in the ECETOC TRA 3 Tier 1 consumer model, the dilution factor was determined as DF = Room volume / (Room volume + (ACH x Exposure Time x Room Volume). A default factor of 0.6 was assumed for the air changes per hour (ACH).

Dermal, systemic long-term exposure

In the assessment of dermal exposures to N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate arising from the consumer use of cleaning and washing products (PC 35) and furniture, floor and leather care maintenance products (PC 31), the AISE model was used to predict systemic doses following direct skin contact associated with the use of a variety of typical products and following indirect skin contact (e.g. wearing washed clothes). Systemic dermal exposures are expressed as the 'external' dose received via the dermal route in mg/kg bw before absorption and systemic distribution.
The following algorithm was used to predict the systemic dose following direct skin contact with products.

$Dermal_{sys}$	=	(F1 x C x T_{der} x F2 x F3 x S_{der} x n) / BW
$Dermal_{sys}$	=	Systemic dose following dermal exposures (mg/kg bw/day)
F1	=	Ingredient fraction by weight (fraction)
C	=	Concentration in wash solution (mg/cm^3)
S_{der}	=	Surface area exposed skin (cm^2)
n	=	Daily frequency of product use
T_{der}	=	Thickness of product layer in contact with skin (cm)
F2	=	Fraction of product layer in contact with skin (fraction)
F3	=	Fraction remaining on skin
BW	=	Bodyweight (kg)

The following algorithm was used to predict the systemic dose following indirect skin contact with cleaning products (e.g. wearing washed clothes).

$Dermal_{sys}$	=	(F1 x (M x (F'/W) x FD x FL) x S_{der} x F2 x F3) / BW
$Dermal_{sys}$	=	Systemic dose following dermal exposures (mg/kg bw/day)
F1	=	Ingredient fraction by weight (fraction)
M	=	Amount of undiluted product used (g)
F'	=	Fraction remaining in final liquor before spinning (fraction)
W	=	Total fabric weight (g)
FD	=	Fabric density (mg/cm^2)
FL	=	Fraction of liquor remaining in fabric after final spinning (fraction)
S_{der}	=	Surface area exposed skin (cm^2)
F2	=	Fraction of product layer in contact with skin (fraction)
F3	=	Fraction remaining on skin
BW	=	Bodyweight (kg)

The AISE REACT model uses a conservative approach for assessing dermal exposures associated with the use of cleaners, assuming that the complete surface area of two hands will be exposed when using these products. This is considered unlikely and exposures have been refined, taking into account assumptions for these

products made in the ConExpo model. According to the RIVM Cleaning Products Fact-sheet, when using all-purpose cleaners (liquids cleaners, spray cleaners and wipes) exposures would typically occur to the palm of one hand (0.25 x area of hands) 215 cm^2. This parameter has therefore been used in the exposure assessment. The following algorithm was used to predict the system dose following direct skin contact when wearing fabric treated with ironing aids:

$Dermal_{sys}$	=	(F1 x M x 1000 x F2 x F3) / BW
$Dermal_{sys}$	=	Systemic dose following dermal exposures (mg/kg bw/day)
F1	=	Ingredient fraction by weight (fraction)
M	=	Amount of undiluted product used (g)
F2	=	Fraction of product layer in contact with skin (fraction)
F3	=	Fraction remaining on skin
BW	=	Bodyweight (kg)

Oral, systemic long-term exposures
In the assessment of oral exposures to N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate from the consumer use of cleaning products, indirect oral exposures to residues on dishes hand-washed or machine- washed using a variety of products were predicted. Systemic oral exposures are expressed as the 'external' dose received via the oral route in mg/kg bw before absorption and systemic distribution. The following algorithm was used to predict indirect systemic oral exposures:

$Oral_{sys}$	=	(F1 x C x Ta x Sa) / BW
$Oral_{sys}$	=	Systemic dose following oral exposures (mg/kg bw/day)
F1	=	Ingredient fraction by weight (fraction)
C	=	Concentration in product (mg/ml)
Ta	=	Amount of water left on dishes after rinsing
Sa	=	area of dishes in daily contact with food (cm^2)

N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is classified as corrosive R34 (causes burns) and R41 (risk of serious damage to the eye). In the absence of adequate dose-response data, it is not possible to derive DNELs for acute systemic effects, and local dermal and inhalation effects. Therefore, a qualitative risk assessment is required for acute systemic exposures, and local inhalation and local dermal exposures.

9.8.1. Environmental contributing scenario 1: Wide dispersive indoor use of processing aids

9.8.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily wide dispersive use: <= 5.5E-7 tonnes/day *Default calculated value*
• Percentage of tonnage used at regional scale: = 10 %
Other conditions affecting environmental exposure
• Municipal STP: Yes (Wat: 87.79 %;)
• Discharge rate of STP: <= 2E3 m3/d
• Application of the STP sludge on agricultural soil: Yes
• Receiving surface water flow rate: >= 1.8E4 m3/d

9.8.1.2. Releases

The local releases to the environment are reported in the following table.

Table 74. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 100%
Release	**Release factor estimation method**	**Explanation / Justification**
		Final release factor: 100% **Local release rate:** 5.5E-4 kg/day
Air	ERC based	**Initial release factor:** 100% **Final release factor:** 100%
Soil	ERC based	**Final release factor:** 0%

Releases to waste

No further releases to waste which are relevant for the environmental risk assessment are foreseen and emissions relevant to establishment of environmental PECs are stated above.

Any emission to solid waste (landfill) or to specialized waste disposal companies or processes are not considered to be under the scope of REACH as these are regulated under dedicated waste and local regulatory statutes.

9.8.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 75. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 2.751E-5 mg/L	RCR = 0.028
Sediment (freshwater)	**Local PEC:** 0.416 mg/kg dw	RCR = 0.079
Marine water		Qualitative risk characterisation (see below)
Sediment (marine water)		Qualitative risk characterisation (see below)
Sewage treatment plant	**Local PEC:** 3.358E-5 mg/L	RCR = 2.846E-4
Air		
Agricultural soil	**Local PEC:** 0.098 mg/kg dw	RCR = 0.035
Man via Environment - Inhalation	**Local PEC:** 4.737E-12 mg/m³	RCR = 3.948E-11
Man via Environment - Oral	**Exposure via food consumption:** 0.101 mg/kg bw/day	RCR = 0.29
Man via environment - combined routes		RCR = 0.29

Table 76. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	9.282E-7 mg/kg bw/day	3.249E-5 mg/L
Fish	3.661E-6 mg/kg bw/day	0.002 mg/kg ww
Leaf crops	4.296E-7 mg/kg bw/day	2.506E-5 mg/kg ww
Root crops	0.101 mg/kg bw/day	18.48 mg/kg ww

Meat	1.407E-5 mg/kg bw/day	0.003 mg/kg ww
Milk	8.292E-6 mg/kg bw/day	0.001 mg/kg ww

Conclusion on risk characterisation

No significant exposure expected for marine environments, and as such no risk characterisation is conducted for these compartments.

Risk characterisation ratios (RCRs) were derived for freshwater, freshwater sediment, STP and soil compartments. In a tier 1 assessment using default release factors from the appropriate ERC, all RCRs were found to be less than 1. As such it should be considered that safe use has been demonstrated.

9.8.2. Consumer contributing scenario 1: Washing and cleaning products (PC 35)

9.8.2.1. Conditions of use (contributing scenario)

The tables below show the parameters typically reflecting the use conditions of cleaning and washing products which have been used in the AISE REACT Consumer model to determine systemic long-term exposures.

Table 77: Parameters used in the AISE REACT Consumer Tool to predict inhalation exposure to N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate from the consumer use of cleaning and washing products (PC 35) – Tier 1.5 Assessment

Product category	F1 – Ingredient fraction by weight	C' – Total mass sprayed per use	C''- Room volume	n- Product use frequency	T- duration of exposure	ACH – Air changes per hour	DF – Dilution factor
	Fraction	mg/task	m3	tasks/day	hours	Fraction	Fraction
SURFACE CLEANERS (AISE C7, PC35)							
Spray (neat)	0.003	30000	15	1	0.167	0.6	0.909
LAUNDRY AIDS (AISE C12, PC35)							
Ironing aids – sprays	0.003	20000	20	0.71	1	0.6	0.625

Table 78: Parameters used in the AISE REACT Consumer Tool to predict dermal exposure to N,N- Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate from the consumer use of cleaning and washing products (PC 35) – Tier 1.5 Assessment

Product category (AISE)	Exposure scenario	C	Sder	n	Tder	F2	F3	M	F'	W	FD	FL
		mg/ cm^3	cm^2	tasks/ day	cm			g		g	mg/ cm^2	
LAUNDRY REGULAR (AISE C1, PC35)												

Powder	Direct skin contact hand-wash laundry	10	2082.5	2.6	0.01	1	1	-	-	-	-	-
	Direct skin contact pretreatment laundry	600	857.5	0.5	0.01	1	1	-	-	-	-	-
	Indirect skin contact clothes wearing	-	14315	-	-	0.01	1	290	0.025	3500	10	0.6
Liquid	Direct skin contact hand-wash laundry	10	2082.5	1.4	0.01	1	1	-	-	-	-	-
	Direct skin contact pretreatment laundry	1000	857.5	0.5	0.01	1	1	-	-	-	-	-
	Indirect skin contact clothes wearing	-	14315	-	-	0.01	1	230	0.025	3500	10	0.6
LAUNDRY COMPACT (AISE C2, PC35)												
Powder	Direct skin contact hand-wash laundry	10	2082.5	3	0.01	1	1	-	-	-	-	-
	Direct skin contact pretreatment laundry	600	857.5	0.5	0.01	1	1	-	-	-	-	-
	Indirect skin contact clothes wearing	-	14315	-	-	0.01	1	200	0.025	3500	10	0.6
Liquid/g el	Direct skin contact hand-wash laundry	10	2082.5	1.4	0.01	1	1	-	-	-	-	-
	Direct skin	1000	857.5	0.05	0.01	1	1	-	-	-	-	-
Product category (AISE)	**Exposure scenario**	**C**	**Sder**	**n**	**Tder**	**F2**	**F3**	**M**	**F'**	**W**	**FD**	**FL**
		mg/cm^3	**cm^2**	**tasks/day**	**cm**			**g**		**g**	**mg/cm^2**	
	contact pretreatment laundry											

	Indirect skin contact clothes wearing	-	14315	-	-	0.01	1	140	0.025	3500	10	0.6
Tablet	Direct skin contact hand-wash laundry	10	2082.5	1.4	0.01	1	1	-	-	-	-	-
	Indirect skin contact clothes wearing	-	14315	-	-	0.01	1	135	0.025	3500	10	0.6
FABRIC CONDITIONER (AISE C3, PC35)												
Liquid regular	Direct skin contact hand-wash laundry	10	2082.5	1.4	0.01	1	1	-	-	-	-	-
	Indirect skin contact clothes wearing	-	14315	-	-	0.01	1	140	0.025	3500	10	0.6
Liquid concentrate	Direct skin contact hand-wash laundry	10	2082.5	1.4	0.01	1	1	-	-	-	-	-
	Indirect skin contact clothes wearing	-	14315	-	-	0.01	1	90	0.025	3500	10	0.6
LAUNDRY ADDITIVES (AISE C4, PC35)												
Powder bleach	Direct skin contact hand-wash laundry	10	2082.5	0.6	0.01	1	1	-	-	-	-	-
	Indirect skin contact clothes wearing	-	14315	-	-	0.01	1	70	0.025	3500	10	0.6
Liquid bleach	Direct skin contact hand-wash laundry	10	2082.5	0.6	0.01	1	1	-	-	-	-	-
	Direct skin contact	1000	857.5	0.5	0.01	1	1	-	-	-	-	-
Product category (AISE)	**Exposure scenario**	**C**	**Sder**	**n**	**Tder**	**F2**	**F3**	**M**	**F'**	**W**	**FD**	**FL**
		mg/cm³	**cm²**	**tasks/day**	**cm**			**g**		**g**	**mg/cm²**	
	pretreatment laundry											

	Indirect skin contact clothes wearing	-	14315	-	-	0.01	1	100	0.025	3500	10	0.6
Tablet	Direct skin contact hand-wash laundry	10	2082.5	0.6	0.01	1	1	-	-	-	-	-
	Indirect skin contact clothes wearing	-	14315	-	-	0.01	1	30	0.025	3500	10	0.6
HAND DISHWASHING (AISE C5, PC35)												
Liquid regular	Direct skin contact dish-washing;	1	2082.5	3	0.01	1	1	-	-	-	-	-
Liquid concentrate	Direct contact dish-washing	1	2082.5	3	0.01	1	1	-	-	-	-	-
SURFACE CLEANERS (AISE C7, PC35)												
Liquid (a)	Direct skin contact, cleaning surfaces	22	215.0[a]	1	0.01	1	1	-	-	-	-	-
Powder (a)		8	215.0[a]	1	0.01	1	1	-	-	-	-	-
Gel (neat)		1000	215.0[a]	1	0.01	1	1	-	-	-	-	-
Spray (neat)	Direct skin contact, cleaning surfaces	1000	215.0[a]	1	0.01	1	1	-	-	-	-	-
LAUNDRY AIDS (AISE C12, PC35)												
Ironing aids (spray)	Indirect skin contact via fabric wear	-	-	-	-	0.01	1	20	-	-	-	-
WIPES (AISE C15, PC35)												
Bathroo	Direct contact with lotion on	1000	215.0[a]	1	0.01	1	1	-	-	-	-	-
Product category (AISE)	**Exposure scenario**	**C**	**Sder**	**n**	**Tder**	**F2**	**F3**	**M**	**F'**	**W**	**FD**	**FL**
		mg/cm^3	**cm^2**	**tasks/day**	**cm**			**g**		**g**	**mg/cm^2**	

m	wipes											
Kitchen	Direct contact with lotion on wipes	1000	215.0[a]	0.5	0.01	1	1	-	-	-	-	-
Floor	Direct contact with lotion on wipes	1000	215.0[a]	0.3	0.01	1	1	-	-	-	-	-
Key: **C-Concentration in wash solution; Sder –Dermal surface area; n-Product use frequency/day; Tder –Thickness of product layer in contact with skin; F2-Fraction transferred from solution to skin; F3-Fraction remaining on skin; M-Amount of undiluted product used; F'-Fraction remaining in final liquor before spinning; W-Total fabric weight; FD-Fabric density; FL-Fraction of liquor remaining fabric after final spinning**												
Parameters used in AISE REACT Consumer Tool. F1 - Ingredient fraction : 0.003 (0.3% w/w); BW - body weight: 60 kg; [a] *RIVM Cleaning Products Factsheet – Palm of one hand (0.25 area of hands)*												

