Druckdatum: 10.05.2017

Versionsnummer 3

überarbeitet am: 10.05.2017



Versionsnummer 3

überarbeitet am: 10.05.2017

D210	(Fortsetzung von Seite 1) $(Fortsetzung von Seite 1)$	
P210	Von Hitze, heißen Oberflächen, Funken, offenen Flammen und anderen Zundquellen	
	fernhalten. Nicht rauchen.	
P241	Explosionsgeschützte elektrische Geräte/Lüftungsanlagen/Beleuchtungsanlagen	
	verwenden.	
P301+P310	BEI VERSCHLUCKEN: Sofort GIFTINFORMATIONSZENTRUM/Arzt anrufen.	
<i>P303+P361+P35</i> .	3 BEI BERÜHRUNG MIT DER HAUT (oder dem Haar): Alle kontaminierten	
	Kleidungsstücke sofort ausziehen. Haut mit Wasser abwaschen/duschen.	
P405	Unter Verschluss aufbewahren.	
P501	Entsorgung des Inhalts / des Behälters gemäß den örtlichen / regionalen / nationalen/	
	internationalen Vorschriften.	
2.3 Sonstige Gefahren		
· Ergebnisse der PBT- und vPvB-Beurteilung		
• <b>PBT:</b> Nicht anwendbar.		

• **vPvB:** Nicht anwendbar.

#### ABSCHNITT 3: Zusammensetzung/Angaben zu Bestandteilen

- · 3.1 Stoffe
- · CAS-Nr. Bezeichnung
- 8008-57-9 Blutorangenöl
- · Identifikationsnummer(n) EINECS CAS: 8028-48-6
- · EG-Nummer: 232-433-8

#### ABSCHNITT 4: Erste-Hilfe-Maßnahmen

- · 4.1 Beschreibung der Erste-Hilfe-Maßnahmen
- · Allgemeine Hinweise: Mit Produkt verunreinigte Kleidungsstücke unverzüglich entfernen.
- · Nach Einatmen:

Reichlich Frischluftzufuhr und sicherheitshalber Arzt aufsuchen.

Bei Bewußtlosigkeit Lagerung und Transport in stabiler Seitenlage.

- · Nach Hautkontakt: Sofort mit Wasser und Seife abwaschen und gut nachspülen.
- · Nach Augenkontakt: Augen bei geöffnetem Lidspalt mehrere Minuten mit fließendem Wasser spülen.
- · Nach Verschlucken: Sofort ärztlichen Rat einholen.
- 4.2 Wichtigste akute und verzögert auftretende Symptome und Wirkungen
- Keine weiteren relevanten Informationen verfügbar.
- · 4.3 Hinweise auf ärztliche Soforthilfe oder Spezialbehandlung

Keine weiteren relevanten Informationen verfügbar.

#### ABSCHNITT 5: Maßnahmen zur Brandbekämpfung

- · 5.1 Löschmittel
- Geeignete Löschmittel:

CO2, Löschpulver oder Wassersprühstrahl. Größeren Brand mit Wassersprühstrahl oder alkoholbeständigem Schaum bekämpfen.

- Aus Sicherheitsgründen ungeeignete Löschmittel: Wasser im Vollstrahl
- 5.2 Besondere vom Stoff oder Gemisch ausgehende Gefahren
- Keine weiteren relevanten Informationen verfügbar.
- · 5.3 Hinweise für die Brandbekämpfung
- · Besondere Schutzausrüstung: Keine besonderen Maßnahmen erforderlich.

#### ABSCHNITT 6: Maßnahmen bei unbeabsichtigter Freisetzung

· 6.1 Personenbezogene Vorsichtsmaßnahmen, Schutzausrüstungen und in Notfällen anzuwendende Verfahren

Schutzausrüstung tragen. Ungeschützte Personen fernhalten.

(Fortsetzung auf Seite 3)

ЭE

Druckdatum: 10.05.2017

Versionsnummer 3

überarbeitet am: 10.05.2017

#### Handelsname: Blutorangenöl

#### · 6.2 Umweltschutzmaßnahmen:

Nicht in die Kanalisation oder in Gewässer gelangen lassen. Bei Eindringen in Gewässer oder Kanalisation zuständige Behörden benachrichtigen. Nicht in die Kanalisation/Oberflächenwasser/Grundwasser gelangen lassen.

**6.3 Methoden und Material für Rückhaltung und Reinigung:** Mit flüssigkeitsbindendem Material (Sand, Kieselgur, Säurebinder, Universalbinder, Sägemehl) aufnehmen. Kontaminiertes Material als Abfall nach Abschnitt 13 entsorgen.

Für ausreichende Lüftung sorgen. • 6.4 Verweis auf andere Abschnitte

Informationen zur sicheren Handhabung siehe Abschnitt 7.

Informationen zur persönlichen Schutzausrüstung siehe Abschnitt 8. Informationen zur Entsorgung siehe Abschnitt 13.

njormationen zur Entsorgung siene Abschnitt 15.

# ABSCHNITT 7: Handhabung und Lagerung

· 7.1 Schutzmaßnahmen zur sicheren Handhabung Für gute Belüftung/Absaugung am Arbeitsplatz sorgen. Aerosolbildung vermeiden.

Hinweise zum Brand- und Explosionsschutz:
Zündquellen fernhalten - nicht rauchen.
Maßnahmen gegen elektrostatische Aufladung treffen.

· 7.2 Bedingungen zur sicheren Lagerung unter Berücksichtigung von Unverträglichkeiten

· Lagerung:

· Anforderung an Lagerräume und Behälter: Unter Verschluss aufbewahren.

· Zusammenlagerungshinweise: Nicht erforderlich.

· Weitere Angaben zu den Lagerbedingungen: Behälter dicht geschlossen halten.

· Lagerklasse:

· Klassifizierung nach Betriebssicherheitsverordnung (BetrSichV): Entzündbare Flüssigkeiten

· 7.3 Spezifische Endanwendungen Keine weiteren relevanten Informationen verfügbar.

### ABSCHNITT 8: Begrenzung und Überwachung der Exposition/Persönliche Schutzausrüstungen

· Zusätzliche Hinweise zur Gestaltung technischer Anlagen: Keine weiteren Angaben, siehe Abschnitt 7.

· 8.1 Zu überwachende Parameter

· Bestandteile mit arbeitsplatzbezogenen, zu überwachenden Grenzwerten: Entfällt.

· Zusätzliche Hinweise: Als Grundlage dienten die bei der Erstellung gültigen Listen.

· 8.2 Begrenzung und Überwachung der Exposition

· Persönliche Schutzausrüstung:

· Allgemeine Schutz- und Hygienemaßnahmen:

Von Nahrungsmitteln, Getränken und Futtermitteln fernhalten.

Beschmutzte, getränkte Kleidung sofort ausziehen.

Vor den Pausen und bei Arbeitsende Hände waschen.

Berührung mit der Haut vermeiden.

Berührung mit den Augen und der Haut vermeiden.

· Atemschutz:

Bei kurzzeitiger oder geringer Belastung Atemfiltergerät; bei intensiver bzw. längerer Exposition umluftunabhängiges Atemschutzgerät verwenden.

Handschutz:



Schutzhandschuhe

(Fortsetzung auf Seite 4)

(Fortsetzung von Seite 2)

Druckdatum: 10.05.2017

Versionsnummer 3

überarbeitet am: 10.05.2017

#### Handelsname: Blutorangenöl

(Fortsetzung von Seite 3) Das Handschuhmaterial muss undurchlässig und beständig gegen das Produkt / den Stoff / die Zubereitung sein.

Aufgrund fehlender Tests kann keine Empfehlung zum Handschuhmaterial für das Produkt / die Zubereitung / das Chemikaliengemisch abgegeben werden.

Auswahl des Handschuhmaterials unter Beachtung der Durchbruchzeiten, Permeationsraten und der Degradation.

· Handschuhmaterial

Die Auswahl eines geeigneten Handschuhs ist nicht nur vom Material, sondern auch von weiteren Qualitätsmerkmalen abhängig und von Hersteller zu Hersteller unterschiedlich.

- · Durchdringungszeit des Handschuhmaterials
- Die genaue Durchbruchzeit ist beim Schutzhandschuhhersteller zu erfahren und einzuhalten.
- · Augenschutz:



Dichtschließende Schutzbrille

### ABSCHNITT 9: Physikalische und chemische Eigenschaften

• 9.1 Angaben zu den grundlegenden ph	ysikalischen und chemischen Eigenschaften
· Allgemeine Angaben	
· Aussenen: Form.	Klar flüssia
rorm: Farba	Klur, jlussig Golh his braun
· Coruch	Charakteristisch
· Garuchsschwalla:	Nicht hestimmt
Gerüchsschweite.	
· pH-Wert:	Nicht bestimmt.
· Zustandsänderung	
Schmelzpunkt/Gefrierpunkt:	Nicht bestimmt.
Siedebeginn und Siedebereich:	Nicht bestimmt.
· Flammpunkt:	51 °C
· Entzündbarkeit (fest, gasförmig):	Nicht anwendbar.
· Zersetzungstemperatur:	Nicht bestimmt.
· Selbstentzündungstemperatur:	Nicht bestimmt.
• Explosive Eigenschaften:	Das Produkt ist nicht explosionsgefährlich, jedoch ist die Bildung explosionsgefährlicher Dampf-/Luftgemische möglich.
· Explosionsgrenzen:	
Untere:	Nicht bestimmt.
Obere:	Nicht bestimmt.
· Mittlere Dichte bei 20 °C:	0,848 g/cm <sup>3</sup>
· Relative Dichte	Nicht bestimmt.
· Dampfdichte	Nicht bestimmt.
· Verdampfungsgeschwindigkeit	Nicht bestimmt.
· Löslichkeit in / Mischbarkeit mit	
Wasser:	Nicht bzw. wenig mischbar.
· Verteilungskoeffizient: n-Octanol/Was	s <b>ser:</b> Nicht bestimmt.
· Viskosität:	
Dynamisch:	Nicht bestimmt.
Kinematisch:	Nicht bestimmt.
	(Fortsetzung auf Seite 5)

Druckdatum: 10.05.2017

Versionsnummer 3

überarbeitet am: 10.05.2017

(Fortsetzung von Seite 4)

Handelsname: Blutorangenöl

• 9.2 Sonstige Angaben

Keine weiteren relevanten Informationen verfügbar.

### ABSCHNITT 10: Stabilität und Reaktivität

· 10.1 Reaktivität Keine weiteren relevanten Informationen verfügbar.

· 10.2 Chemische Stabilität

• Thermische Zersetzung / zu vermeidende Bedingungen:

Keine Zersetzung bei bestimmungsgemäßer Verwendung.

· 10.3 Möglichkeit gefährlicher Reaktionen Keine gefährlichen Reaktionen bekannt.

• 10.4 Zu vermeidende Bedingungen Keine weiteren relevanten Informationen verfügbar.

• 10.5 Unverträgliche Materialien: Keine weiteren relevanten Informationen verfügbar.

• 10.6 Gefährliche Zersetzungsprodukte: Keine gefährlichen Zersetzungsprodukte bekannt.

#### ABSCHNITT 11: Toxikologische Angaben

· 11.1 Angaben zu toxikologischen Wirkungen

· Akute Toxizität Aufgrund der verfügbaren Daten sind die Einstufungskriterien nicht erfüllt.

· Primäre Reizwirkung:

· Ätz-/Reizwirkung auf die Haut

Verursacht Hautreizungen.

· Schwere Augenschädigung/-reizung

- Aufgrund der verfügbaren Daten sind die Einstufungskriterien nicht erfüllt.
- Sensibilisierung der Atemwege/Haut
- Kann allergische Hautreaktionen verursachen.
- · CMR-Wirkungen (krebserzeugende, erbgutverändernde und fortpflanzungsgefährdende Wirkung)
- · Keimzell-Mutagenität Aufgrund der verfügbaren Daten sind die Einstufungskriterien nicht erfüllt.
- · Karzinogenität Aufgrund der verfügbaren Daten sind die Einstufungskriterien nicht erfüllt.
- · Reproduktionstoxizität Aufgrund der verfügbaren Daten sind die Einstufungskriterien nicht erfüllt.
- · Spezifische Zielorgan-Toxizität bei einmaliger Exposition
- Aufgrund der verfügbaren Daten sind die Einstufungskriterien nicht erfüllt.
- Spezifische Zielorgan-Toxizität bei wiederholter Exposition
- Aufgrund der verfügbaren Daten sind die Einstufungskriterien nicht erfüllt.

· Aspirationsgefahr

Kann bei Verschlucken und Eindringen in die Atemwege tödlich sein.

ABSCHNITT 12: Umweltbezogene Angaben

· 12.1 Toxizität

- · Aquatische Toxizität: Keine weiteren relevanten Informationen verfügbar.
- · 12.2 Persistenz und Abbaubarkeit Keine weiteren relevanten Informationen verfügbar.
- 12.3 Bioakkumulationspotenzial Keine weiteren relevanten Informationen verfügbar.
- · 12.4 Mobilität im Boden Keine weiteren relevanten Informationen verfügbar.
- · Ökotoxische Wirkungen:
- · Bemerkung: Giftig für Fische.
- · Weitere ökologische Hinweise:

• Allgemeine Hinweise:

Wassergefährdungsklasse 3 (Selbsteinstufung): stark wassergefährdend

Nicht in das Grundwasser, in Gewässer oder in die Kanalisation gelangen lassen, auch nicht in kleinen Mengen.

Trinkwassergefährdung bereits beim Auslaufen geringster Mengen in den Untergrund. In Gewässern auch giftig für Fische und Plankton.

giftig für Wasserorganismen

- · 12.5 Ergebnisse der PBT- und vPvB-Beurteilung
- **PBT:** Nicht anwendbar.
- vPvB: Nicht anwendbar.

(Fortsetzung auf Seite 6)

- DE

Druckdatum: 10.05.2017

Versionsnummer 3

überarbeitet am: 10.05.2017

Handelsname: Blutorangenöl

(Fortsetzung von Seite 5)

· 12.6 Andere schädliche Wirkungen Keine weiteren relevanten Informationen verfügbar.

# ABSCHNITT 13: Hinweise zur Entsorgung

· 13.1 Verfahren der Abfallbehandlung

• Empfehlung: Darf nicht zusammen mit Hausmüll entsorgt werden. Nicht in die Kanalisation gelangen lassen.