Table 79: Parameters used in the AISE REACT Consumer Tool to predict oral exposure to N,N-Didecyl- N-methyl-poly(oxyethyl)ammonium Propionate from the consumer use of cleaning and washing products (PC 35) – Tier 1.5 Assessment

Product category (AISE)	**Exposure scenario**	**F1 – Ingredien t fraction by weight**	**C – Concentra tion in product**	**Ta – amount of water left on dishes after rinsing**	**Sa – area of dishes in daily contact with food**	**BW – body weight**
		Fraction	**mg/ml**	**ml/cm²**	**cm²**	**kg**
HAND DISHWASHING (AISE C5, PC35)						
Liquid regular (a)	Oral – Indirect exposure to residues	0.003	1	5.5×10^{-5}	5400	60
Liquid concentra te (a)	Oral – indirect exposure to residues	0.003	1	5.5×10^{-5}	5400	60
MACHINE DISHWASHING (AISE C6, PC35)						
Powder	Oral – indirect exposure to residues	0.003	1	5.5×10^{-5}	5400	60
Liquid	Oral – indirect exposure to residues	0.003	1	5.5×10^{-5}	5400	60
Tablet	Oral – indirect exposure to residues	0.003	1	5.5×10^{-5}	5400	60

9.8.2.2. Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 80: Inhalation, dermal and oral (chronic, long-term) exposures predicted the consumer use of cleaning and washing products (PC 35)

Product category (AISE)	Exposure scenario	Predicted Inhalation exposure	Predicted dermal exposure	Predicted oral exposure	RCR Inhalation route	RCR Dermal route	RCR Oral route	RCR Combined routes
		Inhalation exposure concentration mg/m^3	Systemic dose (mg/kg bw/day)	Systemic dose (mg/kg bw/day)				
LAUNDRY REGULAR (AISE C1, PC35)								
Powder	Direct skin contact hand-wash laundry		0.027			0.08		0.08
	Direct skin contact pretreatment laundry		0.129			0.37		0.37
	Indirect skin contact clothes wearing		8.9×10^{-5}			2.54×10^{-4}		2.54×10^{-4}
	TOTAL DERMAL EXPOSURE		0.156			0.45		0.45
Liquid	Direct skin contact hand-wash laundry		0.015			0.04		0.04
	Direct skin contact pretreatment laundry		0.214			0.61		0.61
	Indirect skin contact clothes wearing		7.06×10^{-5}			2.02×10^{-4}		2.02×10^{-4}
	TOTAL DERMAL EXPOSURE		0.229			0.65		0.65
LAUNDRY COMPACT (AISE C2, PC35)								

Powder	Direct skin contact hand-wash laundry		0.031			0.09		0.09
	Direct skin contact pretreatment laundry		0.129			0.37		0.37
Product category (AISE)	**Exposure scenario**	**Predicte d Inhalatio n exposure**	**Predicte d dermal exposur e**	**Predicte d oral exposur e**	**RCR Inhalati on route**	**RCR Derm al route**	**RCR Oral route**	**RCR Combin ed routes**
		Inhalatio n exposure concentr ation mg/m³	**Systemi c dose (mg/kg bw/day)**	**Systemi c dose (mg/kg bw/day)**				
	Indirect skin contact clothes wearing		6.14 x 10^{-5}			1.75 x 10^{-4}		1.75 x 10^{-4}
	TOTAL DERMAL EXPOSURE		0.160			0.46		0.46
Liquid/ gel	Direct skin contact hand-wash laundry		0.015			0.04		0.04
	Direct skin contact pretreatment laundry		0.214			0.61		0.61
	Indirect skin contact clothes wearing		4.29 x 10^{-5}			1.23 x 10^{-4}		1.23 x 10^{-4}
	TOTAL DERMAL EXPOSURE		0.229			0.65		0.65
Tablet	Direct skin contact hand-wash laundry		0.015			0.04		0.04
	Indirect skin contact clothes wearing		4.14 x 10^{-5}			1.18 x 10^{-4}		1.18 x 10^{-4}

	TOTAL DERMAL EXPOSURE		0.015			0.04		0.04
FABRIC CONDITIONER (AISE C3, PC35								
Liquid regular	Direct skin contact hand-wash laundry		0.015			0.04		0.04
	Indirect skin contact clothes		4.29×10^{-5}			1.23×10^{-4}		1.23×10^{-4}
Product category (AISE)	**Exposure scenario**	**Predicted Inhalation exposure**	**Predicted dermal exposure**	**Predicted oral exposure**	**RCR Inhalation route**	**RCR Dermal route**	**RCR Oral route**	**RCR Combined routes**
		Inhalation exposure concentration mg/m^3	**Systemic dose (mg/kg bw/day)**	**Systemic dose (mg/kg bw/day)**				
	wearing							
	TOTAL DERMAL EXPOSURE		0.015			0.04		0.04
Liquid concen tr-ate	Direct skin contact hand-wash laundry		0.010			0.03		0.03
	Indirect skin contact clothes wearing		1.84×10^{-5}			5.26×10^{-5}		5.26×10^{-5}
	TOTAL DERMAL EXPOSURE		0.010			0.03		0.03
LAUNDRY ADDITIVES (AISE C4, PC35)								
Powder bleach	Direct skin contact hand-wash laundry		6.25×10^{-3}			0.02		0.02
	Indirect skin contact clothes wearing		2.15×10^{-5}			6.14×10^{-5}		6.14×10^{-5}
	TOTAL DERMAL EXPOSURE		6.27×10^{-3}			0.02		0.02

Liquid bleach	Direct skin contact hand-wash laundry		6.25 x 10^{-3}			0.02		0.02
	Direct skin contact pretreatment laundry		0.214			0.61		0.61
	Indirect skin contact clothes wearing		3.07 x 10^{-5}			8.76 x 10^{-5}		8.76 x 10^{-5}
Product category (AISE)	**Exposure scenario**	**Predicted Inhalation exposure**	**Predicted dermal exposure**	**Predicted oral exposure**	**RCR Inhalation route**	**RCR Dermal route**	**RCR Oral route**	**RCR Combined routes**
		Inhalation exposure concentration mg/m³	**Systemic dose (mg/kg bw/day)**	**Systemic dose (mg/kg bw/day)**				
	TOTAL DERMAL EXPOSURE		0.221			0.63		0.63
Tablet	Direct skin contact hand-wash laundry		1.04 x 10^{-2}			0.03		0.03
	Indirect skin contact clothes wearing		9.20 x 10^{-6}			2.63 x 10^{-5}		2.63 x 10^{-5}
	TOTAL DERMAL EXPOSURE		1.04 x 10^{-2}			0.03		0.03
HAND DISHWASHING (AISE C5, PC35)								
Liquid regular	Direct skin contact dish-washing; Oral – indirect exposure to residues		3.12 x 10^{-3}	1.49 x 10^{-5}		0.01	4.24 x 10^{-5}	0.01

Liquid concentrate	Direct contact dish-washing Oral – indirect exposure to residues		4.79 x 10^{-2}	1.49 x 10^{-5}		0.14	4.24 x 10^{-5}	0.14
MACHINE DISHWASHING (AISE C6, PC35)								
Powder	Oral – indirect exposure to residues			1.49 x 10^{-5}			4.24 x 10^{-5}	4.24 x 10^{-5}
Liquid	Oral – indirect exposure to residues			1.49 x 10^{-5}			4.24 x 10^{-5}	4.24 x 10^{-5}
Tablet	Oral – indirect			1.49 x 10^{-5}			4.24 x 10^{-5}	4.24 x 10^{-5}
Product category (AISE)	**Exposure scenario**	**Predicted Inhalation exposure**	**Predicted dermal exposure**	**Predicted oral exposure**	**RCR Inhalation route**	**RCR Dermal route**	**RCR Oral route**	**RCR Combined routes**
		Inhalation exposure concentration mg/m³	**Systemic dose (mg/kg bw/day)**	**Systemic dose (mg/kg bw/day)**				
	exposure to residues							
SURFACE CLEANERS (AISE C7, PC35)								
Liquid (a)	Direct skin contact, cleaning surfaces		1.18 x 10^{-3}			3.38 x 10^{-3}		3.38 x 10^{-3}
Powder (a)			8.60 x 10^{-4}			2.46 x 10^{-3}		2.46 x 10^{-3}
Gel (neat)			0.108			0.31		0.31
Spray (neat)	Direct skin contact, cleaning surfaces Inhalation during spraying	3.8 x 10^{-2}	0.108		0.32	0.31		0.61
LAUNDRY AIDS (AISE C12, PC35)								

Ironing aids (spray)	Indirect skin contact via fabric wear Inhalation during spraying	5.5 x 10^{-2}	1.00 x 10^{-2}		0.46	0.03		0.73
WIPES (AISE C15, PC35)								
Bathroom	Direct contact with lotion on wipes		0.108			0.31		
Kitchen	Direct contact with lotion on wipes		0.054			0.15		
Floor	Direct contact with lotion on wipes		0.032			0.09		

Conclusion on risk characterisation

Consumers may be exposed to N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate when using a variety of cleaning and washing products (PC35). Inhalation, dermal and oral routes arising from the use of these products were assessed using default parameters and algorithms from AISE REACT Consumer Tool, modified as appropriate. It is assumed that consumers using these products will not wear gloves or use any other PPE.

Inhalation exposures to N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate were assessed for scenarios involving the use of products generating aerosols (e.g. spraying cleaning products). Direct dermal exposures were assessed for the consumer use of cleaning products whereas indirect dermal exposures were assessed for the wearing of washed clothes. Indirect oral exposures to residues on surfaces were assessed (e.g. residues on dinner plates after dishwashing)

Oral, dermal and inhalation exposures were derived as daily exposures. Chronic, long-term oral, dermal and inhalation exposures were derived as the daily exposures considered as a daily, repeated dose. In a characterisation of the human health risks posed by the consumer use of these products, these exposure estimates were compared with inhalation, dermal or oral DNELs as appropriate. The results of the risk characterisation are shown in the previous section. The RCR for combined exposures for oral, dermal and inhalation routes are given as the sum of RCRs for oral, dermal and inhalation routes as appropriate.

The predicted long-term dermal exposures associated with the consumer use of cleaning and washing products (PC 35) were not found to exceed the dermal systemic DNEL of 0.35 mg/kg bw/day. The predicted long-term inhalation exposure concentrations were not found to exceed the inhalation DNEL of 0.12 mg/m^3. The predicted long-term oral exposures were not found to exceed the oral systemic DNEL of 0.35 mg/kg bw/day. The overall RCR for combined routes of exposure did not exceed 1 for any product use scenario. On the basis of the assumptions made in the exposure assessment and this risk characterisation, it can be concluded that the use of washing and cleaning products (PC35) containing N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate at concentrations up to 0.3 % w/w does not pose an unacceptable health risk to consumers with respect to systemic toxicity.

N,N-Didecyl-N-methylpoly(oxyethyl)ammonium propionate is classified as Corrosive (Category 1B) and Irreversible Effects on the Eye (Category 1) according to Regulation (EC) No 1272/2008 therefore a qualitative risk assessment is required for local inhalation and local dermal effects.

Consumers cannot be expected to wear personal protective equipment (PPE) such as gloves when using common household products; exposure may therefore occur during use of products containing N,N-Didecyl-N- methylpoly(oxyethyl)ammonium propionate. Whilst the substance is classified as corrosive, corrosivity or irritant effects are not predicted at the low in-use concentrations (0.1-0.3%) found in consumer products. The in-use concentration of the substance in consumer products is below the CLP generic concentration limit of 1% for the classification of mixtures as irritant or corrosive. The in-use concentration of the substance in consumer products is also below the

maximum non-irritating concentration of 0.5% identified in a range-finding study in guinea pigs (Allen 1994; Lonza Report 2344); only minimal effects were identified at a level of 1% in this study. It can therefore be concluded that consumer products containing concentrations of N,N-Didecyl-N-methylpoly(oxyethyl)ammonium propionate of 0.1-0.3% will not be irritating or corrosive, therefore the consumer using these products will be negligible and the use of personal protective equipment (PPE) is not required.

9.8.3. Consumer contributing scenario 2: Furniture floor and leather care (PC 31)

9.8.3.1. Conditions of use (contributing scenario)

The tables below show the parameters typically reflecting the use conditions of furtniture and leather care products which have been used in the AISE REACT Consumer model to determine systemic long-term exposures.

Table 81: Parameters used in the AISE REACT Consumer Tool to predict inhalation exposure to N,N- Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate from the consumer use of floor and leather care products (PC 31) – Tier 1.5 Assessment

Product category	F1 – Ingredient fraction by weight	C' – Total mass sprayed per use	C''- Room volume	n- Product use frequency	T- duration of exposure	ACH – Air changes per hour	DF – Dilution factor
	Fraction	mg/task	m^3	tasks/day	hours	Fraction	Fraction
FURNITURE, FLOOR & LEATHER CARE MAINTENANCE PRODUCTS (AISE C20, PC 31)							
Spray	0.003	60000	58	0.43	1	0.6	0.625

Table 82: Parameters used in the AISE REACT Consumer Tool to predict dermal exposure to N,N- Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate from the consumer use of floor and leather care products (PC 31) – Tier 1.5 Assessment

Product category (AISE)	Exposure scenario	C	Sder	n	Tder	F2	F3	M	F'	W	FD-	FL
		mg/cm^3	cm^2	tasks/day	cm			g		g	mg/cm^2	
FURNITURE, FLOOR & LEATHER CARE MAINTENANCE PRODUCTS (AISE C20, PC31)												
Spray	Direct skin contact while spraying	1000	215.0[a]	0.430	0.01	1	1	-	-	-	-	-

Key: **C-Concentration in wash solution; Sder –Dermal surface area; n-Product use frequency/day; Tder –Thickness of product layer in contact with skin; F2-Fraction transferred from solution to skin; F3-Fraction remaining on skin; M-Amount of undiluted product used; F'-Fraction remaining in final liquor before spinning; W-Total fabric weight; FD-Fabric density; FL-Fraction of liquor remaining fabric after final spinning**

Parameters used in AISE REACT Consumer Tool. F1 - Ingredient fraction : 0.003 (0.3% w/w); BW - body weight: 60 kg;

[a] *RIVM Cleaning Products Factsheet – Palm of one hand (0.25 area of hands)*

9.8.3.2. Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 83: Inhalation, dermal and oral (chronic, long-term) exposures predicted for the consumer use of furniture, floor and leather care products (PC31)

Product category (AISE)	Exposure scenario	Predicted inhalation exposure	Predicted dermal exposure	RCR Inhalation route	RCR Dermal route	RCR Combined routes
		Inhalation exposure concentration mg/m³	Systemic dose (mg/kg bw/day)			
FURNITURE, FLOOR & LEATHER CARE MAINTENANCE PRODUCTS (AISE C20, PC31)						
Spray	Direct skin contact while spraying	3.5×10^{-2}	0.046	0.29	0.13	0.42

Conclusion on risk characterisation

Consumers may be exposed to N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate when using furniture, floor and leather care maintenance products (PC 31). Inhalation and dermal exposures arising from the use of these products were assessed using default parameters and algorithms from AISE REACT Consumer Tool, modified as appropriate. It is assumed that consumers using these products will not wear gloves or use any other PPE.
Inhalation exposures to N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate were assessed for scenarios involving the use of products generating aerosols (e.g. spraying the products). Direct dermal exposures were assessed for the consumer use of these products.
Oral, dermal and inhalation exposures were derived as daily exposures. Chronic, long-term oral, dermal and inhalation exposures were derived as the daily exposures considered as a daily, repeated dose. In a characterisation of the human health risks posed by the consumer use of these products, these exposure estimates were compared with inhalation, dermal or oral DNELs as appropriate. The results of the risk characterisation are shown in the previous section. The RCR for combined exposures for dermal and inhalation routes are given as the sum of RCRs for the dermal and inhalation routes.
The predicted long-term dermal exposures associated with the consumer use of furniture, floor and leather care products (PC 31) were not found to exceed the dermal systemic DNEL of 0.35 mg/kg bw/day. The predicted long-term inhalation exposure concentrations were not found to exceed the inhalation DNEL of 0.12 mg/m³. The overall RCR for combined routes of exposure did not exceed 1 for any product use scenario. On the basis of the assumptions made in the exposure assessment and this risk characterisation, it can be concluded that the use of furniture, floor and leather care products (PC 31) containing N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate at concentrations up to 0.3 % w/w does not pose an unacceptable health risk to consumers with respect to systemic toxicity.
N,N-Didecyl-N-methylpoly(oxyethyl)ammonium propionate is classified as Corrosive (Category 1B) and Irreversible Effects on the Eye (Category 1) according to Regulation (EC) No 1272/2008 therefore a qualitative risk assessment is required for local inhalation and local dermal effects.
Consumers cannot be expected to wear personal protective equipment (PPE) such as gloves when using common household products; exposure may therefore occur during use of products containing N,N-Didecyl-N- methylpoly(oxyethyl)ammonium propionate. Whilst the substance is classified as corrosive, corrosivity or irritant effects are not predicted at the low in-use concentrations (0.1-0.3%) found in consumer products. The in-use concentration of the substance in consumer products is

below the CLP generic concentration limit of 1% for the classification of mixtures as irritant or corrosive. The in-use concentration of the substance in consumer products is also below the maximum non-irritating concentration of 0.5% identified in a range-finding study in guinea pigs (Allen 1994; Lonza Report 2344); only minimal effects were identified at a level of 1% in this study. It can therefore be concluded that consumer products containing concentrations of N,N-Didecyl-N-methylpoly(oxyethyl)ammonium propionate of 0.1-0.3% will not be irritating or corrosive, therefore the consumer using these products will be negligible and the use of personal protective equipment (PPE) is not required.

Scenari di esposizione relativi al componente GPL

2

1. Produzione di stream di gas di petrolio in altri gas di petrolio
2. Distribuzione di altri gas di petrolio
3. Formulazione di altri gas di petrolio
4. Uso di altri gas di petrolio in agenti espandenti - Industriale
5. Uso di altri gas di petrolio in combustibili - Industriale
6. Uso di altri gas di petrolio in combustibili - Professionale
7. Uso di altri gas di petrolio in combustibili - Consumatore
8. Uso di altri gas di petrolio in fluidi funzionali - Industriale
9. Uso di altri gas di petrolio in fluidi funzionali - Professionale
10. Uso di altri gas di petrolio nella produzione di polimeri - Industriale
11. Uso di altri gas di petrolio nella produzione di polimeri - Industriale
12. Uso di altri gas di petrolio nella produzione di polimeri - Professionale

Scenario di esposizione 1: produzione di stream di gas di petrolio in altri gas di petrolio

Sezione 1 Titolo dello scenario di esposizione

Titolo: Produzione di altri gas di petrolio

Descrizione Utilizzo:

Settore di utilizzo: industriale (SU3,SU8, SU9)
Categorie di processo: PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC15
Categorie di rilascio ambientale: ERC1, ERC4

Processi, compiti, attività coperte
Lavorazione della sostanza o suo impiego come prodotto chimico di processo o agente di estrazione. Comprende il riciclo/recupero, il trasferimento di materiale, lo stoccaggio, il campionamento, le attività di laboratorio associate, la manutenzione e le operazioni di carico (su imbarcazioni/chiatte, carri cisterna su ruota o rotaia e contenitori per lo stoccaggio di prodotti sfusi).

Sezione 2 Condizioni operative e misure di gestione del rischio

Campo per dichiarazioni aggiuntive intese a spiegare lo scenario, se necessario

Sezione 2.1 Controllo delle esposizioni del dipendente

Caratteristiche del prodotto
Forma fisica del prodotto
Liquido, pressione di vapore > 10 kPa

Concentrazione della sostanza nel prodotto
Copre una percentuale di sostanza nel prodotto fino al 100% (se non altrimenti indicato)

Quantità utilizzate
Non applicabile

Frequenza e durata dell'utilizzo
Copre un'esposizione giornaliera fino a 8 ore (se non altrimenti specificato)

Fattori umani non influenzati dalla gestione dei rischi: *Non applicabile*

Altre condizioni operative che coinvolgono le esposizioni dei lavoratori
Presuppone l'utilizzo del prodotto ad una temperatura non superiore a 20° rispetto alla temperatura ambiente;
Presuppone un contenuto massimo di Butadiene di 1% e un contenuto massimo di Benzene di 1%.
Presuppone l'applicazione di uno standard di base adeguato in materia di igiene nell'ambiente lavorativo

Scenari correlati
Misure di gestione dei rischi
Nota: elencare le frasi standard secondo la gerarchia di controllo indicata nel modello ECHA: 1. *Misure tecniche per impedire il rilascio,* 2. *Misure tecniche per impedire la dispersione, 3. Misure organizzative,* 4. *Protezione personale. Le frasi tra virgolette sono solo consigli di buone pratiche, al di là della valutazione sulla sicurezza chimica REACH e possono essere comunicate nella Sezione 5 dell'ES o nelle sezioni principali dell'SDS*.

Misure generali (agenti cancerogeni)
Considerare progressi tecnici e aggiornamenti dei processi (automazione inclusa) per l'eliminazione delle dispersioni. Limitare l'esposizione adottando misure quali sistemi chiusi, impianti dedicati e appositi impianti di aspirazione generale/localizzata dell'aria esausta. Drenare i sistemi e ripulire le linee di trasferimento prima di interrompere il contenimento. Pulire/spurgare le apparecchiature, ove possibile, prima della manutenzione. Ove esiste la possibilità di esposizione: limitare l'accesso al solo personale autorizzato, garantire agli operatori una formazione specifica sulle attività e sulle operazioni da compiere al fine di minimizzare il rischio di esposizione, indossare guanti e tute di protezione per prevenire la contaminazione della pelle, utilizzare un dispositivo di protezione delle vie respiratorie quando richiesto per determinati scenari di esposizione, eliminare immediatamente le eventuali fuoriuscite e smaltire i rifiuti in condizioni di sicurezza.
Garantire l'adozione di sistemi di lavoro sicuri o di soluzioni equivalenti per la gestione dei rischi. Ispezionare, verificare e sottoporre a regolare manutenzione tutti i dispositivi e le misure di controllo.Prendere in considerazione la necessità di un sistema di sorveglianza sanitario basato sulla valutazione dei rischi

Scenario di esposizione 1: produzione di stream di gas di petrolio in altri gas di petrolio (segue)

Sezione 2.1 Controllo delle esposizioni del dipendente (segue)

Esposizioni generali (sistemi chiusi)
Manipolare la sostanza in un sistema chiuso

Esposizioni generali (sistemi chiusi). Con raccolta campione. Con esposizione occasionale controllata
Manipolare la sostanza in un sistema chiuso

Esposizioni generali (sistemi chiusi). Utilizzo in processi discontinui sotto contenimento
Manipolare la sostanza in un sistema chiuso

Esposizioni generali (sistemi aperti). Processo discontinuo. Con raccolta campione.
Manipolare la sostanza all'interno di un sistema prevalentemente chiuso provvisto di ventilazione a estrazione . Fornire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora); altrimenti Assicurarsi che l'attività venga intrapresa all'esterno. Evitare di compiere attività che comportino un'esposizione superiore ad 1 ora

Campionatura durante il processo
Manipolare la sostanza in un sistema chiuso. Utilizzare un sistema di campionatura studiato per controllare le esposizioni. Fornire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora); altrimenti assicurarsi che l'attività venga intrapresa all'esterno

Attività di laboratorio
Manipolare solo sotto una cappa chimica o ricorrere a metodi equivalenti per ridurre al minimo i rischi di esposizione

Trasferimento prodotti sfusi (sistemi aperti)
Manipolare la sostanza in un sistema chiuso. Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione

Trasferimenti prodotti sfusi (sistemi chiusi).
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione

Pulizia e manutenzione delle apparecchiature.
Drenare il sistema prima dell'apertura o della manutenzione delle apparecchiature. Provvedere una ventilazione ad estrazione presso i punti in cui si verificano emissioni

Stoccaggio. Con esposizione occasionale controllata
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione. Immagazzinare la sostanza all'interno di un sistema chiuso

Sezione 2.2 Controllo delle esposizioni ambientali

La sostanza non è classificata - non si richiede una valutazione dell'esposizione ambientale

Sezione 3 Stima delle esposizioni

Sezione 3.1. Salute
Ai fini della valutazione del livello di esposizione sul luogo di lavoro, laddove non espressamente indicato, è stato utilizzato il metodo ECETOC TRA.

Quando si osservano le misure della gestione del rischio (RMM) e le condizioni operative raccomandate (OC), non si prevede di superare i DNEL attesi e i ratei della caratterizzazione del rischio risultanti si ritiene saranno inferiori a 1 come indicato nell'Appendice A.

Sezione 3.2 Ambiente
La conferma dell'uso sicuro è stata ottenuta attraverso un approccio qualitativo

Sezione 4 Guida per la verifica della conformità con lo scenario di esposizione

Sezione 4.1 Salute
Confermare che RMM e OC sono come descritte o di efficienza equivalente. Vedere Appendice A per i dettagli su efficienze e OC

Scheda

Scenario di esposizione 1: produzione di stream di gas di petrolio in altri gas di petrolio (segue)

Sezione 4.2 Ambiente
Non sono richieste misure aggiuntive di gestione dei rischi.

Sezione 5
Consigli aggiuntivi di buone pratiche oltre la valutazione della sicurezza chimica REACH (Sezione Opzionale)

Nota: Le misure riportate in questa sezione non sono state prese in considerazione nelle stime delle esposizioni relative allo scenario di esposizione presentato in precedenza. Non sono soggette agli obblighi definiti dall'Articolo 37 (4) della normativa REACH

Controllo delle esposizioni del dipendente
Selezione di frasi rilevanti per lo scenario di esposizione
Frasi RMM di buone pratiche possono essere inserite in questa sezione o consolidate nelle molteplici sezioni dell'SDS, a seconda della preferenza della registrazione e della funzionalità del sistema e-SDS disponibile.

Controllo delle esposizioni ambientali
Non applicabile

Scenario di esposizione 2: Distribuzione di altri gas di petrolio

Sezione 1 Titolo dello scenario di esposizione

Titolo: Distribuzione di altri gas di petrolio

Descrizione Utilizzo:

Settore di utilizzo: industriale (SU3, SU8, SU9)
Categorie di processo: PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC9, PROC15
Categorie di rilascio ambientale: ERC1 - 7

Processi, compiti, attività coperte
Carico (su imbarcazioni/chiatte, carri cisterna su ruota o rotaia, e contenitori IBC) e reimballaggio (in fusti e piccoli contenitori) della sostanza, compreso la distribuzione e le attività di laboratorio associate.

Sezione 2 Condizioni operative e misure di gestione del rischio

Campo per dichiarazioni aggiuntive intese a spiegare lo scenario, se necessario

Sezione 2.1 Controllo delle esposizioni del dipendente

Caratteristiche del prodotto
Forma fisica del prodotto
Liquido, pressione di vapore > 10 kPa

Concentrazione della sostanza nel prodotto
Copre una percentuale di sostanza nel prodotto fino al 100% (se non altrimenti indicato)

Quantità utilizzate
Non applicabile

Frequenza e durata dell'utilizzo
Copre un'esposizione giornaliera fino a 8 ore (se non altrimenti specificato)

Fattori umani non influenzati dalla gestione dei rischi
Non applicabile

Altre condizioni operative che coinvolgono le esposizioni dei lavoratori
Presuppone l'utilizzo del prodotto ad una temperatura non superiore a 20° rispetto alla temperatura ambiente.
Presuppone un contenuto massimo di Butadiene di 1% e un contenuto massimo di Benzene di 1%.
Presuppone l'applicazione di uno standard di base adeguato in materia di igiene nell'ambiente lavorativo.

Scenari correlati
Misure di gestione dei rischi
Nota: elencare le frasi standard secondo la gerarchia di controllo indicata nel modello ECHA: 1. *Misure tecniche per impedire il rilascio,* 2. *Misure tecniche per impedire la dispersione, 3. Misure organizzative,* 4. *Protezione personale. Le frasi tra virgolette sono solo consigli di buone pratiche, al di là della valutazione sulla sicurezza chimica REACH e possono essere comunicate nella Sezione 5 dell'ES o nelle sezioni principali dell'SDS*.