· Ungereinigte Verpackungen:

· Empfehlung: Entsorgung gemäß den behördlichen Vorschriften.

ADR, IMDG, IATA	UN1169
14.2 Ordnungsgemäße UN-Versandbezeichnung	
ADR	1169 EXTRAKTE, AROMATISCH, FLÜSSIG
IMDC	UMWELTGEFAHRDEND
IMDG	MARINE POLLUTANT
IATA	EXTRACTS, AROMATIC, LIQUID
14.3 Transportgefahrenklassen	
ADR, IMDG	
Klasse	3 Entzündbare flüssige Stoffe
Gefahrzettel	3
IATA	
Class	3 Entzündbare flüssige Stoffe
Label	3
14.4 Verpackungsgruppe	
ADR, IMDG, IATA	111
14.5 Umweltgefahren:	Das Produkt enthält umweltgefährdende Stoff
Marina pollutant:	Blutorangenöl Nein
	Symbol (Fisch und Baum)
Besondere Kennzeichnung (ADR):	Symbol (Fisch und Baum)
14.6 Besondere Vorsichtsmaßnahmen für den	
Verwender	Achtung: Entzündbare flüssige Stoffe
Kemler-Zahl:	30
EMS-Nummer:	F-E,S-D
Stowage Category	A
14.7 Massengutbeförderung gemäß Anhang II de	S

Druckdatum: 10.05.2017

Versionsnummer 3

überarbeitet am: 10.05.2017

Handelsname: Blutorangenöl

	(Fortsetzung von Seite 6)
· Transport/weitere Angaben:	
·ADR	
· Begrenzte Menge (LQ)	5L
· Freigestellte Mengen (EQ)	Code: El
	Höchste Nettomenge je Innenverpackung: 30 ml
	Höchste Nettomenge je Außenverpackung: 1000 ml
Beförderungskategorie	3
· Tunnelbeschränkungscode	D/E
· IMDG	
· Limited quantities (LQ)	5L
$\cdot$ Excepted quantities ( $\widetilde{E}Q$ )	Code: El
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 1169 EXTRAKTE, AROMATISCH, FLÜSSIG, 3, III, UMWELTGEFÄHRDEND

# ABSCHNITT 15: Rechtsvorschriften

· 15.1 Vorschriften zu Sicherheit, Gesundheits- und Umweltschutz/spezifische Rechtsvorschriften für den Stoff oder das Gemisch

· Richtlinie 2012/18/EU

· Namentlich aufgeführte gefährliche Stoffe - ANHANG I Der Stoff ist nicht enthalten.

· Seveso-Kategorie

E2 Gewässergefährdend

P5c ENTZÜNDBARE FLÜSSIGKEITEN

- Mengenschwelle (in Tonnen) für die Anwendung in Betrieben der unteren Klasse 200 t
- Mengenschwelle (in Tonnen) für die Anwendung in Betrieben der oberen Klasse 500 t
- · VERORDNUNG (EG) Nr. 1907/2006 ANHANG XVII Beschränkungsbedingungen: 3

· Nationale Vorschriften:

Lagerklasse nach TRGS 510: 3

· Wassergefährdungsklasse (Einstufung gemäß VwVwS): WGK 3 (Selbsteinstufung): stark wassergefährdend.

· 15.2 Stoffsicherheitsbeurteilung: Eine Stoffsicherheitsbeurteilung wurde nicht durchgeführt.

#### **ABSCHNITT 16: Sonstige Angaben**

Die Angaben stützen sich auf den heutigen Stand unserer Kenntnisse, sie stellen jedoch keine Zusicherung von Produkteigenschaften dar und begründen kein vertragliches Rechtsverhältnis.

· Empfohlene Einschränkung der Anwendung Nur für gewerbliche Anwendung.

· Datenblatt ausstellender Bereich: Abteilung Produktsicherheit

· Ansprechpartner: Frau Regina Tretter

· Abkürzungen und Akronyme:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society) GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)

*PBT: Persistent, Bioaccumulative and Toxic* 

(Fortsetzung auf Seite 8)

DE

Druckdatum: 10.05.2017

Versionsnummer 3

überarbeitet am: 10.05.2017

(Fortsetzung von Seite 7)

#### Handelsname: Blutorangenöl

vPvB: very Persistent and very Bioaccumulative Flam. Liq. 3: Entzündbare Flüssigkeiten – Kategorie 3 Skin Irrit. 2: Hautreizende/-ätzende Wirkung – Kategorie 2 Skin Sens. 1: Sensibilisierung der Haut – Kategorie 1 Asp. Tox. 1: Aspirationsgefahr – Kategorie 1 Aquatic Chronic 2: Gewässergefährdend - langfristig gewässergefährdend – Kategorie 2 • \* Daten gegenüber der Vorversion geändert

DE

# **ES FOR COMMUNICATION**

# **Table of Contents**

3
4
5
16
30
67
98
99

Substance Name: Orange oil

EC Number: 232-433-8

CAS Number: 8028-48-6

**Registration Number:** 

Date of Generation/Revision: 2012-04-23

Author: Royal Haskoning

# Reader guide to the appendix

The appendix to the exposure scenario describes how Orange oil can be extracted from the fruit/plant material, processed and used in an industrial, professional or consumer setting.

The table of contents will help you to find your particular type of use of the substance Orange oil. The name of each exposure scenario describes both the covered activity and information on the type of facility and type of product covered. You only need to concern yourself with the scenarios describing uses applicable to your own use and those of your users.

In the sections relating to each use, you will find which uses are covered and what operational conditions and risk management measures are needed to use the substance safely. Each exposure scenario is built up as follows:

Section 1: Title of the exposure scenario. Provides the relevant Environmental Release Categories (ERCs) and Process Categories (PROCs) for contributing scenarios, together with a description of the activities covered.

Section 2: Conditions of use affecting exposure. Provides an overview of the operational conditions and risk management measures used for the risk characterization for each of the contributing scenarios covered. For the environmental assessment the following information is present:

- Maximum amount per site (both daily and yearly)
- Maximum number of emission days
- Minimum flow of a river onto which the STP discharges its effluent

• Information regarding the treatment of waste water (including the minimum STP discharge rate) For the worker exposure the following information is present:

- % of Orange oil in any mixtures used
- The form of the mixture in which Orange oil is used

Most items listed in the subsection "Other operational conditions" are a refined description of the process category covered. NB: if a use differs from the description, it should be verified using the information in section 4 if the use is actually covered. The following information can be found here (among others):

- Maximum duration of use per shift
- Indoor or outdoor use
- Assumed process temperature

In the subsection "Technical and operational conditions and measures" an overview of the risk management measures that need to be in place is given.

Section 3: Exposure estimation and reference to its source. This section contains information on the exposure estimation methods, the calculated exposure values and risk characterization ratios (RCR). This section can be used in the generation of a mixture (extended) Safety Data Sheet, when scaling is used to determine if a use is covered, or when a downstream user performs his own Chemical Safety Assessment. When making a downstream user assessment or when applying scaling, the RCR listed in Section 3 may not be exceeded.

Section 4: Guidance to DU to evaluate whether he works inside the boundaries set by the ES. This section provides guidance to the downstream user to determine if he works within the boundaries set in the exposure scenario. It provides information which can be used in scaling operations, e.g. the assumed effectiveness of risk management measures.

# **0.** Good practices applicable to all worker ES

#### Generic organisational measures

- Minimise number of staff exposed;
- 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.

# Generic personal protective equipment

PPE for sensitizers (98% effective dermal)

- Substance/task appropriate gloves [PPE18];
- Skin coverage with appropriate barrier material based on potential for contact with the chemicals;
- Substance/task appropriate respirator;
- Optional face shield;
- Eye protection.

# 1. ES 1: Manufacturing stage; Manufacturing of Orange oil

1. Title of Exposure scenario	
Environment:	ERC 1
* ENV1a Extraction of fruits/plant material and processing of oil/water emulsion	
* ENV1b Extraction of fruits/plant material and processing of oil/water emulsion	
* ENV2 Further refinement of essential oils	
Worker	
Manufacture in closed process, no likelihood of exposure	PROC 1
Manufacture in closed, continuous process with occasional controlled exposure	PROC 2
Manufacture in closed batch process (synthesis or formulation)	PROC 3
Manufacture in batch and other process (synthesis) where opportunity for exposure arises	PROC 4
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at	PROC 8b
dedicated facilities	
Use as laboratory reagent	PROC 15

#### 2. Conditions of use affecting exposure

2.1 Control of environmental exposure:

ENV1a Extraction of fruits/plant material and processing of oil/water emulsion (ERC 1) ENV1b Extraction of fruits/plant material and processing of oil/water emulsion (ERC 1) ENV2 Further refinement of essential oils (ERC 1)

#### 2.1.1 Control of environmental exposure:

ENV1a Extraction of fruits/plant material and processing of oil/water emulsion (ERC 1)

#### Amounts used

Daily amount per site <= 17.5 tonnes/day

Annual amount per site <= 3.5E3 tonnes/year

Frequency and duration of use

Emission days / year = 200 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.1.2 Control of environmental exposure:

ENV1b Extraction of fruits/plant material and processing of oil/water emulsion (ERC 1)

Amounts used

Daily amount per site <= 0.632 tonnes/day

Annual amount per site <= 126.4 tonnes/year

Frequency and duration of use

Emission days / year = 200 days/year

#### Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

**2.1.3 Control of environmental exposure:** ENV2 Further refinement of essential oils (ERC 1)

Amounts used

Daily amount per site <= 0.632 tonnes/day

Annual amount per site <= 230.7 tonnes/year

Frequency and duration of use

Emission days / year = 365 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.2 Control of workers exposure for Manufacture in closed process, no likelihood of exposure (PROC 1)

**Product characteristics** 

Covers percentage substance in the product up to 100 % (unless stated differently)

Liquid

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use

Assumes activities are at room temperature.

Exposed skin surface assumed: One hand face only (240 cm2)

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. \* Open surface 1-3 m<sup>2</sup>.

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.3 Control of workers exposure for** Manufacture in closed, continuous process with occasional controlled exposure (PROC 2)

**Product characteristics** 

Covers percentage substance in the product up to 100 % (unless stated differently)

Liquid

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm2)

Assumes activities are at room temperature.

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. \* Open surface 1-3 m<sup>2</sup>.

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Transfer of liquid products - falling liquids

\*Splash loading

\*Avoid carrying out operation for more than 0.5 hour

\* For each use event, covers use amounts up to 0.1-1 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.4 Control of workers exposure for Manufacture in closed batch process (synthesis or formulation) (PROC3)

Product characteristics

Covers percentage substance in the product up to 100 % (unless stated differently)

Liquid

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

#### Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: One hand face only (240 cm2)

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. \* Open surface 1-3 m<sup>2</sup>.

Undertake operation under enclosed conditions.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.5 Control of workers exposure for** Manufacture in batch and other process (synthesis) where opportunity for exposure arises (**PROC 4**)

**Product characteristics** 

Covers percentage substance in the product up to 100 % (unless stated differently).

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm2).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. \* Open surface 1-3 m<sup>2</sup>.

Use in batch and other process (synthesis) where opportunity for exposure arises.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Put lids on containers immediately after use.

Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.6 Control of workers exposure for** Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (**PROC 8b**)

**Product characteristics** 

Covers percentage substance in the product up to 100 % (unless stated differently)

Liquid

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Transfer of liquid products - falling liquids \*Submerged loading

\*For each use event, covers use amounts up to 100-1000 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.7 Control of workers exposure for Use as laboratory reagent (PROC 15)

**Product characteristics** 

Covers percentage substance in the product up to 100 % (unless stated differently)

Liquid

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: One hand face only (240 cm2)

Assumes activities are at room temperature.

Activities with open liquid surfaces or open reservoirs - activity with undisturbed surfaces (no aerosol formation).

\*Open surface  $< 0.1 \text{ m}^2$ .

Transfer of liquid products - falling liquids

\*Splash loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to 0.1-1 l/minute.

\*Submerged loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to <0.1 l/minute.

Handling that reduces contact between product and adjacent air.

#### Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**3. Exposure estimation and reference to its source** 

The environmental exposure estimates were calculated according to EUSES version 2.1.2. Degradation in the STP was calculated according to first-order kinetics.