Misure generali (agenti cancerogeni)
Considerare progressi tecnici e aggiornamenti dei processi (automazione inclusa) per l'eliminazione delle dispersioni. Limitare l'esposizione adottando misure quali sistemi chiusi, impianti dedicati e appositi impianti di aspirazione generale/localizzata dell'aria esausta. Drenare i sistemi e ripulire le linee di trasferimento prima di interrompere il contenimento. Pulire/spurgare le apparecchiature, ove possibile, prima della manutenzione. Ove esiste la possibilità di esposizione: limitare l'accesso al solo personale autorizzato, garantire agli operatori una formazione specifica sulle attività e sulle operazioni da compiere al fine di minimizzare il rischio di esposizione, indossare guanti e tute di protezione per prevenire la contaminazione della pelle, utilizzare un dispositivo di protezione delle vie respiratorie quando richiesto per determinati scenari di esposizione, eliminare immediatamente le eventuali fuoriuscite e smaltire i rifiuti in condizioni di sicurezza.
Garantire l'adozione di sistemi di lavoro sicuri o di soluzioni equivalenti per la gestione dei rischi. Ispezionare, verificare e sottoporre a regolare manutenzione tutti i dispositivi e le misure di controllo.Prendere in considerazione la necessità di un sistema di sorveglianza sanitario basato sulla valutazione dei rischi.

Scenario di esposizione 2: Distribuzione di altri gas di petrolio (segue)

Sezione 2.1 Controllo delle esposizioni del dipendente (segue)

Esposizioni generali (sistemi chiusi)
Manipolare la sostanza in un sistema chiuso

Esposizioni generali (sistemi chiusi). Con raccolta campione. Con esposizione occasionale controllata
Manipolare la sostanza in un sistema chiuso. Effettuare il campionamento tramite un circuito chiuso o altro sistema, al fine di evitare l'esposizione

Esposizioni generali (sistemi chiusi). Utilizzo in processi discontinui sotto contenimento
Manipolare la sostanza in un sistema chiuso. Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora). Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione.

Esposizioni generali (sistemi aperti). Processo discontinuo. Con raccolta campione.
Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora). Effettuare il campionamento tramite un circuito chiuso o altro sistema, al fine di evitare l'esposizione

Campionatura durante il processo
Effettuare il campionamento tramite un circuito chiuso o altro sistema, al fine di evitare l'esposizione.

Attività di laboratorio
Manipolare solo sotto una cappa chimica o ricorrere a metodi equivalenti per ridurre al minimo i rischi di esposizione

Trasferimento prodotti sfusi (sistemi chiusi)
Manipolare la sostanza in un sistema chiuso. Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione.

Riempimento fusti e piccoli contenitori
Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora). Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione

Pulizia e manutenzione delle apparecchiature.
Drenare e spurgare il sistema prima dell'apertura o della manutenzione delle apparecchiature. Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora).

Stoccaggio. Con esposizione occasionale controllata
Immagazzinare la sostanza all'interno di un sistema chiuso. Immagazzinare la sostanza all'interno di un sistema chiuso. Assicurarsi che l'operazione sia effettuata all'esterno

Sezione 2.2 Controllo delle esposizioni ambientali

La sostanza non è classificata - non si richiede una valutazione dell'esposizione ambientale

Sezione 3 Stima delle esposizioni

Sezione 3.1. Salute
Ai fini della valutazione del livello di esposizione sul luogo di lavoro, laddove non espressamente indicato, è stato utilizzato il metodo ECETOC TRA. G21

Quando si osservano le misure della gestione del rischio (RMM) e le condizioni operative raccomandate (OC), non si prevede di superare i DNEL attesi e i ratei della caratterizzazione del rischio risultanti si ritiene saranno inferiori a 1 come indicato nell'Appendice A.

Sezione 3.2 Ambiente
La conferma dell'uso sicuro è stata ottenuta attraverso un approccio qualitativo

Sezione 4 Guida per la verifica della conformità con lo scenario di esposizione

Sezione 4.1 Salute
Confermare che RMM e OC sono come descritte o di efficienza equivalente. Vedere Appendice A per i dettagli su efficienze e OC

Scenario di esposizione 2: Distribuzione di altri gas di petrolio (segue)

Sezione 4.2 Ambiente
Non sono richieste misure aggiuntive di gestione dei rischi.

Sezione 5
Consigli aggiuntivi di buone pratiche oltre la valutazione della sicurezza chimica REACH (Sezione Opzionale)

Nota: Le misure riportate in questa sezione non sono state prese in considerazione nelle stime delle esposizioni relative allo scenario di esposizione presentato in precedenza. Non sono soggette agli obblighi definiti dall'Articolo 37 (4) della normativa REACH

Controllo delle esposizioni del dipendente
Selezione di frasi rilevanti per lo scenario di esposizione
Frasi RMM di buone pratiche possono essere inserite in questa sezione o consolidate nelle molteplici sezioni dell'SDS, a seconda della preferenza della registrazione e della funzionalità del sistema e-SDS disponibile.

Controllo delle esposizioni ambientali
Non applicabile

Scenario di esposizione 3: Formulazione di altri gas di petrolio

Sezione 1 Titolo dello scenario di esposizione

Titolo: Formulazione e (re)imballaggio delle sostanze e delle miscele di altri gas di petrolio

Descrizione Utilizzo:

Settore di utilizzo: industriale (SU3, SU10)
Categorie di processo: PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15
Categorie di rilascio ambientale: ERC2

Processi, compiti, attività coperte
Formulazione, imballaggio e reimballaggio della sostanza e delle sue miscele in operazioni discontinue o continue, compresi lo stoccaggio, il trasferimento di materiali, la miscelazione, l'imballaggio su scala grande e piccola, la manutenzione e le attività di laboratorio associate..

Sezione 2 Condizioni operative e misure di gestione del rischio

Campo per dichiarazioni aggiuntive intese a spiegare lo scenario, se necessario

Sezione 2.1 Controllo delle esposizioni del dipendente

Caratteristiche del prodotto
Forma fisica del prodotto
Liquido, pressione di vapore > 10 kPa

Concentrazione della sostanza nel prodotto
Copre una percentuale di sostanza nel prodotto fino al 100% (se non altrimenti indicato)

Quantità utilizzate
Non applicabile

Frequenza e durata dell'utilizzo
Copre un'esposizione giornaliera fino a 8 ore (se non altrimenti specificato)

Fattori umani non influenzati dalla gestione dei rischi
Non applicabile

Altre condizioni operative che coinvolgono le esposizioni dei lavoratori
Presuppone l'utilizzo del prodotto ad una temperatura non superiore a 20° rispetto alla temperatura ambiente.
Presuppone un contenuto massimo di Butadiene di 1% e un contenuto massimo di Benzene di 1%.
Presuppone l'applicazione di uno standard di base adeguato in materia di igiene nell'ambiente lavorativo.

Scenari correlati
Misure di gestione dei rischi
Nota: elencare le frasi standard secondo la gerarchia di controllo indicata nel modello ECHA: 1. *Misure tecniche per impedire il rilascio,* 2. *Misure tecniche per impedire la dispersione, 3. Misure organizzative,* 4. *Protezione personale. Le frasi tra virgolette sono solo consigli di buone pratiche, al di là della valutazione sulla sicurezza chimica REACH e possono essere comunicate nella Sezione 5 dell'ES o nelle sezioni principali dell'SDS*.

Misure generali (agenti cancerogeni)
Considerare progressi tecnici e aggiornamenti dei processi (automazione inclusa) per l'eliminazione delle dispersioni. Limitare l'esposizione adottando misure quali sistemi chiusi, impianti dedicati e appositi impianti di aspirazione generale/localizzata dell'aria esausta. Drenare i sistemi e ripulire le linee di trasferimento prima di interrompere il contenimento. Pulire/spurgare le apparecchiature, ove possibile, prima della manutenzione. Ove esiste la possibilità di esposizione: limitare l'accesso al solo personale autorizzato, garantire agli operatori una formazione specifica sulle attività e sulle operazioni da compiere al fine di minimizzare il rischio di esposizione, indossare guanti e tute di protezione per prevenire la contaminazione della pelle, utilizzare un dispositivo di protezione delle vie respiratorie quando richiesto per determinati scenari di esposizione, eliminare immediatamente le eventuali fuoriuscite e smaltire i rifiuti in condizioni di sicurezza.
Garantire l'adozione di sistemi di lavoro sicuri o di soluzioni equivalenti per la gestione dei rischi. Ispezionare, verificare e sottoporre a regolare manutenzione tutti i dispositivi e le misure di controllo.Prendere in considerazione la necessità di un sistema di sorveglianza sanitario basato sulla valutazione dei rischi.

Scenario di esposizione 3: Formulazione di altri gas di petrolio (segue)

Sezione 2.1 Controllo delle esposizioni del dipendente (segue)

Esposizioni generali (sistemi chiusi)
Manipolare la sostanza in un sistema chiuso

Esposizioni generali (sistemi chiusi). Con raccolta campione. Con esposizione occasionale controllata
Manipolare la sostanza in un sistema chiuso. Effettuare il campionamento tramite un circuito chiuso o altro sistema, al fine di evitare l'esposizione

Esposizioni generali (sistemi chiusi). Utilizzo in processi discontinui sotto contenimento
Manipolare la sostanza in un sistema chiuso. Limitare l'esposizione tramite il parziale isolamento delle operazioni o delle apparecchiature e garantire una corretta ventilazione di estrazione in caso di aperture.

Esposizioni generali (sistemi aperti). Processo discontinuo. Con raccolta campione.
Effettuare il campionamento tramite un circuito chiuso o altro sistema, al fine di evitare l'esposizione

Campionatura durante il processo
Effettuare il campionamento tramite un circuito chiuso o altro sistema, al fine di evitare l'esposizione.

Attività di laboratorio
Manipolare solo sotto una cappa chimica o ricorrere a metodi equivalenti per ridurre al minimo i rischi di esposizione

Trasferimento prodotti sfusi
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione.

Operazioni di miscelazione (sistemi aperti)
Provvedere una ventilazione ad estrazione presso i punti in cui si verificano emissioni. Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora).

Riempimento fusti e piccoli contenitori
Limitare l'esposizione tramite il parziale isolamento delle operazioni o delle apparecchiature e garantire una corretta ventilazione di estrazione in caso di aperture. Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora).

Pulizia e manutenzione delle apparecchiature.
Drenare e spurgare il sistema prima dell'apertura o della manutenzione delle apparecchiature. Ripulire immediatamente le eventuali fuoriuscite. Indossare una maschera intera (conforme allo standard EN140) dotata di filtro di tipo A o superiore. Conservare i drenaggi in contenitori a tenuta stagna in attesa dello smaltimento o del successivo riciclo

Stoccaggio. Con esposizione occasionale controllata
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione. Immagazzinare la sostanza all'interno di un sistema chiuso

Sezione 2.2 Controllo delle esposizioni ambientali

La sostanza non è classificata - non si richiede una valutazione dell'esposizione ambientale

Sezione 3 Stima delle esposizioni

Sezione 3.1. Salute
Ai fini della valutazione del livello di esposizione sul luogo di lavoro, laddove non espressamente indicato, è stato utilizzato il metodo ECETOC TRA.

Quando si osservano le misure della gestione del rischio (RMM) e le condizioni operative raccomandate (OC), non si prevede di superare i DNEL attesi e i ratei della caratterizzazione del rischio risultanti si ritiene saranno inferiori a 1 come indicato nell'Appendice A.

Sezione 3.2 Ambiente
La conferma dell'uso sicuro è stata ottenuta attraverso un approccio qualitativo

Sezione 4 Guida per la verifica della conformità con lo scenario di esposizione

Sezione 4.1 Salute
Confermare che RMM e OC sono come descritte o di efficienza equivalente. Vedere Appendice A per i dettagli su efficienze e OC

Scenario di esposizione 3: Formulazione di altri gas di petrolio (segue)

Sezione 4.2 Ambiente
Non sono richieste misure aggiuntive di gestione dei rischi.

Sezione 5
Consigli aggiuntivi di buone pratiche oltre la valutazione della sicurezza chimica REACH (Sezione Opzionale)

Nota: Le misure riportate in questa sezione non sono state prese in considerazione nelle stime delle esposizioni relative allo scenario di esposizione presentato in precedenza. Non sono soggette agli obblighi definiti dall'Articolo 37 (4) della normativa REACH

Controllo delle esposizioni del dipendente
Selezione di frasi rilevanti per lo scenario di esposizione
Frasi RMM di buone pratiche possono essere inserite in questa sezione o consolidate nelle molteplici sezioni dell'SDS, a seconda della preferenza della registrazione e della funzionalità del sistema e-SDS disponibile.

Controllo delle esposizioni ambientali
Non applicabile

Scenario di esposizione 4: Uso di altri gas di petrolio in agenti espandenti - industriale

Sezione 1 Titolo dello scenario di esposizione

Titolo: Uso di altri gas di petrolio in agenti

Descrizione Utilizzo:

Settore di utilizzo: industriale (SU3)
Categorie di processo: PROC1, PROC2, PROC3, PROC8b, PROC9, PROC12
Categorie di rilascio ambientale: ERC4

Processi, compiti, attività coperte
Impiego come agente espandente per schiume rigide e flessibili. Comprende il trasferimento del materiale, la miscelazione, l'iniezione, la reticolazione, il taglio, lo stoccaggio e l'imballaggio.

Sezione 2 Condizioni operative e misure di gestione del rischio

Campo per dichiarazioni aggiuntive intese a spiegare lo scenario, se necessario

Sezione 2.1 Controllo delle esposizioni del dipendente

Caratteristiche del prodotto
Forma fisica del prodotto
Liquido, pressione di vapore > 10 kPa

Concentrazione della sostanza nel prodotto
Copre una percentuale di sostanza nel prodotto fino al 100% (se non altrimenti indicato)

Quantità utilizzate
Non applicabile

Frequenza e durata dell'utilizzo
Copre un'esposizione giornaliera fino a 8 ore (se non altrimenti specificato)

Fattori umani non influenzati dalla gestione dei rischi
Non applicabile

Altre condizioni operative che coinvolgono le esposizioni dei lavoratori
Presuppone l'utilizzo del prodotto ad una temperatura non superiore a 20° rispetto alla temperatura ambiente.
Presuppone un contenuto massimo di Butadiene di 1% e un contenuto massimo di Benzene di 1%.
Presuppone l'applicazione di uno standard di base adeguato in materia di igiene nell'ambiente lavorativo.

Scenari correlati
Misure di gestione dei rischi
Nota: elencare le frasi standard secondo la gerarchia di controllo indicata nel modello ECHA: 1. *Misure tecniche per impedire il rilascio,* 2. *Misure tecniche per impedire la dispersione, 3. Misure organizzative,* 4. *Protezione personale. Le frasi tra virgolette sono solo consigli di buone pratiche, al di là della valutazione sulla sicurezza chimica REACH e possono essere comunicate nella Sezione 5 dell'ES o nelle sezioni principali dell'SDS*.