Environment

ENV1a Extraction of fruits/plant material and processing of oil/water emulsion

Release route	Release rate (kg/day)	Release estimation method
Water	0	Site-specific information
Air	210	Site-specific information
Soil	1.75	ERC 1

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	5.96E-4 mg/L	0.11
Freshwater (sediment)	0.146 mg/kg dw	0.112
Marine water (pelagic)	4.91E-5 mg/L	0.091
Marine water (sediment)	0.012 mg/kg dw	0.092
Effluent	0 mg/L	0
Agricultural soil	0.003 mg/kg dw	0.011

ENV1b Extraction of fruits/plant material and processing of oil/water emulsion			
Release route	Release rate (kg/day)	Release estimation method	
Water	1.264	Site-specific information	
Air	7.584	Site-specific information	
Soil	0.063	ERC 1	

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013

Agricultural soil		0.261 mg/kg dw	1
<b>Environment</b> ENV2 Further re	efinement of essential oils		
Release route	Release rate (kg/day)	Release estimation	n method
Water	1.264	Site-specific inform	nation
Air	7.584	Site-specific inform	nation

ERC 1

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

**Risk characterisation for man via the environment** ENV1a Extraction of fruits/plant material and processing of oil/water emulsion

Inhalation: RCR = 0.004

0.063

Soil

Oral: RCR = 2.154E-4

**Risk characterisation for man via the environment** ENV1b Extraction of fruits/plant material and processing of oil/water emulsion

Inhalation: RCR = 2.041E-4

Oral: RCR = 8.114E-4

**Risk characterisation for man via the environment** ENV2 Further refinement of essential oils

Inhalation: RCR = 3.181E-4

Oral: RCR = 0.001

Worker exposure						
Long-term, systemic	Long-term, systemic					
Contributing scenario	Inhalation	Dermal	Combined routes	Exposure estimation Method		
Manufacture in closed process, no likelihood of exposure (PROC 1)	Exposure: 1.5 mg/m <sup>3</sup> RCR: 0.048	Exposure: 0.007 mg/kg bw/day RCR: 7.713E- 4	RCR: 0.049	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: High level containment) Derm: Extended TRA workers		

Manufacture in closed, continuous process with occasional controlled exposure (PROC 2)	Exposure: 1.6 mg/m <sup>3</sup> RCR: 0.051	Exposure: 0.027 mg/kg bw/day RCR: 0.003	RCR: 0.055	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: High level containment) Derm: Extended TRA workers
Manufacture in closed batch process (synthesis or formulation) (PROC 3)	Exposure: 15 mg/m <sup>3</sup> RCR: 0.482	Exposure: 0.007 mg/kg bw/day RCR: 7.713E- 4	RCR: 0.483	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: Medium level containment) Derm: Extended TRA workers
Manufacture in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)	Exposure: 6.1 mg/m <sup>3</sup> RCR: 0.196	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.212	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: Low level containment, general ventilation) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)	Exposure: 18 mg/m <sup>3</sup> RCR: 0.579	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.594	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: General ventilation) Derm: Extended TRA workers
Use as laboratory reagent (PROC 15)	Exposure: 14 mg/m <sup>3</sup> RCR: 0.45	Exposure: 0.007 mg/kg bw/day RCR: 7.713E- 4	RCR: 0.451	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. No RMM) Derm: Extended TRA workers

#### Acute systemic

Not required as no hazard identified

# Local effects via inhalation route

Not required as no hazard identified

### Local effects via dermal route

(moderate hazard level). The use of gloves and generic organisational measures were proposed as Risk Management Measures to control the risk. Residual exposure was quantitatively estimated and assessed.				
Contributing scenario	Acute	Long term	<b>Exposure estimation Method</b>	
Manufacture in closed process, no likelihood of exposure (PROC 1)	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)	
Manufacture in closed, continuous process with occasional controlled exposure (PROC 2)	Exposure: 0.008 mg/cm <sup>2</sup> RCR: 0.043	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)	
Manufacture in closed batch process (synthesis or formulation) (PROC 3)	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)	

Exposure: 0.04 N/A

Exposure: 0.04 N/A

N/A

mg/cm<sup>2</sup>

mg/cm<sup>2</sup>

RCR: 0.215

RCR: 0.215

Exposure:

 $0.004 \text{ mg/cm}^2$ 

RCR: 0.022

Acute: External exposure estimation tool (Quantitative

Acute: External exposure

Acute: External exposure estimation tool (Quantitative

estimation tool (Quantitative

assessment of residual exposure)

assessment of residual exposure)

assessment of residual exposure)

A qualitative approach was used to assess the risk of sensitization in accordance with REACH Guidance R &

Manufacture in batch and other process

Transfer of substance or preparation

Use as laboratory reagent (PROC 15)

arises (PROC 4)

(synthesis) where opportunity for exposure

(charging/discharging) from/to vessels/large

containers at dedicated facilities (PROC 8b)

#### 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

#### Environment

The daily amount per site as mentioned in section 2.1 is the maximum amount (kg/day) that may be safely used, taking into account the default operational conditions as specified in section 2.1 and the release fractions as specified in section 3. This amount is defined as  $M_{Safe}$ .

To evaluate the compliance of specific compounding sites, the site-specific substance use rate ( $M_{Site}$ ) and days emitting ( $T_{Emission, Site}$ ), onsite and offsite emission controls and subsequent total substance emission Reduction Efficiency ( $RE_{Total, Site} = 1 - [(1 - RE_{Onsite, Site}) \times (1 - RE_{Offsite, Site})])$ , sewage treatment plant effluent flow rate ( $G_{Effluent, Site}$ ) and receiving water dilution factor ( $q_{Site}$ ) need to be known.

It is simpler and thus may be preferable to some users to compare  $M_{Site}$  with  $M_{Safe}$ . Adequate control of risk exists if the following conditions are met: [RE<sub>Total, Site</sub>  $\geq$  RE<sub>Total, SpERC</sub>, G<sub>Effluent, Site</sub>  $\geq$  G<sub>Effluent, SpERC</sub>, and q<sub>Site</sub>  $\geq$  q<sub>SpERC</sub>] and  $M_{Safe} \geq M_{Site}$ .

In case the above comparison does not show safe use, the following scaling possibilities are advised:

- The risk is driven by soil. As a default it is assumed that STP sludge is applied on agricultural soil. However this may not always be the case. If the STP sludge is not applied to soil, the RCR for agricultural soil will decrease significantly and therefore the amount that may be used will increase.
- When STP sludge is not applied to soil, the risk will be driven by surface water and sediment. The RCR for these protection targets is lower and therefore the volume can be increased with a factor of approximately 1.7 assuming all other conditions stay equal. If the volume is then not yet high enough, scaling based on municipal STP discharge rate and receiving river flow rate is advised.
- As mentioned in section 3, degradation in the STP has been calculated according to first-order kinetics in the model EUSES. This implies that the concentration in the effluent is proportional to the concentration in the influent and so the predicted concentration in effluent depends on the use volume. An alternative approach is to use Monod kinetics in EUSES. This can be applied for readily biodegradable substances in case: a) the release to the WWTP/STP is more or less continuous so the specific bacteria responsible for biodegradation will be able to maintain themselves in the system and b) the total COD load remains within the specifications of the WWTP/STP. When this approach is applied, the substance concentration in the STP effluent is independent of the concentration in the influent and therefore the use volume, and will remain below 50 µg/l. This implies that under these circumstances M<sub>safe</sub> is theoretically unlimited.

#### Human health

A DU works within the boundaries of this ES if he fulfills the conditions of use set in section 2. Table 4.1 provides an overview of the assumed effectiveness for the different RMM. The DU can use this effectiveness estimation in order to assess if any deviating RMM will also provide safe use. This is done by multiplying the relevant RCR with the effectiveness of the RMM implemented at the workplace and dividing it by the effectiveness of the RMM listed in section 2. If the shift duration is greater than 8 hours per day, the long term systemic DNELs have to be adapted with the using the following equation, derived from the Brief and Scala model: DNEL Reduction Factor = (8 x hours worked in shift) x ((24 – hours worked in shift) / 16). This equation can not be used to adapt a DNEL for a shift duration shorter than 8 hours. With the adapted DNEL, the DU can recalculate the RCR by dividing the exposure estimation in section 3 with the adapted DNEL. If the RCR is smaller than 0.725 (1 - 0.275 or 1 - (Sum of all man through environment and generic consumer exposure), the downstreamuser works within the boundaries set by the ES.

Table 4.1 Effectiveness of risk management	Table 4.1 Effectiveness of risk management measures (RMM).				
Risk management measure	Assumed effectiveness <sup>1</sup>		Source of effectiveness		
	Inhalatory	Dermal			
High level containment - Process fully	99.9%	99.9%	Advanced REACH tool (www.advancedreachtool.com).		
enclosed (air tight) and the integrity of the					
enclosure is monitored at least once a					
month (containment is not breached).					
Medium level containment - Undertake	99%	33%	Advanced REACH tool (www.advancedreachtool.com) for		
operation under enclosed conditions.			the inhalatory effectiveness, the dermal effectiveness is		
			assumed to be 1/3 of the inhalatory effectiveness.		
Low level containment - Put lids on	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for		
containers immediately after use.			the inhalatory effectiveness, the dermal effectiveness is		
			assumed to be 1/3 of the inhalatory effectiveness.		

#### Table 4.1 Effectiveness of risk management measures (RMM).

<sup>1</sup> All effectiveness's listed are only valid if the RMM is properly designed, installed (if applicable), used and maintained.

Working outdoor / natural ventilation	30%	-	Advanced REACH tool (www.advancedreachtool.com)
General ventilation (mechanical)	50%	-	Advanced REACH tool (www.advancedreachtool.com).
Local exhaust ventilation, fixed capturing	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for
hood			the inhalatory effectiveness, the dermal effectiveness is
			assumed to be 1/3 of the inhalatory effectiveness.
Local exhaust ventilation, other system	50%	17%	Advanced REACH tool (www.advancedreachtool.com) for
			the inhalatory effectiveness, the dermal effectiveness is
			assumed to be 1/3 of the inhalatory effectiveness.
Laminar flow booth	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for
			the inhalatory effectiveness, the dermal effectiveness is
			assumed to be 1/3 of the inhalatory effectiveness.
Respirator (Wear a full face respirator	95%	Not	Advanced REACH tool (www.advancedreachtool.com).
conforming to EN140 with Type A / P2		applicable	
filter or better. APF >20))			
Respirator (Wear a respirator (half face	90%	Not	Advanced REACH tool (www.advancedreachtool.com).
mask) conforming to EN140 with Type A		applicable	
filter / P2 filter or better. APF >10)			
Reduction of duration of exposure			ECETOC TRA (http://www.ecetoc.org/tra) for the
$> 60$ and $\leq 240$ minutes per shift	40%	40%	inhalatory effectiveness, expert judgment for dermal
$> 15$ and $\leq = 60$ minutes per shift	80%	80%	effectiveness.
<= 15 minutes per shift	90%	80%	
Concentration of substance in mixture			ECETOC TRA (http://www.ecetoc.org/tra) for the
> 5% and <= 25%	40%	75%	inhalatory effectiveness, expert judgment for dermal
> 1% and $<= 5%$	80%	95%	effectiveness.
<= 1%	90%	99%	

# 2. ES 2: Formulation (SU 3); Blending / Compounding

1. Title of Exposure scenario	
Environment:	ERC 2
* Blending of mixtures and distribution	
* Compounding of fragrance oils (generic large/medium sites)	
* Compounding of fragrance oils (generic small sites)	
Worker	
Formulation and distribution / compounding in closed system, no likelihood of exposure	PROC 1
Formulation and distribution / compounding in closed, continuous process with occasional controlled exposure	PROC 2
Formulation and distribution / compounding in closed batch process (synthesis or formulation)	PROC 3
Formulation and distribution / compounding in batch and other process (synthesis) where opportunity for exposure arises	PROC 4
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	PROC 5
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non- dedicated facilities	PROC 8a
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	PROC 8b
Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	PROC 9
Use as laboratory reagent	PROC 15

2.	Conditions	of use	affecting	exposure
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2.1 Control of environmental exposure:

Blending of mixtures and distribution (ERC 2)

Compounding of fragrance oils (generic large/medium sites) (ERC 2) Compounding of fragrance oils (generic small sites) (ERC 2)

**2.1.1 Control of environmental exposure:** Blending of mixtures and distribution (ERC 2)

Amounts used

Daily amount per site <= 0.063 tonnes/day

Annual amount per site <= 6.32 tonnes/year

Frequency and duration of use

Emission days / year = 100 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.1.2 Control of environmental exposure: Compounding of fragrance oils (generic large/medium sites) (ERC
2) Amounts used
Daily amount per site $\leq = 0.632$ toppes/day
Daily amount per site $< -0.052$ tomics day
Annual amount per site <= 158 tonnes/year
Emission days / year = 250 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4 \text{ m}3/d$
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate >= 2E3 m3/d
STP sludge is applied on agricultural soil
2.1.3 Control of environmental exposure: Compounding of fragrance oils (generic small sites) (ERC 2)
Amounts used
Daily amount per site <= 0.253 tonnes/day
Annual amount per site <= 63.2 tonnes/year
Frequency and duration of use
Emission days / year = 250 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate >= 1.8E4 m3/d
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate >= 2E3 m3/d
STP sludge is applied on agricultural soil
<b>2.2 Control of workers exposure for</b> Formulation and distribution / compounding in closed system, no likelihood of exposure ( <b>PROC 1</b> )
Product characteristics
Covers percentage substance in the product up to 100 % (unless stated differently).
Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: One hand face only (240 cm2).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. \* Open surface 1-3 m<sup>2</sup>.

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

#### Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.3 Control of workers exposure for** Formulation and distribution / compounding in closed, continuous process with occasional controlled exposure (**PROC 2**)

#### **Product characteristics**

Covers percentage substance in the product up to 100 % (unless stated differently).

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm2).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. \* Open surface 1-3 m<sup>2</sup>.

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Transfer of liquid products - falling liquids. \*Splash loading. \*Avoid carrying out operation for more than 0.5 hour. \*For each use event, covers use amounts up to 0.1-1 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

<b>2.4 Control of workers exposure for</b> Formulation and distribution / compounding in closed batch process (synthesis or formulation) ( <b>PROC 3</b> )
Product characteristics
Covers percentage substance in the product up to 100 % (unless stated differently).
Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: One hand face only (240 cm2).
Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. * Open surface 1-3 m <sup>2</sup> .
Undertake operation under enclosed conditions.
Technical and organisational conditions and measures
Demonstrahle and effective housely aming practices are in place
Demonstrable and effective housekeeping practices are in place.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
<b>2.5 Control of workers exposure for</b> Formulation and distribution / compounding in batch and other process (synthesis) where opportunity for exposure arises ( <b>PROC 4</b> )
Product characteristics
Covers percentage substance in the product up to 100 % (unless stated differently).
Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: Two hands face (480 cm2).
Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. * Open surface 1-3 m <sup>2</sup> .
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.

Put lids on containers immediately after use.

Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.6 Control of workers exposure for** Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (**PROC 5**)

**Product characteristics** 

Covers percentage substance in the product up to 100 % (unless stated differently).

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm2).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. \* Open surface 1-3 m<sup>2</sup>.

Transfer of liquid products - falling liquids. \*Submerged loading.

\*Submerged loading.

\*Avoid carrying out operation for more than 1 hour. \*For each use event, covers use amounts up to 100-1000 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Activity with agitated surfaces: Put lids on containers immediately after use.

*Transfer of liquid products*: Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.7 Control of workers exposure for** Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (**PROC 8a**)

#### **Product characteristics**

Covers percentage substance in the product up to 100 % (unless stated differently)

Liquid.

Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: Two hands (960 cm2).
Transfer of liquid products - falling liquids. *Splash loading. *For each use event, covers use amounts up to 100-1000 l/minute.
Handling that reduces contact between product and adjacent air.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Put lids on containers immediately after use.
Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
<b>2.8 Control of workers exposure for</b> Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities ( <b>PROC 8b</b> )
Product characteristics
Covers percentage substance in the product up to 100 % (unless stated differently)
Liquid
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: Two hands face (480 cm2).
Transfer of liquid products - falling liquids. *Submerged loading. *For each use event, covers use amounts up to 100-1000 l/minute.
Handling that reduces contact between product and adjacent air.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.

Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.9 Control of workers exposure for** Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)

#### Product characteristics

Covers concentrations up to: 50%

Liquid

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

#### Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm2).

Transfer of liquid products - falling liquids.

\*Splash loading.

\*For each use event, covers use amounts up to 10-100 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.10 Control of workers exposure for Use as laboratory reagent (PROC 15)

Product characteristics

Covers percentage substance in the product up to 100 % (unless stated differently)

Liquid

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: One hand face only (240 cm2).

Activities with open liquid surfaces or open reservoirs - activity with undisturbed surfaces (no aerosol formation)

\*Open surface < 0.1 m<sup>2</sup>

Transfer of liquid products - falling liquids. \*Splash loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to 0.1-1 l/minute.

\*Submerged loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to <0.1 l/minute.

Handling that reduces contact between product and adjacent air.

#### Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

#### **3. Exposure estimation and reference to its source**

The environmental exposure estimates were calculated according to EUSES version 2.1.2. Degradation in the STP was calculated according to first-order kinetics.

Environment

Blending of mixtures and distribution

Release route	Release rate (kg/day)	Release estimation method		
Water	1.264	ERC - ERC 2		
Air	1.58	ERC - ERC 2		
Soil	0.006	ERC - ERC 2		

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment Compounding of fragrance oils (generic large/medium sites)				
Release route	Release rate (kg/day)	Release estimation method		
Water	1.264	SPERC (Compounding of fragrance oils - Compounding of fragrance oils medium/large compounder)		
Air	15.8	SPERC (Compounding of fragrance oils - Compounding of fragrance oils medium/large compounder)		
Soil	0.063	SPERC		

fragrance oils medium/large compounder)
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Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment Compounding of fragrance oils (generic small sites)				
Release route	Release rate (kg/day)	Release estimation method		
Water	1.264	SPERC (Compounding of fragrance oils - Compounding of fragrance oils small compounder)		
Air	6.32	SPERC (Compounding of fragrance oils - Compounding of fragrance oils small compounder)		
Soil	0.025	SPERC (Compounding of fragrance oils - Compounding of fragrance oils small compounder)		

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

**Risk characterisation for man via the environment** Blending of mixtures and distribution

Inhalation: RCR = 7.983E-5

Oral: RCR = 6.351E-4

**Risk characterisation for man via the environment** Compounding of fragrance oils (generic large/medium sites)

Inhalation: RCR = 4.262E-4

Oral: RCR = 9.009E-4

**Risk characterisation for man via the environment** Compounding of fragrance oils (generic small sites)

Inhalation: RCR = 2.101E-4

Oral: RCR = 8.976E-4

Worker exposure				
Long-term, systemic				
Contributing scenario	Inhalation	Dermal	Combined routes	Exposure estimation Method
Formulation and distribution / compounding in closed system, no likelihood of exposure (PROC 1)	Exposure: 1.5 mg/m <sup>3</sup> RCR: 0.048	Exposure: 0.007 mg/kg bw/day RCR: 7.713E- 4	RCR: 0.049	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: High level containment) Derm: Extended TRA
				workers
Formulation and distribution / compounding in closed, continuous process with occasional controlled exposure (PROC 2)	Exposure: 1.6 mg/m <sup>3</sup> RCR: 0.051	Exposure: 0.027 mg/kg bw/day RCR: 0.003	RCR: 0.055	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: High level containment)
				Derm: Extended TRA workers
Formulation and distribution / compounding in closed batch process (synthesis or formulation) (PROC 3)	Exposure: 15 mg/m <sup>3</sup> RCR: 0.482	Exposure: 0.007 mg/kg bw/day RCR: 7.713E- 4	RCR: 0.483	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: Medium level containment)
				Derm: Extended TRA workers
Formulation and distribution / compounding in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)	Exposure: 6.1 mg/m <sup>3</sup> RCR: 0.196	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.212	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: Low level containment, general ventilation)
				Derm: Extended TRA workers
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)	Exposure: 16 mg/m <sup>3</sup> RCR: 0.515	Exposure: 0.274 mg/kg bw/day RCR: 0.031	RCR: 0.545	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: Low level containment, general ventilation) Derm: Extended TR A

				workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non- dedicated facilities (PROC 8a)	Exposure: 18 mg/m <sup>3</sup> RCR: 0.579	Exposure: 0.274 mg/kg bw/day RCR: 0.031	RCR: 0.61	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: Low level containment, general ventilation) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)	Exposure: 18 mg/m <sup>3</sup> RCR: 0.579	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.594	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. RMM: General ventilation) Derm: Extended TRA workers
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)	Exposure: 13 mg/m <sup>3</sup> RCR: 0.418	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.426	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Use as laboratory reagent (PROC 15)	Exposure: 14 mg/m <sup>3</sup> RCR: 0.45	Exposure: 0.007 mg/kg bw/day RCR: 7.713E- 4	RCR: 0.451	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 100%. No RMM) Derm: Extended TRA workers

#### Acute systemic

Not required as no hazard identified

#### Local effects via inhalation route

Not required as no hazard identified

#### Local effects via dermal route

A qualitative approach was used to assess the risk of sensitization in accordance with REACH Guidance R.8 (moderate hazard level). The use of gloves and generic organisational measures were proposed as Risk Management Measures to control the risk. Residual exposure was quantitatively estimated and assessed.

<b>Contributing scenario</b>	Acute	Long term	<b>Exposure estimation Method</b>
Formulation and distribution / compounding	Exposure:	N/A	Acute: External exposure
in closed system, no likelihood of exposure	0.004 mg/cm <sup>2</sup>		estimation tool (Quantitative
(PROC 1)	RCR: 0.022		assessment of residual exposure)

Formulation and distribution / compounding	Exposure:	N/A	Acute: External exposure
in closed, continuous process with	0.008 mg/cm <sup>2</sup>		estimation tool (Quantitative
occasional controlled exposure (PROC 2)	RCR: 0.043		assessment of residual exposure)
Formulation and distribution / compounding	Exposure:	N/A	Acute: External exposure
in closed batch process (synthesis or	0.004 mg/cm <sup>2</sup>		estimation tool (Quantitative
formulation) (PROC 3)	RCR: 0.022		assessment of residual exposure)
Formulation and distribution / compounding	Exposure: 0.04	N/A	Acute: External exposure
in batch and other process (synthesis) where	mg/cm²		estimation tool (Quantitative
opportunity for exposure arises (PROC 4)	RCR: 0.215		assessment of residual exposure)
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)	Exposure: 0.08 mg/cm <sup>2</sup> RCR: 0.431	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)	Exposure: 0.04 mg/cm² RCR: 0.215	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation	Exposure: 0.04	N/A	Acute: External exposure
(charging/discharging) from/to vessels/large	mg/cm²		estimation tool (Quantitative
containers at dedicated facilities (PROC 8b)	RCR: 0.215		assessment of residual exposure)
Transfer of substance or preparation into	Exposure: 0.02	N/A	Acute: External exposure
small containers (dedicated filling line,	mg/cm <sup>2</sup>		estimation tool (Quantitative
including weighing) (PROC 9)	RCR: 0.108		assessment of residual exposure)
Use as laboratory reagent (PROC 15)	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)

#### 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

#### Environment

The daily amount per site as mentioned in section 2.1 is the maximum amount (kg/day) that may be safely used, taking into account the default operational conditions as specified in section 2.1 and the release fractions as specified in section 3. This amount is defined as  $M_{Safe}$ .

To evaluate the compliance of specific compounding sites, the site-specific substance use rate ( $M_{Site}$ ) and days emitting ( $T_{Emission, Site}$ ), onsite and offsite emission controls and subsequent total substance emission Reduction Efficiency ( $RE_{Total, Site} = 1 - [(1 - RE_{Onsite, Site}) \times (1 - RE_{Offsite, Site})])$ , sewage treatment plant effluent flow rate ( $G_{Effluent, Site}$ ) and receiving water dilution factor ( $q_{Site}$ ) need to be known.

It is simpler and thus may be preferable to some users to compare  $M_{Site}$  with  $M_{Safe}$ . Adequate control of risk exists if the following conditions are met: [RE<sub>Total, Site</sub>  $\geq$  RE<sub>Total, SpERC</sub>, G<sub>Effluent, Site</sub>  $\geq$  G<sub>Effluent, SpERC</sub>, and q<sub>Site</sub>  $\geq$  q<sub>SpERC</sub>] and  $M_{Safe} \geq M_{Site}$ .

In case the above comparison does not show safe use, the following scaling possibilities are advised:

• The risk is driven by soil. As a default it is assumed that STP sludge is applied on agricultural soil.

However this may not always be the case. If the STP sludge is not applied to soil, the RCR for agricultural soil will decrease significantly and therefore the amount that may be used will increase.

- When STP sludge is not applied to soil, the risk will be driven by surface water and sediment. The RCR for these protection targets is lower and therefore the volume can be increased with a factor of approximately 1.7 assuming all other conditions stay equal. If the volume is then not yet high enough, scaling based on municipal STP discharge rate and receiving river flow rate is advised.
- As mentioned in section 3, degradation in the STP has been calculated according to first-order kinetics in the model EUSES. This implies that the concentration in the effluent is proportional to the concentration in the influent and so the predicted concentration in effluent depends on the use volume. An alternative approach is to use Monod kinetics in EUSES. This can be applied for readily biodegradable substances in case: a) the release to the WWTP/STP is more or less continuous so the specific bacteria responsible for biodegradation will be able to maintain themselves in the system and b) the total COD load remains within the specifications of the WWTP/STP. When this approach is applied, the substance concentration in the STP effluent is independent of the concentration in the influent and therefore the use volume, and will remain below 50 µg/l. This implies that under these circumstances M<sub>safe</sub> is theoretically unlimited.

#### <u>Human health</u>

A DU works within the boundaries of this ES if he fulfills the conditions of use set in section 2. Table 4.1 provides an overview of the assumed effectiveness for the different RMM. The DU can use this effectiveness estimation in order to assess if any deviating RMM will also provide safe use. This is done by multiplying the relevant RCR with the effectiveness of the RMM implemented at the workplace and dividing it by the effectiveness of the RMM listed in section 2. If the shift duration is greater than 8 hours per day, the long term systemic DNELs have to be adapted with the using the following equation, derived from the Brief and Scala model: DNEL Reduction Factor =  $(8 \text{ x hours worked in shift}) \times ((24 - \text{hours worked in shift}) / 16)$ . This equation can not be used to adapt a DNEL for a shift duration shorter than 8 hours. With the adapted DNEL, the DU can recalculate the RCR by dividing the exposure estimation in section 3 with the adapted DNEL. If the RCR is smaller than 0.725 (1 - 0.275 or 1 - (Sum of all man through environment and generic consumer exposure), the downstreamuser works within the boundaries set by the ES.

Risk management measure	Assumed effectiveness <sup>2</sup>		Source of effectiveness
	Inhalatory	Dermal	
High level containment - Process fully	99.9%	99.9%	Advanced REACH tool (www.advancedreachtool.com).
enclosed (air tight) and the integrity of the			
enclosure is monitored at least once a			
month (containment is not breached).			
Medium level containment - Undertake	99%	33%	Advanced REACH tool (www.advancedreachtool.com) for
operation under enclosed conditions.			the inhalatory effectiveness, the dermal effectiveness is
			assumed to be 1/3 of the inhalatory effectiveness.
Low level containment - Put lids on	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for
containers immediately after use.			the inhalatory effectiveness, the dermal effectiveness is
			assumed to be 1/3 of the inhalatory effectiveness.
Working outdoor / natural ventilation	30%	-	Advanced REACH tool (www.advancedreachtool.com)
General ventilation (mechanical)	50%	-	Advanced REACH tool (www.advancedreachtool.com).
Local exhaust ventilation, fixed capturing	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for
hood			the inhalatory effectiveness, the dermal effectiveness is
			assumed to be 1/3 of the inhalatory effectiveness.
Local exhaust ventilation, other system	50%	17%	Advanced REACH tool (www.advancedreachtool.com) for
			the inhalatory effectiveness, the dermal effectiveness is
			assumed to be 1/3 of the inhalatory effectiveness.
Laminar flow booth	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for
			the inhalatory effectiveness, the dermal effectiveness is
			assumed to be 1/3 of the inhalatory effectiveness.
Respirator (Wear a full face respirator	95%	Not	Advanced REACH tool (www.advancedreachtool.com).
conforming to EN140 with Type A / P2		applicable	
filter or better. APF >20))	0.004/	N	
Respirator (Wear a respirator (half face	90%	Not	Advanced REACH tool (www.advancedreachtool.com).
mask) conforming to EN140 with Type A		applicable	
filter / P2 filter or better. APF >10)			
Reduction of duration of exposure	400/	400/	ECETOC TRA (http://www.ecetoc.org/tra) for the
> 60 and <= 240 minutes per shift	40%	40%	innalatory effectiveness, expert judgment for dermal
$>$ 15 and $\leq$ = 60 minutes per shift	80%	80%	effectiveness.