Misure generali (agenti cancerogeni)
Considerare progressi tecnici e aggiornamenti dei processi (automazione inclusa) per l'eliminazione delle dispersioni. Limitare l'esposizione adottando misure quali sistemi chiusi, impianti dedicati e appositi impianti di aspirazione generale/localizzata dell'aria esausta. Drenare i sistemi e ripulire le linee di trasferimento prima di interrompere il contenimento. Pulire/spurgare le apparecchiature, ove possibile, prima della manutenzione. Ove esiste la possibilità di esposizione: limitare l'accesso al solo personale autorizzato, garantire agli operatori una formazione specifica sulle attività e sulle operazioni da compiere al fine di minimizzare il rischio di esposizione, indossare guanti e tute di protezione per prevenire la contaminazione della pelle, utilizzare un dispositivo di protezione delle vie respiratorie quando richiesto per determinati scenari di esposizione, eliminare immediatamente le eventuali fuoriuscite e smaltire i rifiuti in condizioni di sicurezza.
Garantire l'adozione di sistemi di lavoro sicuri o di soluzioni equivalenti per la gestione dei rischi. Ispezionare, verificare e sottoporre a regolare manutenzione tutti i dispositivi e le misure di controllo.Prendere in considerazione la necessità di un sistema di sorveglianza sanitario basato sulla valutazione dei rischi

Scenario di esposizione 4: Uso di altri gas di petrolio in agenti espandenti - industriale (segue)

Sezione 2.1 Controllo delle esposizioni del dipendente (segue)

Operazioni di miscelazione (sistemi chiusi)
Manipolare la sostanza in un sistema chiuso. Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora)

Trasferimento materiali
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione
Garantire uno standard adeguato di ventilazione controllata (non meno di 3 -5 ricambi d'aria ogni ora).

Stoccaggio
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione.
Immagazzinare la sostanza all'interno di un sistema chiuso

Riempimento fusti e piccoli contenitori
Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora).

Imballaggio di prodotti semi - sfusi
Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora).

Sezione 2.2 Controllo delle esposizioni ambientali

La sostanza non è classificata - non si richiede una valutazione dell'esposizione ambientale

Sezione 3 Stima delle esposizioni

Sezione 3.1. Salute
Ai fini della valutazione del livello di esposizione sul luogo di lavoro, laddove non espressamente indicato, è stato utilizzato il metodo ECETOC TRA.

Quando si osservano le misure della gestione del rischio (RMM) e le condizioni operative raccomandate (OC), non si prevede di superare i DNEL attesi e i ratei della caratterizzazione del rischio risultanti si ritiene saranno inferiori a 1 come indicato nell'Appendice A.

Sezione 3.2 Ambiente
La conferma dell'uso sicuro è stata ottenuta attraverso un approccio qualitativo

Sezione 4 Guida per la verifica della conformità con lo scenario di esposizione

Sezione 4.1 Salute
Confermare che RMM e OC sono come descritte o di efficienza equivalente. Vedere Appendice A per i dettagli su efficienze e OC

Sezione 4.2 Ambiente
Non sono richieste misure aggiuntive di gestione dei rischi.

Sezione 5
Consigli aggiuntivi di buone pratiche oltre la valutazione della sicurezza chimica REACH (Sezione Opzionale)

Nota: Le misure riportate in questa sezione non sono state prese in considerazione nelle stime delle esposizioni relative allo scenario di esposizione presentato in precedenza. Non sono soggette agli obblighi definiti dall'Articolo 37 (4) della normativa REACH

Controllo delle esposizioni del dipendente
Selezione di frasi rilevanti per lo scenario di esposizione
Frasi RMM di buone pratiche possono essere inserite in questa sezione o consolidate nelle molteplici sezioni dell'SDS, a seconda della preferenza della registrazione e della funzionalità del sistema e-SDS disponibile.

Controllo delle esposizioni ambientali
Non applicabile

Scenario di esposizione 5: Uso di altri gas di petrolio in combustibili - industriale

Sezione 1 Titolo dello scenario di esposizione

Titolo: Uso di altri gas di petrolio in combustibili

Descrizione Utilizzo:

Settore di utilizzo: industriale (SU3)
Categorie di processo: PROC1, PROC2, PROC3, PROC8a, PROC8b, PROC16
Categorie di rilascio ambientale: ERC7

Processi, compiti, attività coperte
Copre l'impiego come combustibile (o additivo per combustibile), comprese le attività associate al trasferimento, uso, manutenzione delle apparecchiature e smaltimento dei rifiuti

Sezione 2 Condizioni operative e misure di gestione del rischio

Campo per dichiarazioni aggiuntive intese a spiegare lo scenario, se necessario

Sezione 2.1 Controllo delle esposizioni del dipendente

Caratteristiche del prodotto
Forma fisica del prodotto
Liquido, pressione di vapore > 10 kPa

Concentrazione della sostanza nel prodotto
Copre una percentuale di sostanza nel prodotto fino al 100% (se non altrimenti indicato)

Quantità utilizzate
Non applicabile

Frequenza e durata dell'utilizzo
Copre un'esposizione giornaliera fino a 8 ore (se non altrimenti specificato)

Fattori umani non influenzati dalla gestione dei rischi
Non applicabile

Altre condizioni operative che coinvolgono le esposizioni dei lavoratori
Presuppone l'utilizzo del prodotto ad una temperatura non superiore a 20° rispetto alla temperatura ambiente.
Presuppone un contenuto massimo di Butadiene di 1% e un contenuto massimo di Benzene di 1%.
Presuppone l'applicazione di uno standard di base adeguato in materia di igiene nell'ambiente lavorativo.

Scenari correlati
Misure di gestione dei rischi
Nota: elencare le frasi standard secondo la gerarchia di controllo indicata nel modello ECHA: 1. *Misure tecniche per impedire il rilascio,* 2. *Misure tecniche per impedire la dispersione, 3. Misure organizzative,* 4. *Protezione personale. Le frasi tra virgolette sono solo consigli di buone pratiche, al di là della valutazione sulla sicurezza chimica REACH e possono essere comunicate nella Sezione 5 dell'ES o nelle sezioni principali dell'SDS*.

Misure generali (agenti cancerogeni)
Considerare progressi tecnici e aggiornamenti dei processi (automazione inclusa) per l'eliminazione delle dispersioni. Limitare l'esposizione adottando misure quali sistemi chiusi, impianti dedicati e appositi impianti di aspirazione generale/localizzata dell'aria esausta. Drenare i sistemi e ripulire le linee di trasferimento prima di interrompere il contenimento. Pulire/spurgare le apparecchiature, ove possibile, prima della manutenzione. Ove esiste la possibilità di esposizione: limitare l'accesso al solo personale autorizzato, garantire agli operatori una formazione specifica sulle attività e sulle operazioni da compiere al fine di minimizzare il rischio di esposizione, indossare guanti e tute di protezione per prevenire la contaminazione della pelle, utilizzare un dispositivo di protezione delle vie respiratorie quando richiesto per determinati scenari di esposizione, eliminare immediatamente le eventuali fuoriuscite e smaltire i rifiuti in condizioni di sicurezza.
Garantire l'adozione di sistemi di lavoro sicuri o di soluzioni equivalenti per la gestione dei rischi. Ispezionare, verificare e sottoporre a regolare manutenzione tutti i dispositivi e le misure di controllo.Prendere in considerazione la necessità di un sistema di sorveglianza sanitario basato sulla valutazione dei rischi

Scenario di esposizione 5: Uso di altri gas di petrolio in combustibili - industriale (segue)

Sezione 2.1 Controllo delle esposizioni del dipendente (segue)

Trasferimento prodotti sfusi
Garantire uno standard adeguato di ventilazione generale (non meno di 3 -5 ricambi d'aria ogni ora).Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione

Trasferimento fusti/lotti
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione. (Indossare guanti di protezione conformi allo standard EN374).

Esposizioni generali (sistemi chiusi)
Manipolare la sostanza in un sistema chiuso (Indossare guanti di protezione conformi allo standard EN374).

Esposizioni generali (sistemi chiusi). Con esposizione occasionale controllata
Manipolare la sostanza all'interno di un sistema prevalentemente chiuso provvisto di ventilazione a estrazione

Esposizioni generali (sistemi chiusi). Processi discontinuo
Manipolare la sostanza all'interno di un sistema prevalentemente chiuso provvisto di ventilazione a estrazione.
Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora).

Esposizioni generali (sistemi aperti).
Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora).

Esposizioni generali (sistemi aperti), (sistemi chiusi). Processo discontinuo
Manipolare la sostanza all'interno di un sistema prevalentemente chiuso provvisto di ventilazione a estrazione.
Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora).

Manutenzione delle apparecchiature.
Drenare e spurgare il sistema prima dell'apertura o della manutenzione delle apparecchiature. Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora).

Pulizia apparecchiature e contenitori
Drenare e spurgare il sistema prima dell'apertura o della manutenzione delle apparecchiature. Drenare e spurgare il sistema prima dell'apertura o della manutenzione delle apparecchiature. Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora).
Consentire l'accesso solo al personale autorizzato.
Applicare le procedure di accesso a luoghi confinati, incluso l'utilizzo di ventilazione forzata.

Stoccaggio.
Immagazzinare la sostanza all'interno di un sistema chiuso

Stoccaggio. Con esposizione occasionale controllata
Provvedere una ventilazione ad estrazione presso i punti in cui si verificano emissioni. Immagazzinare la sostanza all'interno di un sistema chiuso

Sezione 2.2 Controllo delle esposizioni ambientali

La sostanza non è classificata - non si richiede una valutazione dell'esposizione ambientale

Sezione 3 Stima delle esposizioni

Sezione 3.1. Salute
Ai fini della valutazione del livello di esposizione sul luogo di lavoro, laddove non espressamente indicato, è stato utilizzato il metodo ECETOC TRA.

Quando si osservano le misure della gestione del rischio (RMM) e le condizioni operative raccomandate (OC), non si prevede di superare i DNEL attesi e i ratei della caratterizzazione del rischio risultanti si ritiene saranno inferiori a 1 come indicato nell'Appendice A.

Sezione 3.2 Ambiente
La conferma dell'uso sicuro è stata ottenuta attraverso un approccio qualitativo

Scenario di esposizione 5: Uso di altri gas di petrolio in combustibili - industriale (segue)

Sezione 4 Guida per la verifica della conformità con lo scenario di esposizione

Sezione 4.1 Salute
Confermare che RMM e OC sono come descritte o di efficienza equivalente. Vedere Appendice A per i dettagli su efficienze e OC

Sezione 4.2 Ambiente
Non sono richieste misure aggiuntive di gestione dei rischi.

Sezione 5
Consigli aggiuntivi di buone pratiche oltre la valutazione della sicurezza chimica REACH (Sezione Opzionale)

Nota: Le misure riportate in questa sezione non sono state prese in considerazione nelle stime delle esposizioni relative allo scenario di esposizione presentato in precedenza. Non sono soggette agli obblighi definiti dall'Articolo 37 (4) della normativa REACH

Controllo delle esposizioni del dipendente
Selezione di frasi rilevanti per lo scenario di esposizione
Frasi RMM di buone pratiche possono essere inserite in questa sezione o consolidate nelle molteplici sezioni dell'SDS, a seconda della preferenza della registrazione e della funzionalità del sistema e-SDS disponibile.

Controllo delle esposizioni ambientali
Non applicabile

Scenario di esposizione 6: Uso di altri gas di petrolio in combustibili - professionale

Sezione 1 Titolo dello scenario di esposizione

Titolo: Uso di altri gas di petrolio in combustibili

Descrizione Utilizzo:

Settore di utilizzo: industriale (SU22)
Categorie di processo: PROC1, PROC2, PROC3, PROC8a, PROC8b, PROC16
Categorie di rilascio ambientale: ERC9A, ERC9B

Processi, compiti, attività coperte
Copre l'impiego come combustibile (o additivo per combustibile), comprese le attività associate al trasferimento, uso, manutenzione delle apparecchiature e smaltimento dei rifiuti

Sezione 2 Condizioni operative e misure di gestione del rischio

Campo per dichiarazioni aggiuntive intese a spiegare lo scenario, se necessario

Sezione 2.1 Controllo delle esposizioni del dipendente

Caratteristiche del prodotto
Forma fisica del prodotto
Liquido, pressione di vapore > 10 kPa

Concentrazione della sostanza nel prodotto
Copre una percentuale di sostanza nel prodotto fino al 100% (se non altrimenti indicato)

Quantità utilizzate
Non applicabile

Frequenza e durata dell'utilizzo
Copre un'esposizione giornaliera fino a 8 ore (se non altrimenti specificato)

Fattori umani non influenzati dalla gestione dei rischi
Non applicabile

Altre condizioni operative che coinvolgono le esposizioni dei lavoratori
Presuppone l'utilizzo del prodotto ad una temperatura non superiore a 20° rispetto alla temperatura ambiente.
Presuppone un contenuto massimo di Butadiene di 1% e un contenuto massimo di Benzene di 1%.
Presuppone l'applicazione di uno standard di base adeguato in materia di igiene nell'ambiente lavorativo.

Scenari correlati
Misure di gestione dei rischi
Nota: elencare le frasi standard secondo la gerarchia di controllo indicata nel modello ECHA: 1. *Misure tecniche per impedire il rilascio,* 2. *Misure tecniche per impedire la dispersione, 3. Misure organizzative,* 4. *Protezione personale. Le frasi tra virgolette sono solo consigli di buone pratiche, al di là della valutazione sulla sicurezza chimica REACH e possono essere comunicate nella Sezione 5 dell'ES o nelle sezioni principali dell'SDS*.