#### Table 4.1 Effectiveness of risk management measures (RMM).

<sup>&</sup>lt;sup>2</sup> All effectiveness's listed are only valid if the RMM is properly designed, installed (if applicable), used and maintained.
<= 15 minutes per shift	90%	80%	
Concentration of substance in mixture			ECETOC TRA (http://www.ecetoc.org/tra) for the
> 5% and $<= 25%$	40%	75%	inhalatory effectiveness, expert judgment for dermal
> 1% and $<= 5%$	80%	95%	effectiveness.
<= 1%	90%	99%	

# 3. ES 3: Formulation (SU 3); Formulation

## **1. Title of Exposure scenario**

Environment:	ERC 2
* Formulation AISE 1, 5 and 7 - Formulation of Detergents/Maintenance Products: Granular	
Detergent - Regular (large scale), Granular Detergent -Compact (small scale), Low Viscosity	
Liquids (large scale)	
* Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15 - Formulation of	
Detergents/Maintenance Products: Granular Detergent -Regular (medium scale), Low Viscosity	
Liquids (medium scale), High viscosity Liquids (large scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, heir conditioner, shower cal, form bath) (large scale), hedware scan	
(medium and large scale)	
* Formulation AISE 3 9 and 11 and COLIPA 2 and 16 - Formulation of Detergents/Maintenance	
Products: Granular Detergent -Regular (small scale). Low Viscosity Liquids (small scale). High	
Viscosity Liquids (medium scale); Formulation Cosmetics: low viscosity liquids (Shampoo, hair	
conditioner, shower gel, foam bath) (medium scale), body care soap (small scale)	
* Formulation AISE 12 and COLIPA 3 - Formulation of Detergents/Maintenance Products: High	
Viscosity Liquids (small scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair	
conditioner, shower gel, foam bath) (small scale)	
* Formulation COLIPA 6 and 8 - Formulation of Cosmetics: Medium Viscosity Body Care	
Products (medium scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up	
Toundation) (large scale) * Formulation AISE 4 Formulation of Datargants/Maintanance Products: Granular Datargant	
Compact (large scale)	
* Formulation AISE 6 - Formulation of Detergents/Maintenance Products: Granular Detergent -	
Compact (small scale)	
* Formulation COLIPA 4, 7 and 9 - Formulation of Cosmetics: Fine Fragrances - Cleaning with	
Water (medium scale), Medium Viscosity Body Care Products (small scale), Non-liquid Creams	
(skin care, body care, mascara, solar oil, make-up foundation) (medium scale)	
* Formulation COLIPA 5 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water	
(small scale)	
* Formulation COLIPA 10 - Formulation of Cosmetics: Non-liquid Creams (skin care, body care,	
* CEDE 7 Exampletion of Dourder Continue and Inka Solida	
* CEPE 8 9 - Formulation of Liquid Coatings and Inks - Jones Scale and Small Scale	
* ESVOC 4 - Formulation of solvents and solvent based products	
* FEICA 2.3 - Formulation of Solvent Borne adhesives - Volatiles (Large Scale and Small Scale)	
* EFCC2 - Formulation of Construction Chemicals - Use of Volatile substances (additives)	
Worker	
Formulation in closed process, no likelihood of exposure - liquid	PROC 1
Formulation in closed process, no likelihood of exposure - solid	PROC 1
Formulation in closed, continuous process with occasional controlled exposure - liquid	PROC 2
Formulation in closed, continuous process with occasional controlled exposure - solid	PROC 2
Formulation in closed batch process (synthesis or formulation) - liquid	PROC 3
Formulation in closed batch process (synthesis or formulation) - solid	PROC 3
Formulation in batch and other process (synthesis) where opportunity for exposure arises - liquid	PROC 4
Formulation in batch and other process (synthesis) where opportunity for exposure arises - solid	PROC 4
Mixing or blending in batch processes for formulation of preparations and articles (multistage	PROC 5
and/or significant contact) - liquid	
Mixing or blending in batch processes for formulation of preparations and articles (multistage	PROC 5
and/or significant contact) - solid	
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-	PROC 8a

dedicated facilities - liquid	
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non- dedicated facilities - solid	PROC 8a
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid	PROC 8b
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid	PROC 8b
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid	PROC 9
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid	PROC 9
Roller application or brushing - liquid	PROC 10
Treatment of articles by dipping and pouring - liquid	PROC 13
Formulation of preparations or articles by tabletting, compression, extrusion, pelletisation - solid	PROC 14
Use as laboratory reagent - liquid	PROC 15
Use as laboratory reagent - solid	PROC 15

### 2. Conditions of use affecting exposure

#### 2.1 Control of environmental exposure:

Formulation AISE 1, 5 and 7 - Formulation of Detergents/Maintenance Products: Granular Detergent – Regular (large scale), Granular Detergent -Compact (small scale), Low Viscosity Liquids (large scale)

Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (medium scale), Low Viscosity Liquids (medium scale), High Viscosity Liquids (large scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (large scale), body care soap (medium and large scale)

Formulation AISE 3, 9 and 11 and COLIPA 2 and 16 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (small scale), Low Viscosity Liquids (small scale), High Viscosity Liquids (medium scale); Formulation Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (medium scale), body care soap (small scale)

Formulation AISE 12 and COLIPA 3 - Formulation of Detergents/Maintenance Products: High Viscosity Liquids (small scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (small scale)

Formulation COLIPA 6 and 8 - Formulation of Cosmetics: Medium Viscosity Body Care Products (medium scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (large scale)

Formulation AISE 4 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (large scale)

Formulation AISE 6 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (small scale)

Formulation COLIPA 4, 7 and 9 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (medium scale), Medium Viscosity Body Care Products (small scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (medium scale)

Formulation COLIPA 5 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (small scale)

Formulation COLIPA 10 - Formulation of Cosmetics: Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (small scale)

CEPE 7 - Formulation of Powder Coatings and Inks - Solids

CEPE 8, 9 - Formulation of Liquid Coatings and Inks - Large Scale and Small Scale

ESVOC 4 - Formulation of solvents and solvent based products

FEICA 2,3 - Formulation of Solvent Borne adhesives - Volatiles (Large Scale and Small Scale)

EFCC2 - Formulation of Construction Chemicals - Use of Volatile substances (additives)

2.1.1 Control of environmental exposure:

Formulation AISE 1, 5 and 7 - Formulation of Detergents/Maintenance Products: Granular Detergent – Regular (large scale), Granular Detergent -Compact (small scale), Low Viscosity Liquids (large scale) (ERC 2)

Amounts used

Daily amount per site  $\leq 0.1$  tonnes/day

Annual amount per site <= 1 tonnes/year

Frequency and duration of use

Emission days / year = not specified

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.1.2 Control of environmental exposure:

Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (medium scale), Low Viscosity Liquids (medium scale), High Viscosity Liquids (large scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (large scale), body care soap (medium and large scale) (ERC 2)

Amounts used

Daily amount per site <= 1.264 tonnes/day

Annual amount per site <= 278.1 tonnes/year

Frequency and duration of use

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.1.3 Control of environmental exposure:

Formulation AISE 3, 9 and 11 and COLIPA 2 and 16 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (small scale), Low Viscosity Liquids (small scale), High Viscosity Liquids (medium scale); Formulation Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (medium scale), body care soap (small scale) (ERC 2)

## Amounts used

Daily amount per site  $\leq 0.632$  tonnes/day

Annual amount per site <= 139 tonnes/year

Frequency and duration of use

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.1.4 Control of environmental exposure:

Formulation AISE 12 and COLIPA 3 - Formulation of Detergents/Maintenance Products: High Viscosity Liquids (small scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (small scale) (ERC 2)

Amounts used

Daily amount per site <= 0.316 tonnes/day

Annual amount per site <= 69.52 tonnes/year

Frequency and duration of use

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.1.5 Control of environmental exposure:

Formulation COLIPA 6 and 8 - Formulation of Cosmetics: Medium Viscosity Body Care Products (medium scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (large scale) (ERC 2)

Amounts used

Daily amount per site <= 0.126 tonnes/day

Annual amount per site <= 27.8 tonnes/year

Frequency and duration of use

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate >= 2E3 m3/d

STP sludge is applied on agricultural soil

2.1.6 Control of environmental exposure:

Formulation AISE 4 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (large scale) (ERC 2)

Amounts used

Daily amount per site <= 126.4 tonnes/day

Annual amount per site <= 2.781E4 tonnes/year

Frequency and duration of use

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate >= 2E3 m3/d

STP sludge is applied on agricultural soil

2.1.7 Control of environmental exposure:

Formulation AISE 6 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (small scale) (ERC 2)

Amounts used

Daily amount per site <= 6.32 tonnes/day

Annual amount per site <= 1.39E3 tonnes/year

Frequency and duration of use

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate >= 2E3 m3/d

STP sludge is applied on agricultural soil

## 2.1.8 Control of environmental exposure:

Formulation COLIPA 4, 7 and 9 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (medium scale), Medium Viscosity Body Care Products (small scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (medium scale) (ERC 2)

#### Amounts used

Daily amount per site <= 0.063 tonnes/day

Annual amount per site <= 13.9 tonnes/year

Frequency and duration of use

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.1.9 Control of environmental exposure:

Formulation COLIPA 5 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (small scale) (ERC 2)

Amounts used

Daily amount per site  $\leq 0.042$  tonnes/day

Annual amount per site <= 9.27 tonnes/year

Frequency and duration of use

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.1.10 Control of environmental exposure:

Formulation COLIPA 10 - Formulation of Cosmetics: Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (small scale) (ERC 2)

Amounts used

Daily amount per site  $\leq 0.032$  tonnes/day

Annual amount per site <= 0.695 tonnes/year

Frequency and duration of use

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m3/d}$ 

STP sludge is applied on agricultural soil

2.1.11 Control of environmental exposure:

CEPE 7 - Formulation of Powder Coatings and Inks - Solids (ERC 2)

## Amounts used

Daily amount per site <= 0.253 tonnes/day

Annual amount per site <= 56.93 tonnes/year

Frequency and duration of use

Emission days / year = 225 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.1.12 Control of environmental exposure:

CEPE 8, 9 - Formulation of Liquid Coatings and Inks - Large Scale and Small Scale (ERC 2)

Amounts used

Daily amount per site <= 122.2 tonnes/day

Annual amount per site <= 2.75E4 tonnes/year

Frequency and duration of use

Emission days / year = 225 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate >= 1.8E4 m3/d

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.1.13 Control of environmental exposure:

ESVOC 4 - Formulation of solvents and solvent based products (ERC 2)

Amounts used

Daily amount per site <= 6.3 tonnes/day

Annual amount per site <= 1.89E3 tonnes/year

Frequency and duration of use

Emission days / year = 300 days/year

## Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.1.14 Control of environmental exposure:

FEICA 2,3 - Formulation of Solvent Borne adhesives - Volatiles (Large Scale and Small Scale) (ERC 2)

Amounts used

Daily amount per site <= 4.55 tonnes/day

Annual amount per site <= 1E3 tonnes/year

Frequency and duration of use

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.1.15 Control of environmental exposure:

EFCC2 - Formulation of Construction Chemicals - Use of Volatile substances (additives) (ERC 2)

Amounts used

Daily amount per site <= 0.253 tonnes/day

Annual amount per site <= 6.32 tonnes/year

Frequency and duration of use

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

**2.2 Control of workers exposure for** Formulation in closed process, no likelihood of exposure - liquid (PROC 1)

Product characteristics			
Covers concentrations up to: 50%			
Liquid			
Amount used, frequency and duration of use/exposure			
Covers daily exposures up to 8 hours (unless stated differently).			
Other operational conditions affecting workers exposure			
Indoor use.			
Assumes activities are at room temperature.			
Exposed skin surface assumed: One hand face only (240 cm2).			
Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. * Open surface 1-3 m <sup>2</sup> .			
Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).			
Technical and organisational conditions and measures			
Demonstrable and effective housekeeping practices are in place.			
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.			
Use suitable eye protection.			
Wear suitable coveralls to prevent exposure to the skin.			
<b>2.3 Control of workers exposure for</b> Formulation in closed process, no likelihood of exposure - solid ( <b>PROC</b> 1)			
Product characteristics			
Covers concentrations up to: 10%			
Solid, medium dustiness.			
Amount used, frequency and duration of use/exposure			
Covers daily exposures up to 8 hours (unless stated differently).			
Other operational conditions affecting workers exposure			
Indoor use.			
Exposed skin surface assumed: One hand face only (240 cm2)			
Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation. *For each use event, covers use amounts up to 100-1000 kg			
Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).			
Technical and organisational conditions and measures			

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.4 Control of workers exposure for** Formulation in closed, continuous process with occasional controlled exposure - liquid (**PROC 2**)

#### Product characteristics

Covers concentrations up to: 50%

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

#### Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm2).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. \* Open surface 1-3 m<sup>2</sup>.

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Transfer of liquid products - falling liquids

\*Splash loading

\*Avoid carrying out operation for more than 0.5 hour.

\*For each use event, covers use amounts up to 0.1-1 l/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.5 Control of workers exposure for** Formulation in closed, continuous process with occasional controlled exposure - solid (**PROC 2**)

**Product characteristics** 

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm2)

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

\*For each use event, covers use amounts up to 100-1000 kg.

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

*Transfer of solid products - falling powders.* \*Avoid carrying out operation for more than 0.5 hour. \*For each use event, covers use amounts up to 0.1-1 kg/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.6 Control of workers exposure for** Formulation in closed batch process (synthesis or formulation) - liquid (**PROC 3**)

Product characteristics

Covers concentrations up to: 50%

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: One hand face only (240 cm2).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. \* Open surface 1-3 m<sup>2</sup>.

Use in closed batch process (synthesis or formulation). \*Undertake operation under enclosed conditions.

Transfer of liquid products - falling liquids.

\*Splash loading.

\*Avoid carrying out operation for more than 0.5 hour. \*For each use event, covers use amounts up to 0.1-1 l/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.7 Control of workers exposure for** Formulation in closed batch process (synthesis or formulation) - solid (**PROC 3**)

## Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

#### Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: One hand face only (240 cm2).

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

\*For each use event, covers use amounts up to 100-1000 kg. \*Undertake operation under enclosed conditions.

Transfer of solid products - falling powders.

\*Avoid carrying out operation for more than 0.5 hour. \*For each use event, covers use amounts up to 0.1-1 kg/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.8 Control of workers exposure for** Formulation in batch and other process (synthesis) where opportunity for exposure arises - liquid (**PROC 4**)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

#### Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm2).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. \*Open surface 1-3 m<sup>2</sup>.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Put lids on containers immediately after use.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.9 Control of workers exposure for** Formulation in batch and other process (synthesis) where opportunity for exposure arises - solid (**PROC 4**)

**Product characteristics** 

Covers concentrations up to: 10%.

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm2).

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

\*For each use event, covers use amounts up to 100-1000 kg.

*Transfer of solid products - falling powders.* \*Avoid carrying out operation for more than 0.5 hour.

\*For each use event, covers use amounts up to 10-100 g/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Put lids on containers immediately after use.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.10 Control of workers exposure for** Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - liquid (**PROC 5**)

**Product characteristics** 

Covers concentrations up to: 50%.

Liquid.			
Amount used, frequency and duration of use/exposure			
Covers daily exposures up to 8 hours (unless stated differently).			
Other operational conditions affecting workers exposure			
Indoor use.			
Assumes activities are at room temperature.			
Exposed skin surface assumed: Two hands face (480 cm2).			
Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. * Open surface 1-3 m <sup>2</sup> .			
Technical and organisational conditions and measures			
Demonstrable and effective housekeeping practices are in place.			
Put lids on containers immediately after use.			
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.			
Use suitable eye protection.			
Wear suitable coveralls to prevent exposure to the skin.			
<b>2.11 Control of workers exposure for</b> Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid ( <b>PROC 5</b> )			
Product characteristics			
Covers concentrations up to: 10%			
Solid, medium dustiness.			
Amount used, frequency and duration of use/exposure			
Covers daily exposures up to 8 hours (unless stated differently).			
Other operational conditions affecting workers exposure			
Indoor use.			
Exposed skin surface assumed: Two hands face (480 cm2).			
Movement and open agitation of powders, granules or pelletised material - handling with high level of			
*For each use event, covers use amounts up to 100-1000 kg.			
Transfer of solid products - falling powders. *Avoid carrying out operation for more than 0.5 hour. *For each use event, covers use amounts up to 10-100 g/minute.			
Technical and organisational conditions and measures			
Demonstrable and effective housekeeping practices are in place.			
Put lids on containers immediately after use.			
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision			

controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.12 Control of workers exposure for** Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - liquid (**PROC 8a**)

### **Product characteristics**

Covers concentrations up to: 50%.

Liquid.

#### Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

#### Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands (960 cm2).

Transfer of liquid products - falling liquids.

\*Submerged loading.

\*For each use event, covers use amounts up to 100-1000 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.13 Control of workers exposure for** Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid (**PROC 8a**)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

## Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands (960 cm2).

*Transfer of solid products - falling powders.* \*For each use event, covers use amounts up to 100-1000 kg/minute. Handling that reduces contact between product and adjacent air.

## Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.14 Control of workers exposure for** Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid (**PROC 8b**)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm2).

Transfer of liquid products - falling liquids. \*Submerged loading.

\*For each use event, covers use amounts up to 100-1000 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.15 Control of workers exposure for** Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid (**PROC 8b**)

**Product characteristics** 

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm2).

*Transfer of solid products - falling powders.* \*For each use event, covers use amounts up to 100-1000 kg/minute.

Handling that reduces contact between product and adjacent air.

#### Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.16 Control of workers exposure for** Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (**PROC 9**)

**Product characteristics** 

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm2).

Transfer of liquid products - falling liquids.

\*Splash loading.

\*For each use event, covers use amounts up to 10-100 l/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.17 Control of workers exposure for** Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid (**PROC 9**)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.			
Amount used, frequency and duration of use/exposure			
Covers daily exposures up to 8 hours (unless stated differently).			
Other operational conditions affecting workers exposure			
Indoor use.			
Exposed skin surface assumed: Two hands face (480 cm2).			
<i>Transfer of solid products - falling powders.</i> *For each use event, covers use amounts up to 10-100 kg/minute.			
Handling that reduces contact between product and adjacent air.			
Technical and organisational conditions and measures			
Demonstrable and effective housekeeping practices are in place.			
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.			
Use suitable eye protection.			
Wear suitable coveralls to prevent exposure to the skin.			
2.18 Control of workers exposure for Roller application or brushing - liquid (PROC 10)			
Product characteristics			
Covers concentrations up to: 50%.			
Liquid.			
Amount used, frequency and duration of use/exposure			
Covers daily exposures up to 8 hours (unless stated differently).			
Other operational conditions affecting workers exposure			
Indoor use.			
Assumes activities are at room temperature.			
Exposed skin surface assumed: Two hands (960 cm2).			
Spreading of liquid products (0.3-1.0 m <sup>2</sup> /hour). *Avoid carrying out operation for more than 4 hours.			
Handling of contaminated objects $(0.3-1.0 \text{ m}^2)$ - Contamination > 90 % of surface. *Avoid carrying out operation for more than 4 hours.			
Technical and organisational conditions and measures			
General measures applicable to all activities:			
Demonstrable and effective housekeeping practices are in place.			
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.			
Use suitable eye protection.			

Wear suitable coveralls to prevent exposure to the skin.		
Use above 5% concentration: *Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).		
2.19 Control of workers exposure for Treatment of articles by dipping and pouring - liquid (PROC 13)		
Product characteristics		
Covers concentrations up to: 50%.		
Liquid.		
Amount used, frequency and duration of use/exposure		
Covers daily exposures up to 8 hours (unless stated differently).		
Other operational conditions affecting workers exposure		
Indoor use.		
Assumes activities are at room temperature.		
Exposed skin surface assumed: Two hands face (480 cm2).		
Activities with open liquid surfaces or open reservoirs - activity with undisturbed surfaces (no aerosol formation). * <i>Use above 25% concentration</i> : Open surface 1-3 m <sup>2</sup> *Open surface 0.3-1 m <sup>2</sup>		
*Avoid carrying out operation for more than 4 hours.		
Handling of contaminated objects (0.3-1.0 m <sup>2</sup> ) - Contamination > 90 % of surface. *Avoid carrying out operation for more than 4 hours.		
Technical and organisational conditions and measures		
General measures applicable to all activities:		
Demonstrable and effective housekeeping practices are in place.		
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.		
Use suitable eye protection.		
Wear suitable coveralls to prevent exposure to the skin.		
<i>Use between 5- 25% concentration:</i> *Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).		
Use above 25% concentration: *Local exhaust ventilation - efficiency of at least [%]: 50. *Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).		
2.20 Control of workers exposure for Formulation of preparations or articles by tabletting, compression,		

extrusion, pelletisation - solid (PROC 14)
Product characteristics
Covers concentrations up to: 10%
Solid, low dustiness.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently)
Other operational conditions affecting workers exposure
Indoor use.
Exposed skin surface assumed: Two hands face (480 cm2).
Tabletting, compression, extrusion or pelletisation. *For each use event, covers use amounts up to 100-1000 kg/minute.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
2.21 Control of workers exposure for Use as laboratory reagent - liquid (PROC 15)
Product characteristics
Covers concentrations up to: 50%.
Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: One hand face only (240 cm2).
Activities with open liquid surfaces or open reservoirs - activity with undisturbed surfaces (no aerosol formation). *Open surface < 0.1 m <sup>2</sup>
Transfer of liquid products - falling liquids. *Splash loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to 0.1-1 l/minute. *Submerged loading.Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to <0.1 l/minute. Handling that reduces contact between product and adjacent air.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.22 Control of workers exposure for** Use as laboratory reagent - solid (**PROC 15**)

## Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

#### Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

#### Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: One hand face only (240 cm2).

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

\*For each use event, covers use amounts up to <10 gram/minute.

Transfer of solid products - falling powders.

\*Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to 10-100 gram/minute.

\*Carefully handle the substance to minimise releases. Ensure operatives are trained to minimise exposures. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to <10 gram/minute.

#### Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

#### **3. Exposure estimation and reference to its source**

The environmental exposure estimates were calculated according to EUSES version 2.1.2. Degradation in the STP was calculated according to first-order kinetics.

#### Environment

Formulation AISE 1, 5 and 7 - Formulation of Detergents/Maintenance Products: Granular Detergent – Regular (large scale), Granular Detergent -Compact (small scale), Low Viscosity Liquids (large scale).

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 1, 5 and 7)
Air	2.528	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 1, 5 and 7)

Soil	0	SPERC
		(AISE and COLIPA SpERCs for formulation -
		Formulation AISE 1, 5 and 7)

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (medium scale), Low Viscosity Liquids (medium scale), High Viscosity Liquids (large scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (large scale), body care soap (medium and large scale).

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15)
Air	0.253	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15)

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

## Environment

Formulation AISE 3, 9 and 11 and COLIPA 2 and 16 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (small scale), Low Viscosity Liquids (small scale), High Viscosity Liquids (medium scale); Formulation Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (medium scale), body care soap (small scale)

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 3, 9 and 11 and COLIPA 2 and 16)

Air	0.126	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 3, 9 and 11 and COLIPA 2 and 16)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 3, 9 and 11 and COLIPA 2 and 16)

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Formulation AISE 12 and COLIPA 3 - Formulation of Detergents/Maintenance Products: High Viscosity Liquids (small scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (small scale)

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 12 and COLIPA 3)
Air	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 12 and COLIPA 3)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 12 and COLIPA 3)

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

#### Environment

Formulation COLIPA 6 and 8 - Formulation of Cosmetics: Medium Viscosity Body Care Products (medium scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (large scale)

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 6 and 8)
Air	0	SPERC (AISE and COLIPA SpERCs for formulation -

		Formulation COLIPA 6 and 8)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 6 and 8)

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Formulation AISE 4 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (large scale).

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 4)
Air	25.28	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 4)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 4)

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

## Environment

Formulation AISE 6 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (small scale)

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 6
Air	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 6
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 6

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Formulation COLIPA 4, 7 and 9 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (medium scale), Medium Viscosity Body Care Products (small scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (medium scale)

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 4, 7 and 9)
Air	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 4, 7 and 9)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 4, 7 and 9)

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

<b>Environment</b> Formulation COLIPA 5 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (small scale)		
Release route	Ite Release rate (kg/day) Release estimation method	
Water	1.263	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 5)
Air	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 5)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 5)

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618

Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Formulation COLIPA 10 - Formulation of Cosmetics: Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (small scale)

Release route	Release rate (kg/day)	Release estimation method
Water	1.264	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 10)
Air	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 10)
Soil	0	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 10)

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

<b>Environment</b> CEPE 7 - Formulation of Powder Coatings and Inks – Solids		
Release route	Release rate (kg/day)	Release estimation method
Water	1.265	SPERC (CEPE 7)
Air	0.025	SPERC (CEPE 7)
Soil	0	SPERC (CEPE 7)

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.609
Freshwater (sediment)	0.805 mg/kg dw	0.619
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.599
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

## Environment

CEPE 8, 9 - Formulation of Liquid Coatings and Inks - Large Scale and Small Scale

Release route	Release rate (kg/day)	Release estimation method
Water	0	SPERC (CEPE 8, 9)
Air	7.333	SPERC (CEPE 8, 9)
Soil	0	SPERC (CEPE 8, 9)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	5.96E-4 mg/L	0.11
Freshwater (sediment)	0.146 mg/kg dw	0.112
Marine water (pelagic)	4.91E-5 mg/L	0.091
Marine water (sediment)	0.012 mg/kg dw	0.092
Effluent	0 mg/L	0
Agricultural soil	1.6E-4 mg/kg dw	6.13E-4

Environment ESVOC 4 - Formulation of solvents and solvent based products				
Release routeRelease rate (kg/day)Release estimation method				
Water	1.26	SPERC (ESVOC 4)		
Air	63	SPERC (ESVOC 4)		
Soil	0	SPERC (ESVOC 4)		

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.606
Freshwater (sediment)	0.802 mg/kg dw	0.617
Marine water (pelagic)	3.17E-4 mg/L	0.587
Marine water (sediment)	0.078 mg/kg dw	0.597
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

<b>Environment</b> FEICA 2, 3 - Formulation of Solvent Borne adhesives - Volatiles (Large Scale and Small Scale)					
Release route	Release rate (kg/day)	Release estimation method			
Water	0	SPERC (FEICA 2, 3)			
Air	227.5	SPERC (FEICA 2, 3)			
Soil	0	SPERC (FEICA 2, 3)			

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	5.96E-4 mg/L	0.11

Freshwater (sediment)	0.146 mg/kg dw	0.112
Marine water (pelagic)	4.91E-5 mg/L	0.091
Marine water (sediment)	0.012 mg/kg dw	0.092
Effluent	0 mg/L	0
Agricultural soil	0.004 mg/kg dw	0.014

EFCC2 - Formulation of Construction Chemicals - Use of Volatile substances (additives)				
Release route	Release rate (kg/day)	Release estimation method		
Water	1.265	SPERC (EFCC 2)		
Air	2.53	SPERC (EFCC 2)		
Soil	0	SPERC (EFCC 2)		

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.609
Freshwater (sediment)	0.805 mg/kg dw	0.619
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.599
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

## Risk characterisation for man via the environment

Formulation AISE 1, 5 and 7 - Formulation of Detergents/Maintenance Products: Granular Detergent – Regular (large scale), Granular Detergent -Compact (small scale), Low Viscosity Liquids (large scale)

Inhalation: RCR = 1.162E-4

Oral: RCR = 8.437E-4

#### Risk characterisation for man via the environment

Formulation AISE 2, 8 and 10 and COLIPA 1, 14 and 15 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (medium scale), Low Viscosity Liquids (medium scale), High Viscosity Liquids (large scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (large scale), body care soap (medium and large scale)

Inhalation: RCR = 7.695E-5

Oral: RCR = 8.431E-4

#### Risk characterisation for man via the environment

Formulation AISE 3, 9 and 11 and COLIPA 2 and 16 - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (small scale), Low Viscosity Liquids (small scale), High Viscosity Liquids (medium scale); Formulation Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (medium scale), body care soap (small scale)

Inhalation: RCR = 7.695E-5

Oral: RCR = 8.431E-4

**Risk characterisation for man via the environment** Formulation AISE 12 and COLIPA 3 - Formulation of Detergents/Maintenance Products: High Viscosity Liquids (small scale); Formulation of Cosmetics: low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (small scale)

Inhalation: RCR = 7.695E-5

Oral: RCR = 8.431E-4

**Risk characterisation for man via the environment** Formulation COLIPA 6 and 8 - Formulation of Cosmetics: Medium Viscosity Body Care Products (medium

scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (large scale)

Inhalation: RCR = 7.695E-5

Oral: RCR = 8.431E-4

Risk characterisation for man via the environment

Formulation AISE 4 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (large scale)

Inhalation: RCR = 5.738E-4

Oral: RCR = 8.528E-4

**Risk characterisation for man via the environment** Formulation AISE 6 - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (small scale)

Inhalation: RCR = 9.076E-5

Oral: RCR = 8.433E-4

Risk characterisation for man via the environment

Formulation COLIPA 4, 7 and 9 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (medium scale), Medium Viscosity Body Care Products (small scale), Non-liquid Creams (skin care, body care, mascara, solar oil, make-up foundation) (medium scale)

Inhalation: RCR = 7.695E-5

Oral: RCR = 8.431E-4

**Risk characterisation for man via the environment** Formulation COLIPA 5 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (small scale)

Inhalation: RCR = 7.695E-5

Oral: RCR = 8.431E-4

**Risk characterisation for man via the environment** Formulation COLIPA 10 - Formulation of Cosmetics: Non-liquid Creams (skin care, body care, mascara, solar

oil, make-up foundation) (small scale)