Misure generali (agenti cancerogeni)
Considerare progressi tecnici e aggiornamenti dei processi (automazione inclusa) per l'eliminazione delle dispersioni. Limitare l'esposizione adottando misure quali sistemi chiusi, impianti dedicati e appositi impianti di aspirazione generale/localizzata dell'aria esausta. Drenare i sistemi e ripulire le linee di trasferimento prima di interrompere il contenimento. Pulire/spurgare le apparecchiature, ove possibile, prima della manutenzione. Ove esiste la possibilità di esposizione: limitare l'accesso al solo personale autorizzato, garantire agli operatori una formazione specifica sulle attività e sulle operazioni da compiere al fine di minimizzare il rischio di esposizione, indossare guanti e tute di protezione per prevenire la contaminazione della pelle, utilizzare un dispositivo di protezione delle vie respiratorie quando richiesto per determinati scenari di esposizione, eliminare immediatamente le eventuali fuoriuscite e smaltire i rifiuti in condizioni di sicurezza.
Garantire l'adozione di sistemi di lavoro sicuri o di soluzioni equivalenti per la gestione dei rischi. Ispezionare, verificare e sottoporre a regolare manutenzione tutti i dispositivi e le misure di controllo.Prendere in considerazione la necessità di un sistema di sorveglianza sanitario basato sulla valutazione dei rischi

Scenario di esposizione 6: Uso di altri gas di petrolio in combustibili - professionale (segue)

Sezione 2.1 Controllo delle esposizioni del dipendente (segue)

Trasferimento prodotti sfusi
Garantire uno standard adeguato di ventilazione generale (da 10 a 15 ricambi d'aria ogni ora).Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione. Evitare di compiere attività che comportino un'esposizione superiore a 4 ore.

Trasferimento fusti/lotti
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione. Assicurarsi che l'operazione sia effettuata all'esterno. Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora). Evitare di compiere attività che comportino un'esposizione superiore a 15 minuti

Esposizioni generali (sistemi chiusi)
Manipolare la sostanza in un sistema chiuso.

Esposizioni generali (sistemi chiusi). Con esposizione occasionale controllata
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione. Assicurarsi che l'operazione sia effettuata all'esterno. Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora).

Esposizioni generali (sistemi aperti) (sistemi chiusi). Processi discontinuo
Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora). Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione

Esposizioni generali (sistemi aperti).
Assicurarsi che l'operazione sia effettuata all'esterno. Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora).

Pulizia e manutenzione delle apparecchiature.
Drenare e spurgare il sistema prima dell'apertura o della manutenzione delle apparecchiature. Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione. Assicurarsi che l'operazione sia effettuata all'esterno. Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora). Indossare una maschera intera (conforme allo standard EN140) dotata di filtro di tipo A o superiore

Pulizia apparecchiature e contenitori
Drenare e spurgare il sistema prima dell'apertura o della manutenzione delle apparecchiature. Assicurarsi che l'operazione sia effettuata all'esterno. Garantire uno standard adeguato di ventilazione generale (non meno di 3- 5 ricambi d'aria ogni ora). Indossare una maschera intera (conforme allo standard EN140) dotata di filtro di tipo A o superiore.
Consentire l'accesso solo al personale autorizzato.
Applicare le procedure di accesso a luoghi confinati, incluso l'utilizzo di ventilazione forzata.

Stoccaggio.
Immagazzinare la sostanza all'interno di un sistema chiuso

Sezione 2.2 Controllo delle esposizioni ambientali

La sostanza non è classificata - non si richiede una valutazione dell'esposizione ambientale

Sezione 3 Stima delle esposizioni

Sezione 3.1. Salute
Ai fini della valutazione del livello di esposizione sul luogo di lavoro, laddove non espressamente indicato, è stato utilizzato il metodo ECETOC TRA.

Quando si osservano le misure della gestione del rischio (RMM) e le condizioni operative raccomandate (OC), non si prevede di superare i DNEL attesi e i ratei della caratterizzazione del rischio risultanti si ritiene saranno inferiori a 1 come indicato nell'Appendice A.

Sezione 3.2 Ambiente
La conferma dell'uso sicuro è stata ottenuta attraverso un approccio qualitativo

Scenario di esposizione 6: Uso di altri gas di petrolio in combustibili - professionale (segue)

Sezione 4 Guida per la verifica della conformità con lo scenario di esposizione

Sezione 4.1 Salute
Confermare che RMM e OC sono come descritte o di efficienza equivalente. Vedere Appendice A per i dettagli su efficienze e OC

Sezione 4.2 Ambiente
Non sono richieste misure aggiuntive di gestione dei rischi.

Sezione 5
Consigli aggiuntivi di buone pratiche oltre la valutazione della sicurezza chimica REACH (Sezione Opzionale)

Nota: Le misure riportate in questa sezione non sono state prese in considerazione nelle stime delle esposizioni relative allo scenario di esposizione presentato in precedenza. Non sono soggette agli obblighi definiti dall'Articolo 37 (4) della normativa REACH

Controllo delle esposizioni del dipendente
Selezione di frasi rilevanti per lo scenario di esposizione
Frasi RMM di buone pratiche possono essere inserite in questa sezione o consolidate nelle molteplici sezioni dell'SDS, a seconda della preferenza della registrazione e della funzionalità del sistema e-SDS disponibile.

Controllo delle esposizioni ambientali
Non applicabile

Scenario di esposizione 7: Uso di altri gas di petrolio in combustibili - consumatore

Sezione 1 Titolo dello scenario di esposizione

Titolo: Combustibili

Descrizione Utilizzo:

Settore di utilizzo: industriale (SU21)
Descrizione utilizzo: PC13 Categorie
di rilascio ambientale: -

Processi, compiti, attività coperte
Copre l'impiego da parte del consumatore come combustibile liquido.

Sezione 2 Condizioni operative e misure di gestione del rischio

Campo per dichiarazioni aggiuntive intese a spiegare lo scenario, se necessario

Sezione 2.1 Controllo delle esposizioni dei consumatori finali

Caratteristiche del prodotto
Forma fisica del prodotto
Liquido

Concentrazione della sostanza nel prodotto
Se non altrimenti indicato, copre una percentuale di sostanza nel prodotto fino al 5%

Quantità utilizzate
Se non altrimenti specificato, copre le quantità di utilizzo fino a 45000g; copre l'area di contatto pelle fino a Ocm2

Frequenza e durata dell'utilizzo/esposizione
Se non altrimenti specificato, copre la frequenza di utilizzo fino a 0,143 volte al giorno; copre l'esposizione fino a 0,05 ore per evento

Altre condizioni operative che coinvolgono le esposizioni dei lavoratori
Se non altrimenti specificato si presuppone l'utilizzo a temperature ambiente; si presuppone l'utilizzo in una stanza di 20 m^3; si presuppone un uso con una ventilazione tipica.

Sezione 2.1.1 Categorie di prodotti

PC13 Combustibili - liquido - sottocategorie aggiunte: rifornimento di automobili OC
Se non altrimenti specificato copre concentrazioni fino al 5%; copre l'utilizzo fino a 52 giorni/anno; copre l'utilizzo fino a 1 volta/al giorno di utilizzo; per ciascun evento, copre l'utilizzo di quantità fino a 45000g; copre l'utilizzo esterno; copre l'utilizzo in una stanza di 100m^3; per ciascun uso, copre l'esposizione fino a 0,05h/evento

PC13 Combustibili - liquido - sottocategorie aggiunte: rifornimento di automobili RMM
Nessuna RMM specifica sviluppata oltre le OC indicate

PC13 Combustibili - liquido - sottocategorie aggiunte: rifornimento di automobili OC
Se non altrimenti specificato copre concentrazioni fino al 5%; copre l'utilizzo fino a 26 giorni/anno; copre l'utilizzo fino a 1 volta/al giorno di utilizzo; per ciascun evento, copre l'utilizzo di quantità fino a 13.000g; copre l'utilizzo in una stanza di 20m^3; per ciascun uso, copre l'esposizione fino a 0,03h/evento.

PC13:Combustibili - Uso domestico di bombole di GPL per il riscaldamento e per cucinare RMM
Nessuna RMM specifica sviluppata oltre le OC indicate.

Sezione 2.2 Controllo delle esposizioni ambientali

La sostanza non è classificata - non si richiede una valutazione dell'esposizione ambientale

Sezione 3 Stima delle esposizioni

Sezione 3.1. Salute
Ai fini della valutazione del livello di esposizione sul luogo di lavoro, laddove non espressamente indicato, è stato utilizzato il metodo ECETOC TRA.

Scenario di esposizione 7: Uso di altri gas di petrolio in combustibili - consumatore (segue)

Sezione 3.1. Salute (segue)

Quando si osservano le misure della gestione del rischio (RMM) e le condizioni operative raccomandate (OC), non si prevede di superare i DNEL attesi e i ratei della caratterizzazione del rischio risultanti si ritiene saranno inferiori a 1 come indicato nell'Appendice A.

Sezione 3.2 Ambiente
La conferma dell'uso sicuro è stata ottenuta attraverso un approccio qualitativo [EE8]

Sezione 4 Guida per la verifica della conformità con lo scenario di esposizione

Sezione 4.1 Salute
Confermare che RMM e OC sono come descritte o di efficienza equivalente. Vedere Appendice A per i dettagli su efficienze e OC

Sezione 4.2 Ambiente
Non sono richieste misure aggiuntive di gestione dei rischi.

Sezione 5
Consigli aggiuntivi di buone pratiche oltre la valutazione della sicurezza chimica REACH (Sezione Opzionale)

Nota: Le misure riportate in questa sezione non sono state prese in considerazione nelle stime delle esposizioni relative allo scenario di esposizione presentato in precedenza. Non sono soggette agli obblighi definiti dall'Articolo 37 (4) della normativa REACH

Controllo delle esposizioni del dipendente
Selezione di frasi rilevanti per lo scenario di esposizione
Frasi RMM di buone pratiche possono essere inserite in questa sezione o consolidate nelle molteplici sezioni dell'SDS, a seconda della preferenza della registrazione e della funzionalità del sistema e-SDS disponibile.

Controllo delle esposizioni ambientali
Non applicabile

Scenario di esposizione 8: Uso di altri gas di petrolio in fluidi funzionali - industriale

Sezione 1 Titolo dello scenario di esposizione

Titolo: Uso di altri gas di petrolio in fluidi funzionali

Descrizione Utilizzo:

Settore di utilizzo: industriale (SU3)
Categorie di processo
PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC9
Categorie di rilascio ambientale: ERC7

Processi, compiti, attività coperte
Utilizzo come fluido funzionale, quale isolante per cavi elettrici, fluido termovettore, isolante elettrico, refrigeranti e fluidi idraulici in apparecchiature industriali, comprese le operazioni di manutenzione e il trasferimento di materiale

Sezione 2 Condizioni operative e misure di gestione del rischio

Campo per dichiarazioni aggiuntive intese a spiegare lo scenario, se necessario

Sezione 2.1 Controllo delle esposizioni del dipendente

Caratteristiche del prodotto
Forma fisica del prodotto
Gas o gas liquefatto, pressione di vapore > 10 kPa

Concentrazione della sostanza nel prodotto
Copre una percentuale di sostanza nel prodotto fino al 100% (se non altrimenti indicato).

Quantità utilizzate
Non applicabile

Frequenza e durata dell'utilizzo
Copre un'esposizione giornaliera fino a 8 ore (se non altrimenti specificato).

Fattori umani non influenzati dalla gestione dei rischi
Non applicabile

Altre condizioni operative che coinvolgono le esposizioni dei lavoratori
Presuppone l'utilizzo del prodotto a una temperatura non superiore a 20° rispetto alla temperatura ambiente;
Presuppone un contenuto massimo di Butadiene di 1% e un contenuto massimo di Benzene di 1%.
Presuppone l'applicazione di uno standard di base adeguato in materia di igiene nell'ambiente lavorativo.

Scenari correlati
Misure di gestione dei rischi
Nota: elencare le frasi standard secondo la gerarchia di controllo indicata nel modello ECHA: 1. *Misure tecniche per impedire il rilascio,* 2. *Misure tecniche per impedire la dispersione, 3. Misure organizzative,* 4. *Protezione personale. Le frasi tra virgolette sono solo consigli di buone pratiche, al di là della valutazione sulla sicurezza chimica REACH e possono essere comunicate nella Sezione 5 dell'ES o nelle sezioni principali dell'SDS*.

Misure generali (agenti cancerogeni)
Considerare progressi tecnici e aggiornamenti dei processi (automazione inclusa) per l'eliminazione delle dispersioni. Limitare l'esposizione adottando misure quali sistemi chiusi, impianti dedicati e appositi impianti di aspirazione generale/localizzata dell'aria esausta. Drenare i sistemi e ripulire le linee di trasferimento prima di interrompere il contenimento. Pulire/spurgare le apparecchiature, ove possibile, prima della manutenzione. Ove esiste la possibilità di esposizione: limitare l'accesso al solo personale autorizzato, garantire agli operatori una formazione specifica sulle attività e sulle operazioni da compiere al fine di minimizzare il rischio di esposizione, indossare guanti e tute di protezione per prevenire la contaminazione della pelle, utilizzare un dispositivo di protezione delle vie respiratorie quando richiesto per determinati scenari di esposizione, eliminare immediatamente le eventuali fuoriuscite e smaltire i rifiuti in condizioni di sicurezza.
Garantire l'adozione di sistemi di lavoro sicuri o di soluzioni equivalenti per la gestione dei rischi. Ispezionare, verificare e sottoporre a regolare manutenzione tutti i dispositivi e le misure di controllo.Prendere in considerazione la necessità di un sistema di sorveglianza sanitario basato sulla valutazione dei rischi

Scenario di esposizione 8: Uso di altri gas di petrolio in fluidi funzionali - industriale (segue)

Sezione 2.1 Controllo delle esposizioni del dipendente (segue)

Trasferimento prodotti sfusi
Manipolare la sostanza in un sistema chiuso.

Trasferimento prodotti sfusi. Con esposizione occasionale controllata
Manipolare la sostanza in un sistema chiuso. Provvedere una ventilazione ad estrazione presso i punti in cui si verificano emissioni.

Trasferimento prodotti sfusi. Processo discontinuo
Manipolare la sostanza in un sistema chiuso. Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora). Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione

Trasferimento prodotti sfusi
Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora). Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione.

Trasferimenti fusti/lotti. Struttura dedicata
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione

Riempimento/preparazione delle apparecchiature da fusti o contenitori. Manuale
Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora). Provvedere una ventilazione ad estrazione presso i punti in cui si verificano emissioni

Esposizioni generali (sistemi chiusi).
Limitare l'esposizione tramite il parziale isolamento delle operazioni o delle apparecchiature e garantire una corretta ventilazione di estrazione in caso di aperture

Esposizioni generali (sistemi aperti).
Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora). Provvedere una ventilazione ad estrazione presso i punti in cui si verificano emissioni

Manutenzione delle apparecchiature
Drenare il sistema prima dell'apertura o della manutenzione delle apparecchiature. Provvedere una ventilazione ad estrazione presso i punti in cui si verificano emissioni

Stoccaggio
Immagazzinare la sostanza all'interno di un sistema chiuso

Stoccaggio. Con esposizione occasionale controllata
Immagazzinare la sostanza all'interno di un sistema chiuso. Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione

Sezione 2.2 Controllo delle esposizioni ambientali

La sostanza non è classificata - non si richiede una valutazione dell'esposizione ambientale

Sezione 3 Stima delle esposizioni

Sezione 3.1. Salute
Ai fini della valutazione del livello di esposizione sul luogo di lavoro, laddove non espressamente indicato, è stato utilizzato il metodo ECETOC TRA.