Inhalation: RCR = 6.651E-5

Oral: RCR = 4.986E-4

**Risk characterisation for man via the environment** CEPE 7 - Formulation of Powder Coatings and Inks – Solids

Inhalation: RCR = 7.719E-5

Oral: RCR = 8.515E-4

**Risk characterisation for man via the environment** CEPE 8, 9 - Formulation of Liquid Coatings and Inks - Large Scale and Small Scale Inhalation: RCR = 2.161E-4

Oral: RCR = 1.455E-4

**Risk characterisation for man via the environment** ESVOC 4 - Formulation of solvents and solvent based products

Inhalation: RCR = 0.002

Oral: RCR = 0.001

**Risk characterisation for man via the environment** FEICA 2, 3 - Formulation of Solvent Borne adhesives - Volatiles (Large Scale and Small Scale)

Inhalation: RCR = 0.005

Oral: RCR = 2.293E-4

**Risk characterisation for man via the environment** EFCC2 - Formulation of Construction Chemicals - Use of Volatile substances (additives)

Inhalation: RCR = 1.162E-4

Oral: RCR = 8.437E-4

#### Worker exposure Long-term, systemic Inhalation Dermal Combined **Contributing scenario Exposure estimation** Method routes Formulation in closed process, Exposure: Exposure: RCR: 0.015 Inhal: External exposure no likelihood of exposure estimation tool (Advanced $0.44 \text{ mg/m}^3$ 0.003 mg/kg liquid (PROC 1) bw/day **REACH Tool. OC:** RCR: 0.014 Concentration up to 50%. RCR: 3.857E-RMM: High level 4 containment) Derm: Extended TRA workers RCR: 0.001 Formulation in closed process, Exposure: Exposure: Inhal: External exposure no likelihood of exposure - solid 0.032 mg/m<sup>3</sup> 6.857E-4 estimation tool (Advanced (PROC 1) mg/kg bw/day REACH Tool. Concentration RCR: 0.001 up to 10%. RMM: High level RCR: 7.713Econtainment) 5 Derm: Extended TRA workers Formulation in closed, Exposure: Exposure: RCR: 0.024 Inhal: External exposure 0.014 mg/kg continuous process with $0.69 \text{ mg/m}^3$ estimation tool (Advanced occasional controlled exposure -**REACH Tool. OC:** bw/day RCR: 0.022 liquid (PROC 2) Concentration up to 50%. RMM: High level RCR: 0.002 containment) Derm: Extended TRA

workers

Formulation in closed, continuous process with occasional controlled exposure - solid (PROC 2)	Exposure: 0.036 mg/m <sup>3</sup> RCR: 0.001	Exposure: 0.003 mg/kg bw/day RCR: 3.085E- 4	RCR: 0.001	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: High level containment) Derm: Extended TRA workers
Formulation in closed batch process (synthesis or formulation) - liquid (PROC 3)	Exposure: 4.3 mg/m <sup>3</sup> RCR: 0.138	Exposure: 0.003 mg/kg bw/day RCR: 3.857E- 4	RCR: 0.139	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: Medium level containment) Derm: Extended TRA workers
Formulation in closed batch process (synthesis or formulation) - solid (PROC 3)	Exposure: 0.32 mg/m <sup>3</sup> RCR: 0.01	Exposure: 6.857E-4 mg/kg bw/day RCR: 7.713E- 5	RCR: 0.01	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: Medium level containment) Derm: Extended TRA workers
Formulation in batch and other process (synthesis) where opportunity for exposure arises - liquid (PROC 4)	Exposure: 4.4 mg/m <sup>3</sup> RCR: 0.142	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.149	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: Low level containment) Derm: Extended TRA workers
Formulation in batch and other process (synthesis) where opportunity for exposure arises - solid (PROC 4)	Exposure: 3 mg/m <sup>3</sup> RCR: 0.096	Exposure: 0.014 mg/kg bw/day RCR: 0.002	RCR: 0.098	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - liquid (PROC 5)	Exposure: 4.4 mg/m <sup>3</sup> RCR: 0.142	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.157	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: Low level containment) Derm: Extended TRA workers

Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid (PROC 5)	Exposure: 3 mg/m <sup>3</sup> RCR: 0.096	Exposure: 0.027 mg/kg bw/day RCR: 0.003	RCR: 0.1	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: Low level containment) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non- dedicated facilities - liquid (PROC 8a)	Exposure: 13 mg/m <sup>3</sup> RCR: 0.418	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.433	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non- dedicated facilities - solid (PROC 8a)	Exposure: 3.2 mg/m <sup>3</sup> RCR: 0.103	Exposure: 0.027 mg/kg bw/day RCR: 0.003	RCR: 0.106	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid (PROC 8b)	Exposure: 13 mg/m <sup>3</sup> RCR: 0.418	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.426	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid (PROC 8b)	Exposure: 3.2 mg/m <sup>3</sup> RCR: 0.103	Exposure: 0.014 mg/kg bw/day RCR: 0.002	RCR: 0.104	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (PROC 9)	Exposure: 13 mg/m <sup>3</sup> RCR: 0.418	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.426	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Transfer of substance or preparation into small containers (dedicated filling line, including	Exposure: 0.96 mg/m <sup>3</sup> RCR: 0.031	Exposure: 0.014 mg/kg bw/day	RCR: 0.032	Inhal: External exposure estimation tool (Advanced REACH Tool. OC:

weighing) - solid (PROC 9)		RCR: 0.002		Concentration up to 10%. No RMM)
				Derm: Extended TRA workers
Roller application or brushing - liquid (PROC 10)	Exposure: 16 mg/m <sup>3</sup> RCR: 0.515	Exposure: 0.137 mg/kg bw/day RCR: 0.031	RCR: 0.546	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: General ventilation) Derm: Extended TRA
				workers
Roller application or brushing - liquid (PROC 10)	Exposure: 4 mg/m <sup>3</sup> RCR: 0.129	Exposure: 0.137 mg/kg bw/day RCR: 0.031	RCR: 0.16	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 5%. No RMM)
				Derm: Extended TRA workers
Treatment of articles by dipping and pouring - liquid (PROC 13)	Exposure: 12 mg/m <sup>3</sup> RCR: 0.386	Exposure: 0.069 mg/kg bw/day RCR: 0.015	RCR: 0.401	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: LEV, general ventilation)
				Derm: Extended TRA workers
Treatment of articles by dipping and pouring - liquid (PROC 13)	Exposure: 15 mg/m <sup>3</sup> RCR: 0.482	Exposure: 0.069 mg/kg bw/day RCR: 0.015	RCR: 0.497	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 25%. RMM: General ventilation)
				Derm: Extended TRA workers
Treatment of articles by dipping and pouring - liquid (PROC 13)	Exposure: 2.2 mg/m <sup>3</sup> RCR: 0.071	Exposure: 0.069 mg/kg bw/day RCR: 0.015	RCR: 0.086	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 5%. No RMM)
				Derm: Extended TRA workers
Formulation of preparations or articles by tabletting, compression, extrusion, pelletisation - solid (PROC 14)	Exposure: 0.32 mg/m <sup>3</sup> RCR: 0.01	Exposure: 0.007 mg/kg bw/day RCR: 7.713E- 4	RCR: 0.011	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA

				workers
Use as laboratory reagent - liquid (PROC 15)	Exposure: 4.2 mg/m <sup>3</sup> RCR: 0.135	Exposure: 0.003 mg/kg bw/day RCR: 3.857E- 4	RCR: 0.135	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Use as laboratory reagent - solid (PROC 15)	Exposure: 0.092 mg/m <sup>3</sup> RCR: 0.003	Exposure: 6.857E-4 mg/kg bw/day RCR: 7.713E- 5	RCR: 0.003	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers

### Acute systemic

Not required as no hazard identified

### Local effects via inhalation route

Not required as no hazard identified

#### Local effects via dermal route

A qualitative approach was used to assess the risk of sensitization in accordance with REACH Guidance R.8 (moderate hazard level). The use of gloves and generic organisational measures were proposed as Risk Management Measures to control the risk. Residual exposure was quantitatively estimated and assessed.

Contributing scenario	Acute	Long term	Exposure estimation Method
Formulation in closed process, no likelihood of exposure - liquid (PROC 1)	Exposure: 0.002 mg/cm <sup>2</sup> RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation in closed process, no likelihood of exposure - solid (PROC 1)	Exposure: 3.99E-4 mg/cm <sup>2</sup> RCR: 0.002	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation in closed, continuous process with occasional controlled exposure - liquid (PROC 2)	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation in closed, continuous process with occasional controlled exposure - solid (PROC 2)	Exposure: 8.75E-4 mg/cm <sup>2</sup> RCR: 0.005	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation in closed batch process (synthesis or formulation) - liquid (PROC 3)	Exposure: 0.002 mg/cm <sup>2</sup>	N/A	Acute: External exposure estimation tool (Quantitative

	RCR: 0.011		assessment of residual exposure)
Formulation in closed batch process (synthesis or formulation) - solid (PROC 3)	Exposure: 3.99E-4 mg/cm <sup>2</sup>	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
	RCR: 0.002		
Formulation in batch and other process (synthesis) where opportunity for exposure arises - liquid (PROC 4)	Exposure: 0.02 mg/cm <sup>2</sup> RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation in batch and other process (synthesis) where opportunity for exposure arises - solid (PROC 4)	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - liquid (PROC 5)	Exposure: 0.04 mg/cm <sup>2</sup> RCR: 0.215	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid (PROC 5)	Exposure: 0.008 mg/cm <sup>2</sup> RCR: 0.043	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - liquid (PROC 8a)	Exposure: 0.01 mg/cm <sup>2</sup> RCR: 0.054	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid (PROC 8a)	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid (PROC 8b)	Exposure: 0.02 mg/cm <sup>2</sup> RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid (PROC 8b)	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (PROC 9)	Exposure: 0.02 mg/cm <sup>2</sup> RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative exposure of residual exposure)
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid (PROC 9)	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative exposure of residual exposure)
Roller application or brushing - liquid (PROC 10)*	Exposure: 0.02 mg/cm <sup>2</sup> RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
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Treatment of articles by dipping and pouring - liquid (PROC 13)*	Exposure: 0.02 mg/cm² RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Formulation of preparations or articles by tabletting, compression, extrusion, pelletisation - solid (PROC 14)	Exposure: 0.002 mg/cm <sup>2</sup> RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use as laboratory reagent - liquid (PROC 15)	Exposure: 0.002 mg/cm <sup>2</sup> RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use as laboratory reagent - solid (PROC 15)	Exposure: 3.99E-4 mg/cm <sup>2</sup> RCR: 0.002	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)

\*Exposure estimation and risk characterisation was based on long term systemic dermal exposure value and therefore this value is identical for all concentrations.

## 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

#### **Environment**

The daily amount per site as mentioned in section 2.1 is the maximum amount (kg/day) that may be safely used, taking into account the default operational conditions as specified in section 2.1 and the release fractions as specified in section 3. This amount is defined as  $M_{Safe}$ .

To evaluate the compliance of specific formulation, the site-specific substance use rate ( $M_{Site}$ ) and days emitting ( $T_{Emission, Site}$ ), onsite and offsite emission controls and subsequent total substance emission Reduction Efficiency ( $RE_{Total, Site} = 1 - [(1 - RE_{Onsite, Site}) \times (1 - RE_{Offsite, Site})]$ ), sewage treatment plant effluent flow rate ( $G_{Effluent, Site}$ ) and receiving water dilution factor ( $q_{Site}$ ) need to be known.

It is simpler and thus may be preferable to some users to compare  $M_{Site}$  with  $M_{Safe}$ . Adequate control of risk exists if the following conditions are met:  $[RE_{Total, Site} \ge RE_{Total, SpERC}, G_{Effluent, Site} \ge G_{Effluent, SpERC}, and q_{Site} \ge q_{SpERC}]$  and  $M_{Safe} \ge M_{Site}$ .

In case the above comparison does not show safe use, the following scaling possibilities are advised:

- The risk is driven by soil for nearly all formulation contributing scenarios. As a default it is assumed that STP sludge is applied on agricultural soil. However this may not always be the case. If the STP sludge is not applied to soil, the RCR for agricultural soil will decrease significantly and therefore the amount that may be used will increase.
- When STP sludge is not applied to soil, the risk will be driven by surface water and sediment. The RCR for these protection targets is lower and therefore the volume can be increased with a factor of approximately 1.7 assuming all other conditions stay equal. If the volume is then not yet high enough, scaling based on municipal STP discharge rate and receiving river flow rate is advised.
- As mentioned in section 3, degradation in the STP has been calculated according to first-order kinetics in the model EUSES. This implies that the concentration in the effluent is proportional to the concentration in the influent and so the predicted concentration in effluent depends on the use volume. An alternative approach is to use Monod kinetics in EUSES. This can be applied for readily

biodegradable substances in case: a) the release to the WWTP/STP is more or less continuous so the specific bacteria responsible for biodegradation will be able to maintain themselves in the system and b) the total COD load remains within the specifications of the WWTP/STP. When this approach is applied, the substance concentration in the STP effluent is independent of the concentration in the influent and therefore the use volume, and will remain below 50  $\mu$ g/l. This implies that under these circumstances M<sub>safe</sub> is theoretically unlimited.

#### Human health

A DU works within the boundaries of this ES if he fulfills the conditions of use set in section 2. Table 4.1 provides an overview of the assumed effectiveness for the different RMM. The DU can use this effectiveness estimation in order to assess if any deviating RMM will also provide safe use. This is done by multiplying the relevant RCR with the effectiveness of the RMM implemented at the workplace and dividing it by the effectiveness of the RMM listed in section 2. If the shift duration is greater than 8 hours per day, the long term systemic DNELs have to be adapted with the using the following equation, derived from the Brief and Scala model: DNEL Reduction Factor =  $(8 \text{ x hours worked in shift}) \times ((24 - \text{hours worked in shift}) / 16)$ . This equation can not be used to adapt a DNEL for a shift duration shorter than 8 hours. With the adapted DNEL, the DU can recalculate the RCR by dividing the exposure estimation in section 3 with the adapted DNEL. If the RCR is smaller than 0.725 (1 - 0.275 or 1 - (Sum of all man through environment and generic consumer exposure), the downstreamuser works within the boundaries set by the ES.