Quando si osservano le misure della gestione del rischio (RMM) e le condizioni operative raccomandate (OC), non si prevede di superare i DNEL attesi e i ratei della caratterizzazione del rischio risultanti si ritiene saranno inferiori a 1 come indicato nell'Appendice A.

Sezione 3.2 Ambiente
La conferma dell'uso sicuro è stata ottenuta attraverso un approccio qualitativo

Sezione 4 Guida per la verifica della conformità con lo scenario di esposizione

Sezione 4.1 Salute
Confermare che RMM e OC sono come descritte o di efficienza equivalente. Vedere Appendice A per i dettagli su efficienze e OC

Scenario di esposizione 8: Uso di altri gas di petrolio in fluidi funzionali - industriale (segue)
Sezione 4 Guida per la verifica della conformità con lo scenario di esposizione (segue)

Sezione 4.2 Ambiente
Non sono richieste misure aggiuntive di gestione dei rischi.

Sezione 5
Consigli aggiuntivi di buone pratiche oltre la valutazione della sicurezza chimica REACH (Sezione Opzionale)

Nota: Le misure riportate in questa sezione non sono state prese in considerazione nelle stime delle esposizioni relative allo scenario di esposizione presentato in precedenza. Non sono soggette agli obblighi definiti dall'Articolo 37 (4) della normativa REACH

Controllo delle esposizioni del dipendente
Selezione di frasi rilevanti per lo scenario di esposizione
Frasi RMM di buone pratiche possono essere inserite in questa sezione o consolidate nelle molteplici sezioni dell'SDS, a seconda della preferenza della registrazione e della funzionalità del sistema e-SDS disponibile.

Controllo delle esposizioni ambientali
Non applicabile

Scenario di esposizione 9: Uso di altri gas di petrolio in fluidi funzionali - professionale

Sezione 1 Titolo dello scenario di esposizione

Titolo: Uso di altri gas di petrolio in fluidi funzionali

Descrizione Utilizzo:

Settore di utilizzo: industriale (SU22)
Categorie di processo
PROC1, PROC2, PROC3, PROC8a, PROC9, PROC20
Categorie di rilascio ambientale: ERC9A, ERC9B.

Processi, compiti, attività coperte
Utilizzo come fluido funzionale, quale isolante per cavi elettrici, fluido termovettore, isolante elettrico, refrigeranti e fluidi idraulici in apparecchiature industriali, comprese le operazioni di manutenzione e il trasferimento di materiale

Sezione 2 Condizioni operative e misure di gestione del rischio

Campo per dichiarazioni aggiuntive intese a spiegare lo scenario, se necessario

Sezione 2.1 Controllo delle esposizioni del dipendente

Caratteristiche del prodotto
Forma fisica del prodotto
Liquido, pressione di vapore > 10 kPa

Concentrazione della sostanza nel prodotto
Copre una percentuale di sostanza nel prodotto fino al 100% (se non altrimenti indicato).

Quantità utilizzate
Non applicabile

Frequenza e durata dell'utilizzo
Copre un'esposizione giornaliera fino a 8 ore (se non altrimenti specificato).

Fattori umani non influenzati dalla gestione dei rischi
Non applicabile

Altre condizioni operative che coinvolgono le esposizioni dei lavoratori
Presuppone l'utilizzo del prodotto a una temperatura non superiore a 20° rispetto alla temperatura ambiente;
Presuppone un contenuto massimo di Butadiene di 1% e un contenuto massimo di Benzene di 1%.
Presuppone l'applicazione di uno standard di base adeguato in materia di igiene nell'ambiente lavorativo.

Scenari correlati
Misure di gestione dei rischi
Nota: elencare le frasi standard secondo la gerarchia di controllo indicata nel modello ECHA: 1. *Misure tecniche per impedire il rilascio,* 2. *Misure tecniche per impedire la dispersione, 3. Misure organizzative,* 4. *Protezione personale. Le frasi tra virgolette sono solo consigli di buone pratiche, al di là della valutazione sulla sicurezza chimica REACH e possono essere comunicate nella Sezione 5 dell'ES o nelle sezioni principali dell'SDS*.

Misure generali (agenti cancerogeni)
Considerare progressi tecnici e aggiornamenti dei processi (automazione inclusa) per l'eliminazione delle dispersioni. Limitare l'esposizione adottando misure quali sistemi chiusi, impianti dedicati e appositi impianti di aspirazione generale/localizzata dell'aria esausta. Drenare i sistemi e ripulire le linee di trasferimento prima di interrompere il contenimento. Pulire/spurgare le apparecchiature, ove possibile, prima della manutenzione. Ove esiste la possibilità di esposizione: limitare l'accesso al solo personale autorizzato, garantire agli operatori una formazione specifica sulle attività e sulle operazioni da compiere al fine di minimizzare il rischio di esposizione, indossare guanti e tute di protezione per prevenire la contaminazione della pelle, utilizzare un dispositivo di protezione delle vie respiratorie quando richiesto per determinati scenari di esposizione, eliminare immediatamente le eventuali fuoriuscite e smaltire i rifiuti in condizioni di sicurezza.
Garantire l'adozione di sistemi di lavoro sicuri o di soluzioni equivalenti per la gestione dei rischi. Ispezionare, verificare e sottoporre a regolare manutenzione tutti i dispositivi e le misure di controllo.Prendere in considerazione la necessità di un sistema di sorveglianza sanitario basato sulla valutazione dei rischi

Scenario di esposizione 9: Uso di altri gas di petrolio in fluidi funzionali - professionale (segue)

Sezione 2.1 Controllo delle esposizioni del dipendente (segue)

Trasferimento fusti/lotti. Struttura non dedicata
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione. Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora). Evitare di compiere attività che comportino un'esposizione superiore a 4 ore.

Riempimento/preparazione delle apparecchiature da fusti o contenitori
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione. Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora).

Esposizioni generali (sistemi chiusi).
Manipolare la sostanza in un sistema chiuso.

Manutenzione delle apparecchiature. Struttura non dedicata
Drenare il sistema prima dell'apertura o della manutenzione delle apparecchiature. Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora). Provvedere una ventilazione ad estrazione presso i punti in cui si verificano emissioni

Stoccaggio. Con esposizione occasionale controllata
Assicurarsi che l'operazione sia effettuata all'esterno. Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione. Immagazzinare la sostanza all'interno di un sistema chiuso

Sezione 2.2 Controllo delle esposizioni ambientali

La sostanza non è classificata - non si richiede una valutazione dell'esposizione ambientale

Sezione 3 Stima delle esposizioni

Sezione 3.1. Salute
Ai fini della valutazione del livello di esposizione sul luogo di lavoro, laddove non espressamente indicato, è stato utilizzato il metodo ECETOC TRA.

Quando si osservano le misure della gestione del rischio (RMM) e le condizioni operative raccomandate (OC), non si prevede di superare i DNEL attesi e i ratei della caratterizzazione del rischio risultanti si ritiene saranno inferiori a 1 come indicato nell'Appendice A.

Sezione 3.2 Ambiente
La conferma dell'uso sicuro è stata ottenuta attraverso un approccio qualitativo

Sezione 4 Guida per la verifica della conformità con lo scenario di esposizione

Sezione 4.1 Salute
Confermare che RMM e OC sono come descritte o di efficienza equivalente. Vedere Appendice A per i dettagli su efficienze e OC

Sezione 4.2 Ambiente
Non sono richieste misure aggiuntive di gestione dei rischi.

Sezione 5
Consigli aggiuntivi di buone pratiche oltre la valutazione della sicurezza chimica REACH (Sezione Opzionale)

Nota: Le misure riportate in questa sezione non sono state prese in considerazione nelle stime delle esposizioni relative allo scenario di esposizione presentato in precedenza. Non sono soggette agli obblighi definiti dall'Articolo 37 (4) della normativa REACH

Controllo delle esposizioni del dipendente
Selezione di frasi rilevanti per lo scenario di esposizione
Frasi RMM di buone pratiche possono essere inserite in questa sezione o consolidate nelle molteplici sezioni dell'SDS, a seconda della preferenza della registrazione e della funzionalità del sistema e-SDS disponibile.

Controllo delle esposizioni ambientali
Non applicabile

Scenario di esposizione 10: Uso di altri gas di petrolio nella produzione di polimeri - industriale

Sezione 1 Titolo dello scenario di esposizione

Titolo: Uso di altri gas di petrolio nella produzione di polimeri.

Descrizione Utilizzo:

Settore di utilizzo: industriale (SU3, SU8, SU9)
Categorie di processo
PROC1, PROC2, PROC3, PROC4, PROC5, PROC6, PROC8a, PROC8b, PROC9, PROC14, PROC21
Categorie di rilascio ambientale: ERC6A, ERC6C

Processi, compiti, attività coperte
Produzione di polimeri da monomeri in processi continui e discontinui, compreso lo spruzzo, lo scarico, la manutenzione del reattore e la formazione immediata di prodotti polimerici (composti, pellettizzazione, liberazione di gas dal prodotto).

Sezione 2 Condizioni operative e misure di gestione del rischio

Campo per dichiarazioni aggiuntive intese a spiegare lo scenario, se necessario

Sezione 2.1 Controllo delle esposizioni del dipendente

Caratteristiche del prodotto
Forma fisica del prodotto
Liquido, pressione di vapore > 10 kPa

Concentrazione della sostanza nel prodotto
Copre una percentuale di sostanza nel prodotto fino al 100% (se non altrimenti indicato).

Quantità utilizzate
Non applicabile

Frequenza e durata dell'utilizzo
Copre un'esposizione giornaliera fino a 8 ore (se non altrimenti specificato).

Fattori umani non influenzati dalla gestione dei rischi
Non applicabile

Altre condizioni operative che coinvolgono le esposizioni dei lavoratori
Presuppone l'utilizzo del prodotto a una temperatura non superiore a 20° rispetto alla temperatura ambiente;
Presuppone un contenuto massimo di Butadiene di 1% e un contenuto massimo di Benzene di 1%.
Presuppone l'applicazione di uno standard di base adeguato in materia di igiene nell'ambiente lavorativo.

Scenari correlati
Misure di gestione dei rischi
Nota: elencare le frasi standard secondo la gerarchia di controllo indicata nel modello ECHA: 1. *Misure tecniche per impedire il rilascio,* 2. *Misure tecniche per impedire la dispersione, 3. Misure organizzative,* 4. *Protezione personale. Le frasi tra virgolette sono solo consigli di buone pratiche, al di là della valutazione sulla sicurezza chimica REACH e possono essere comunicate nella Sezione 5 dell'ES o nelle sezioni principali dell'SDS*.

Misure generali (agenti cancerogeni)
Considerare progressi tecnici e aggiornamenti dei processi (automazione inclusa) per l'eliminazione delle dispersioni. Limitare l'esposizione adottando misure quali sistemi chiusi, impianti dedicati e appositi impianti di aspirazione generale/localizzata dell'aria esausta. Drenare i sistemi e ripulire le linee di trasferimento prima di interrompere il contenimento. Pulire/spurgare le apparecchiature, ove possibile, prima della manutenzione. Ove esiste la possibilità di esposizione: limitare l'accesso al solo personale autorizzato, garantire agli operatori una formazione specifica sulle attività e sulle operazioni da compiere al fine di minimizzare il rischio di esposizione, indossare guanti e tute di protezione per prevenire la contaminazione della pelle, utilizzare un dispositivo di protezione delle vie respiratorie quando richiesto per determinati scenari di esposizione, eliminare immediatamente le eventuali fuoriuscite e smaltire i rifiuti in condizioni di sicurezza.
Garantire l'adozione di sistemi di lavoro sicuri o di soluzioni equivalenti per la gestione dei rischi. Ispezionare, verificare e sottoporre a regolare manutenzione tutti i dispositivi e le misure di controllo.Prendere in considerazione la necessità di un sistema di sorveglianza sanitario basato sulla valutazione dei rischi

Scenario di esposizione 10: Uso di altri gas di petrolio nella produzione di polimeri - industriale (segue)

Sezione 2.1 Controllo delle esposizioni del dipendente (segue)

Esposizioni generali (sistemi chiusi). Processo discontinuo. Nessuna campionatura.
Manipolare la sostanza in un sistema chiuso. Nessuna misura specifica identificata

Trasferimento prodotti sfusi. Con raccolta campione
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione.
Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora.

Manutenzione delle apparecchiature
Drenare il sistema prima dell'apertura o della manutenzione delle apparecchiature. Ripulire immediatamente le eventuali fuoriuscite. Indossare una maschera intera (conforme allo standard EN140) dotata di filtro di tipo A o superiore. Conservare i drenaggi in contenitori a tenuta stagna in attesa dello smaltimento o del successivo riciclo

Stoccaggio. Con esposizione occasionale controllata
Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora). Immagazzinare la sostanza all'interno di un sistema chiuso. Non effettuare attività che prevedono la possibilità di esposizione per un periodo superiore a 1 ora.

Sezione 2.2 Controllo delle esposizioni ambientali

La sostanza non è classificata - non si richiede una valutazione dell'esposizione ambientale

Sezione 3 Stima delle esposizioni

Sezione 3.1. Salute
Ai fini della valutazione del livello di esposizione sul luogo di lavoro, laddove non espressamente indicato, è stato utilizzato il metodo ECETOC TRA.

Quando si osservano le misure della gestione del rischio (RMM) e le condizioni operative raccomandate (OC), non si prevede di superare i DNEL attesi e i ratei della caratterizzazione del rischio risultanti si ritiene saranno inferiori a 1 come indicato nell'Appendice A.

Sezione 3.2 Ambiente
La conferma dell'uso sicuro è stata ottenuta attraverso un approccio qualitativo

Sezione 4 Guida per la verifica della conformità con lo scenario di esposizione

Sezione 4.1 Salute
Confermare che RMM e OC sono come descritte o di efficienza equivalente. Vedere Appendice A per i dettagli su efficienze e OC

Sezione 4.2 Ambiente
Non sono richieste misure aggiuntive di gestione dei rischi.

Sezione 5
Consigli aggiuntivi di buone pratiche oltre la valutazione della sicurezza chimica REACH (Sezione Opzionale)

Nota: Le misure riportate in questa sezione non sono state prese in considerazione nelle stime delle esposizioni relative allo scenario di esposizione presentato in precedenza. Non sono soggette agli obblighi definiti dall'Articolo 37 (4) della normativa REACH

Controllo delle esposizioni del dipendente
Selezione di frasi rilevanti per lo scenario di esposizione
Frasi RMM di buone pratiche possono essere inserite in questa sezione o consolidate nelle molteplici sezioni dell'SDS, a seconda della preferenza della registrazione e della funzionalità del sistema e-SDS disponibile.

Controllo delle esposizioni ambientali
Non applicabile

Scenario di esposizione 11: Uso di altri gas di petrolio nella produzione di polimeri - industriale

Sezione 1 Titolo dello scenario di esposizione

Titolo: Uso di altri gas di petrolio nella produzione di polimeri.

Descrizione Utilizzo:

Settore di utilizzo: industriale (SU3, SU10)
Categorie di processo
PROC1, PROC2, PROC3, PROC4, PROC5, PROC6, PROC8a, PROC8b, PROC9, PROC 13, PROC14, PROC21
Categorie di rilascio ambientale: ERC4

Processi, compiti, attività coperte
Lavorazione di polimeri formulati, compresi il trasferimento di materiale, la gestione degli additivi (es: pigmenti, stabilizzatori, riempitivi, plastificanti, ecc.), lo stampaggio, la reticolazione e la sagomatura, la rilavorazione del materiale, lo stoccaggio e la relativa manutenzione.

Sezione 2 Condizioni operative e misure di gestione del rischio

Campo per dichiarazioni aggiuntive intese a spiegare lo scenario, se necessario

Sezione 2.1 Controllo delle esposizioni del dipendente

Caratteristiche del prodotto
Forma fisica del prodotto
Liquido, pressione di vapore > 10 kPa

Concentrazione della sostanza nel prodotto
Copre una percentuale di sostanza nel prodotto fino al 100% (se non altrimenti indicato).

Quantità utilizzate
Non applicabile

Frequenza e durata dell'utilizzo
Copre un'esposizione giornaliera fino a 8 ore (se non altrimenti specificato).

Fattori umani non influenzati dalla gestione dei rischi
Non applicabile

Altre condizioni operative che coinvolgono le esposizioni dei lavoratori
Presuppone l'utilizzo del prodotto a una temperatura non superiore a 20° rispetto alla temperatura ambiente;
Presuppone un contenuto massimo di Butadiene di 1% e un contenuto massimo di Benzene di 1%.
Presuppone l'applicazione di uno standard di base adeguato in materia di igiene nell'ambiente lavorativo.

Scenari correlati
Misure di gestione dei rischi
Nota: elencare le frasi standard secondo la gerarchia di controllo indicata nel modello ECHA: 1. *Misure tecniche per impedire il rilascio,* 2. *Misure tecniche per impedire la dispersione, 3. Misure organizzative,* 4. *Protezione personale. Le frasi tra virgolette sono solo consigli di buone pratiche, al di là della valutazione sulla sicurezza chimica REACH e possono essere comunicate nella Sezione 5 dell'ES o nelle sezioni principali dell'SDS*.

Misure generali (agenti cancerogeni)
Considerare progressi tecnici e aggiornamenti dei processi (automazione inclusa) per l'eliminazione delle dispersioni. Limitare l'esposizione adottando misure quali sistemi chiusi, impianti dedicati e appositi impianti di aspirazione generale/localizzata dell'aria esausta. Drenare i sistemi e ripulire le linee di trasferimento prima di interrompere il contenimento. Pulire/spurgare le apparecchiature, ove possibile, prima della manutenzione. Ove esiste la possibilità di esposizione: limitare l'accesso al solo personale autorizzato, garantire agli operatori una formazione specifica sulle attività e sulle operazioni da compiere al fine di minimizzare il rischio di esposizione, indossare guanti e tute di protezione per prevenire la contaminazione della pelle, utilizzare un dispositivo di protezione delle vie respiratorie quando richiesto per determinati scenari di esposizione, eliminare immediatamente le eventuali fuoriuscite e smaltire i rifiuti in condizioni di sicurezza.
Garantire l'adozione di sistemi di lavoro sicuri o di soluzioni equivalenti per la gestione dei rischi. Ispezionare, verificare e sottoporre a regolare manutenzione tutti i dispositivi e le misure di controllo.Prendere in considerazione la necessità di un sistema di sorveglianza sanitario basato sulla valutazione dei rischi

Scenario di esposizione 11: Uso di altri gas di petrolio nella produzione di polimeri - industriale (segue)

Sezione 2.1 Controllo delle esposizioni del dipendente (segue)

Trasferimento prodotti sfusi. (sistemi chiusi).
Manipolare la sostanza in un sistema chiuso.

Trasferimento prodotti sfusi (sistemi chiusi). Con esposizione occasionale controllata
Manipolare la sostanza in un sistema chiuso. Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione

Trasferimento prodotti sfusi. Struttura dedicata
Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione.

Trasferimento prodotti sfusi. Trasferimenti fusti/lotti.
Garantire uno standard adeguato di ventilazione generale (non meno di 3-5 ricambi d'aria ogni ora). Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione.

Trasferimento prodotti sfusi. Riempimento piccoli contenitori.
Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora). Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione

Manutenzione delle apparecchiature.
Drenare e spurgare il sistema prima dell'apertura o della manutenzione delle apparecchiature. Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora).

Stoccaggio. Con esposizione occasionale controllata
Manipolare la sostanza in un sistema chiuso. Provvedere una ventilazione ad estrazione presso i punti in cui si verificano emissioni. Immagazzinare la sostanza all'interno di un sistema chiuso

Sezione 2.2 Controllo delle esposizioni ambientali

La sostanza non è classificata - non si richiede una valutazione dell'esposizione ambientale

Sezione 3 Stima delle esposizioni

Sezione 3.1. Salute
Ai fini della valutazione del livello di esposizione sul luogo di lavoro, laddove non espressamente indicato, è stato utilizzato il metodo ECETOC TRA.

Quando si osservano le misure della gestione del rischio (RMM) e le condizioni operative raccomandate (OC), non si prevede di superare i DNEL attesi e i ratei della caratterizzazione del rischio risultanti si ritiene saranno inferiori a 1 come indicato nell'Appendice A.

Sezione 3.2 Ambiente
La conferma dell'uso sicuro è stata ottenuta attraverso un approccio qualitativo

Sezione 4 Guida per la verifica della conformità con lo scenario di esposizione

Sezione 4.1 Salute
Confermare che RMM e OC sono come descritte o di efficienza equivalente. Vedere Appendice A per i dettagli su efficienze e OC

Sezione 4.2 Ambiente
Non sono richieste misure aggiuntive di gestione dei rischi.

Scenario di esposizione 11: Uso di altri gas di petrolio nella produzione di polimeri - industriale (segue)

Sezione 5
Consigli aggiuntivi di buone pratiche oltre la valutazione della sicurezza chimica REACH (Sezione Opzionale)

Nota: Le misure riportate in questa sezione non sono state prese in considerazione nelle stime delle esposizioni relative allo scenario di esposizione presentato in precedenza. Non sono soggette agli obblighi definiti dall'Articolo 37 (4) della normativa REACH

Controllo delle esposizioni del dipendente
Selezione di frasi rilevanti per lo scenario di esposizione
Frasi RMM di buone pratiche possono essere inserite in questa sezione o consolidate nelle molteplici sezioni dell'SDS, a seconda della preferenza della registrazione e della funzionalità del sistema e-SDS disponibile.

Controllo delle esposizioni ambientali
Non applicabile

Scenario di esposizione 12: Uso di altri gas di petrolio nella produzione di polimeri - professionale

Sezione 1 Titolo dello scenario di esposizione

Titolo: Uso di altri gas di petrolio nella produzione di polimeri.

Descrizione Utilizzo:

Settore di utilizzo: industriale (SU22)
Categorie di processo
PROC1, PROC2, PROC6, PROC8a, PROC8b, PROC14, PROC21
Categorie di rilascio ambientale: ERC8A, ERC8D

Processi, compiti, attività coperte
Lavorazione di polimeri formulati, compresi il trasferimento di materiale, le attività di stampaggio e sagomatura, la rilavorazione del materiale e la relativa manutenzione.

Sezione 2 Condizioni operative e misure di gestione del rischio

Campo per dichiarazioni aggiuntive intese a spiegare lo scenario, se necessario

Sezione 2.1 Controllo delle esposizioni del dipendente

Caratteristiche del prodotto
Forma fisica del prodotto
Liquido, pressione di vapore > 10 kPa

Concentrazione della sostanza nel prodotto
Copre una percentuale di sostanza nel prodotto fino al 100% (se non altrimenti indicato).

Quantità utilizzate
Non applicabile

Frequenza e durata dell'utilizzo
Copre un'esposizione giornaliera fino a 8 ore (se non altrimenti specificato).

Fattori umani non influenzati dalla gestione dei rischi
Non applicabile

Altre condizioni operative che coinvolgono le esposizioni dei lavoratori
Presuppone l'utilizzo del prodotto a una temperatura non superiore a 20° rispetto alla temperatura ambiente;
Presuppone un contenuto massimo di Butadiene di 1% e un contenuto massimo di Benzene di 1%.
Presuppone l'applicazione di uno standard di base adeguato in materia di igiene nell'ambiente lavorativo.

Scenari correlati
Misure di gestione dei rischi
Nota: elencare le frasi standard secondo la gerarchia di controllo indicata nel modello ECHA: 1. *Misure tecniche per impedire il rilascio,* 2. *Misure tecniche per impedire la dispersione, 3. Misure organizzative,* 4. *Protezione personale. Le frasi tra virgolette sono solo consigli di buone pratiche, al di là della valutazione sulla sicurezza chimica REACH e possono essere comunicate nella Sezione 5 dell'ES o nelle sezioni principali dell'SDS*.

Misure generali (agenti cancerogeni)
Considerare progressi tecnici e aggiornamenti dei processi (automazione inclusa) per l'eliminazione delle dispersioni. Limitare l'esposizione adottando misure quali sistemi chiusi, impianti dedicati e appositi impianti di aspirazione generale/localizzata dell'aria esausta. Drenare i sistemi e ripulire le linee di trasferimento prima di interrompere il contenimento. Pulire/spurgare le apparecchiature, ove possibile, prima della manutenzione. Ove esiste la possibilità di esposizione: limitare l'accesso al solo personale autorizzato, garantire agli operatori una formazione specifica sulle attività e sulle operazioni da compiere al fine di minimizzare il rischio di esposizione, indossare guanti e tute di protezione per prevenire la contaminazione della pelle, utilizzare un dispositivo di protezione delle vie respiratorie quando richiesto per determinati scenari di esposizione, eliminare immediatamente le eventuali fuoriuscite e smaltire i rifiuti in condizioni di sicurezza.
Garantire l'adozione di sistemi di lavoro sicuri o di soluzioni equivalenti per la gestione dei rischi. Ispezionare, verificare e sottoporre a regolare manutenzione tutti i dispositivi e le misure di controllo.Prendere in considerazione la necessità di un sistema di sorveglianza sanitario basato sulla valutazione dei rischi

Scenario di esposizione 12: Uso di altri gas di petrolio nella produzione di polimeri - professionale (segue)

Sezione 2.1 Controllo delle esposizioni del dipendente (segue)

Trasferimento prodotti sfusi. (sistemi chiusi).
Manipolare la sostanza in un sistema chiuso.

Trasferimento prodotti sfusi (sistemi chiusi). Con esposizione occasionale controllata
Manipolare la sostanza in un sistema chiuso. Provvedere una ventilazione ad estrazione presso i punti in cui si verificano emissioni. Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora).

Trasferimento materiali
Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora). Garantire che il trasferimento del materiale avvenga in condizioni di contenimento o ventilazione a estrazione. Non effettuare operazioni per un periodo superiore a 4 ore.

Manutenzione delle apparecchiature.
Drenare il sistema prima dell'apertura o della manutenzione delle apparecchiature. Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora). Indossare una maschera intera (conforme allo standard EN140) dotata di filtro di tipo A o superiore.

Stoccaggio
Immagazzinare la sostanza all'interno di un sistema chiuso

Stoccaggio. Con esposizione occasionale controllata
Garantire uno standard adeguato di ventilazione controllata (da 10 a 15 ricambi d'aria ogni ora). Provvedere una ventilazione ad estrazione presso i punti in cui si verificano emissioni. Immagazzinare la sostanza all'interno di un sistema chiuso

Sezione 2.2 Controllo delle esposizioni ambientali

La sostanza non è classificata - non si richiede una valutazione dell'esposizione ambientale

Sezione 3 Stima delle esposizioni

Sezione 3.1. Salute
Ai fini della valutazione del livello di esposizione sul luogo di lavoro, laddove non espressamente indicato, è stato utilizzato il metodo ECETOC TRA.

Quando si osservano le misure della gestione del rischio (RMM) e le condizioni operative raccomandate (OC), non si prevede di superare i DNEL attesi e i ratei della caratterizzazione del rischio risultanti si ritiene saranno inferiori a 1 come indicato nell'Appendice A.

Sezione 3.2 Ambiente
La conferma dell'uso sicuro è stata ottenuta attraverso un approccio qualitativo

Sezione 4 Guida per la verifica della conformità con lo scenario di esposizione

Sezione 4.1 Salute
Confermare che RMM e OC sono come descritte o di efficienza equivalente. Vedere Appendice A per i dettagli su efficienze e OC

Sezione 4.2 Ambiente
Non sono richieste misure aggiuntive di gestione dei rischi.

Scenario di esposizione 12: Uso di altri gas di petrolio nella produzione di polimeri - professionale (segue)

Sezione 5
Consigli aggiuntivi di buone pratiche oltre la valutazione della sicurezza chimica REACH (Sezione Opzionale)

Nota: Le misure riportate in questa sezione non sono state prese in considerazione nelle stime delle esposizioni relative allo scenario di esposizione presentato in precedenza. Non sono soggette agli obblighi definiti dall'Articolo 37 (4) della normativa REACH

Controllo delle esposizioni del dipendente
Selezione di frasi rilevanti per lo scenario di esposizione
Frasi RMM di buone pratiche possono essere inserite in questa sezione o consolidate nelle molteplici sezioni dell'SDS, a seconda della preferenza della registrazione e della funzionalità del sistema e-SDS disponibile.

Controllo delle esposizioni ambientali
Non applicabile