Risk management measure	Assumed effectiveness <sup>3</sup>		Source of effectiveness	
	Inhalatory	Dermal		
High level containment - Process fully	99.9%	99.9%	Advanced REACH tool (www.advancedreachtool.com).	
enclosed (air tight) and the integrity of the				
enclosure is monitored at least once a				
month (containment is not breached).				
Medium level containment - Undertake	99%	33%	Advanced REACH tool (www.advancedreachtool.com) for	
operation under enclosed conditions.			the inhalatory effectiveness, the dermal effectiveness is	
			assumed to be 1/3 of the inhalatory effectiveness.	
Low level containment - Put lids on	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for	
containers immediately after use.			the inhalatory effectiveness, the dermal effectiveness is	
			assumed to be 1/3 of the inhalatory effectiveness.	
Working outdoor / natural ventilation	30%	-	Advanced REACH tool (www.advancedreachtool.com)	
General ventilation (mechanical)	50%	-	Advanced REACH tool (www.advancedreachtool.com).	
Local exhaust ventilation, fixed capturing	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for	
hood			the inhalatory effectiveness, the dermal effectiveness is	
			assumed to be 1/3 of the inhalatory effectiveness.	
Local exhaust ventilation, other system	50%	17%	Advanced REACH tool (www.advancedreachtool.com) for	
			the inhalatory effectiveness, the dermal effectiveness is	
			assumed to be 1/3 of the inhalatory effectiveness.	
Laminar flow booth	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for	
			the inhalatory effectiveness, the dermal effectiveness is	
			assumed to be 1/3 of the inhalatory effectiveness.	
Respirator (Wear a full face respirator	95%	Not	Advanced REACH tool (www.advancedreachtool.com).	
conforming to EN140 with Type A / P2		applicable		
filter or better. APF >20))				
Respirator (Wear a respirator (half face	90%	Not	Advanced REACH tool (www.advancedreachtool.com).	
mask) conforming to EN140 with Type A		applicable		
filter / P2 filter or better. APF >10)				
Reduction of duration of exposure			ECETOC TRA (http://www.ecetoc.org/tra) for the	
$> 60$ and $\leq 240$ minutes per shift	40%	40%	inhalatory effectiveness, expert judgment for dermal	
$> 15$ and $\leq = 60$ minutes per shift	80%	80%	effectiveness.	
<= 15 minutes per shift	90%	80%		
Concentration of substance in mixture			ECETOC TRA (http://www.ecetoc.org/tra) for the	
> 5% and <= 25%	40%	75%	inhalatory effectiveness, expert judgment for dermal	
> 1% and <= 5%	80%	95%	effectiveness.	
<= 1%	90%	99%		

Table 4.1 Effectiveness of risk management measures (RMM).

<sup>&</sup>lt;sup>3</sup> All effectiveness's listed are only valid if the RMM is properly designed, installed (if applicable), used and maintained.

# 4. ES 4: Industrial end-use (SU 3); Industrial use

1. Title of Exposure scenario	
Environment:	ERC 4, 5
* Industrial use of fragranced products * CEDE 15, 16a, Other sprey costing, Volatiles / Abstement including indeer point courses	
* CEPE 15, 10a - Other spray coating - Volatiles / Adatement including indoor point sources	
* ESVOC 11 - Industrial use of solvents in oil field drilling and production operations	
* ESVOC 13 - Industrial use of formulated lubricants	
* ESVOC 38 - Use of the substance within laboratory setting, including pilot plants	
* FEICA 6, / - Industrial Use of Substances other than Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation	
(Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others	
* FEICA 8,9 - Industrial Use of Solvents in Paper, Board and related Products/ Woodworking and	
joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial	
Building Construction Adhesives/Others adhesives	
Worker	
Use in closed process, no likelihood of exposure - liquid	PROC 1
Use in closed process, no likelihood of exposure - solid	PROC 1
Use in closed, continuous process with occasional controlled exposure - liquid	PROC 2
Use in closed, continuous process with occasional controlled exposure - solid	PROC 2
Use in closed batch process - liquid	PROC 3
Use in closed batch process - solid	PROC 3
Use in batch and other process where opportunity for exposure arises - liquid	PROC 4
Use in batch and other process where opportunity for exposure arises - solid	PROC 4
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - liquid	PROC 5
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid	PROC 5
Industrial and non-industrial spraying - liquid	PROC 7
	PROC 11
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non- dedicated facilities - liquid	PROC 8a
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non- dedicated facilities - solid	PROC 8a
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid	PROC 8b
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid	PROC 8b
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid	PROC 9
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid	PROC 9
Roller application or brushing - liquid	PROC 10
Treatment of articles by dipping and pouring - liquid	PROC 13
Production of preparations or articles by tabletting, compression, extrusion, pelletisation - solid	PROC 14
Use as laboratory reagent - liquid	PROC 15
Use as laboratory reagent - solid	PROC 15

Hand-mixing with intimate contact and only PPE available - liquid

## PROC 19

2. Conditions of use affecting exposure
Control of environmental exposure for Industrial use of fragranced products is included under Chapter 6.
<b>2.1 Control of environmental exposure:</b> CEPE 15, 16a - Other spray coating - Volatiles / Abatement including indoor point sources
CEPE 17a - Other spray coating, indoor use - point sources – Solids
ESVOC 11 - Industrial use of solvents in oil field drilling and production operations
ESVOC 13 - Industrial use of formulated lubricants
ESVOC 38 - Use of the substance within laboratory setting, including pilot plants
FEICA 6,7 - Industrial Use of Substances other than Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others
FEICA 8,9 - Industrial Use of Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others adhesives
<b>2.1.1 Control of environmental exposure:</b> CEPE 15, 16a - Other spray coating - Volatiles / Abatement including indoor point sources (ERC 4)
Amounts used
Daily amount per site <= 0.063 tonnes/day
Annual amount per site <= 13.86 tonnes/year
Frequency and duration of use
Emission days / year = $220 \text{ days/year}$
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4 \text{ m}^{3/d}$
Conditions and measures related to municipal sewage treatment plant
wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3 \text{ m3/d}$
STP sludge is applied on agricultural soil
<b>2.1.2 Control of environmental exposure:</b> CEPE 17a - Other spray coating, indoor use - point sources – Solids (ERC 5)
Amounts used
Daily amount per site <= 9.1 tonnes/day
Annual amount per site <= 2E3 tonnes/year
Frequency and duration of use
Emission days / year = 220 days/year
Other given operational conditions affecting environmental exposure

Receiving river flow rate >= 1.8E4 m3/d

Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\ge 2E3 \text{ m}3/\text{d}$
STP sludge is applied on agricultural soil
<b>2.1.3 Control of environmental exposure:</b> ESVOC 11 - Industrial use of solvents in oil field drilling and production operations (ERC 4)
Amounts used
Daily amount per site <= 0.018 tonnes/day
Annual amount per site <= 0.543 tonnes/year
Frequency and duration of use
Emission days / year = 30 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4 \text{ m}3/d$
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\ge 2E3 \text{ m}3/\text{d}$
STP sludge is applied on agricultural soil
2.1.4 Control of environmental exposure: ESVOC 13 - Industrial use of formulated lubricants (ERC 4)
Amounts used
Daily amount per site <= 42.2 tonnes/day
Annual amount per site <= 844 tonnes/year
Frequency and duration of use
Emission days / year = 20 days/year
Other given operational conditions affecting environmental exposure
Receiving river flow rate $\geq 1.8E4 \text{ m}3/d$
Conditions and measures related to municipal sewage treatment plant
Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).
Municipal STP discharge rate $\geq 2E3 \text{ m}3/\text{d}$
STP sludge is applied on agricultural soil
<b>2.1.5 Control of environmental exposure:</b> ESVOC 38 - Use of the substance within laboratory setting, including pilot plants (ERC 4)
Amounts used
Daily amount per site <= 0.063 tonnes/day
Annual amount per site <= 1.264 tonnes/year
Frequency and duration of use

Emission days / year = 20 days/year

### Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

**2.1.6 Control of environmental exposure:** FEICA 6, 7 - Industrial Use of Substances other than Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others (ERC 5)

Amounts used

Daily amount per site <= 12.5 tonnes/day

Annual amount per site <= 2.75E3 tonnes/year

Frequency and duration of use

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

**2.1.7 Control of environmental exposure:** FEICA 8, 9 - Industrial Use of Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others adhesives (ERC 5)

Amounts used

Daily amount per site <= 1.25 tonnes/day

Annual amount per site <= 275 tonnes/year

Frequency and duration of use

Emission days / year = 220 days/year

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

<b>2.2 Control of workers exposure for</b> Use in closed process, no likelihood of exposure - liquid (PROC 1)
Product characteristics
Covers concentrations on to: 50%
Covers concentrations up to: 50%.
Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: One hand face only (240 cm2).
Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. *Open surface 1-3 m <sup>2</sup> .
Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
2.3 Control of workers exposure for Use in closed process, no likelihood of exposure - solid (PROC 1)
Product characteristics
Covers concentrations up to: 10%
Solid, medium dustiness.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Exposed skin surface assumed: One hand face only (240 cm2)
Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation
*For each use event, covers use amounts up to 100-1000 kg.
Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).
Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.4 Control of workers exposure for Use in closed, continuous process with occasional controlled exposure - liquid (PROC 2)

## Product characteristics

Covers concentrations up to: 50%

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

#### Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm2).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. \*Open surface 1-3 m<sup>2</sup>.

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Transfer of liquid products - falling liquids

\*Splash loading.

\*Avoid carrying out operation for more than 0.5 hour.

\*For each use event, covers use amounts up to 0.1-1 l/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.5 Control of workers exposure for** Use in closed, continuous process with occasional controlled exposure - solid (**PROC 2**)

## **Product characteristics**

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm2)

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

\*For each use event, covers use amounts up to 100-1000 kg.

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

*Transfer of solid products - falling powders.* \*Avoid carrying out operation for more than 0.5 hour. \*For each use event, covers use amounts up to 0.1-1 kg/minute.

Handling that reduces contact between product and adjacent air.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.6 Control of workers exposure for Use in closed batch process - liquid (PROC 3)

Product characteristics

Covers concentrations up to: 50%

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: One hand face only (240 cm2).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. \* Open surface 1-3 m<sup>2</sup>.

Use in closed batch process (synthesis or formulation).

Transfer of liquid products - falling liquids.

\*Splash loading.

\*Avoid carrying out operation for more than 0.5 hour.

\*For each use event, covers use amounts up to 0.1-1 l/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision

controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.7 Control of workers exposure for Use in closed batch process - solid (PROC 3)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: One hand face only (240 cm2).

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

\*For each use event, covers use amounts up to 100-1000 kg.

Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).

Transfer of solid products - falling powders.

\*Avoid carrying out operation for more than 0.5 hour. \*For each use event, covers use amounts up to 0.1-1 kg/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.8 Control of workers exposure for** Use in batch and other process where opportunity for exposure arises - liquid (**PROC 4**)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands face (480 cm2).

Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. \* Open surface 1-3 m<sup>2</sup>.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Put lids on containers immediately after use.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.9 Control of workers exposure for** Use in batch and other process where opportunity for exposure arises - solid (**PROC 4**)

Product characteristics

Covers concentrations up to: 10%

Solid, medium dustiness.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

Other operational conditions affecting workers exposure

Indoor use.

Exposed skin surface assumed: Two hands face (480 cm2).

Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation.

\*For each use event, covers use amounts up to 100-1000 kg.

Transfer of solid products - falling powders.

\*Avoid carrying out operation for more than 0.5 hour. \*For each use event, covers use amounts up to 10-100 g/minute.

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Put lids on containers immediately after use.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.10 Control of workers exposure for** Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - liquid (**PROC 5**)

Product characteristics

Covers concentrations up to: 50%.

Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: Two hands face (480 cm2).
Activities with open liquid surfaces or open reservoirs - activity with agitated surfaces. *Open surface 1-3 m <sup>2</sup> .
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Put lids on containers immediately after use.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
<b>2.11 Control of workers exposure for</b> Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid ( <b>PROC 5</b> )
Product characteristics
Covers concentrations up to: 10%
Solid, medium dustiness.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Exposed skin surface assumed: Two hands face (480 cm2).
Movement and open agitation of powders, granules or pelletised material - handling with high level of
agitation. *For each use event, covers use amounts up to 100-1000 kg.
<i>Transfer of solid products - falling powders.</i> *Avoid carrying out operation for more than 0.5 hour. *For each use event, covers use amounts up to 10-100 g/minute.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Put lids on containers immediately after use.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision

controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

2.12 Control of workers exposure for Industrial and non-industrial spraying - liquid (PROC 7 and 11)

## Product characteristics

Covers concentrations up to: 50%.

Liquid.

#### Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

#### Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are at room temperature.

Exposed skin surface assumed: Two hands and upper wrists (1500 cm2).

Handling of contaminated objects  $(0.3-1 \text{ m}^2)$  - Contamination > 90 % of surface. \*Avoid carrying out operation for more than 4 hours.

Surface spraying with no or low compressed air use. \*Avoid carrying out operation for more than 4 hours.

Industrial: \*Moderate application rate (0.3 - 3 l/minute) \*Ensure that spray direction is only horizontal or downward.

Professional: \*Low application rate (0.03 - 0.3 l/minute) \*Ensure that spray direction is only downward.

For dissolving solids:

*Transfer of solid products - falling powders.* \*Avoid carrying out operation for more than 0.5 hour.

Outdoor use.

Assumes activities are at room temperature.

Professional Use of Façade/surface Cleaning Products.

Covers percentage substance in the product up to 25 %.

Surface spraying with no or low compressed air use. \*Low application rate (0.03 - 0.3 l/minute). \*In any direction (including upwards).

\*Stay upwind/keep distance from source.

Covers percentage substance in the product up to 5 %.
Spraying with high compressed air use. *Moderate application rate (0.3 - 3 l/minute). *In any direction (including upwards). *Stay upwind/keep distance from source.
Technical and organisational conditions and measures
General measures applicable to all activities:
Demonstrable and effective housekeeping practices are in place.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
For industrial use concentration >10%: Spraying: * Carry out in a vented booth provided with laminar airflow. * Use in room with a volume of minimum [m3]: 300 m <sup>3</sup> . * Mechanical ventilation giving at least [ACH]: 1. Handling: * Local exhaust ventilation - efficiency of at least [%]: 90%.
<ul> <li>For professional use concentration &gt;10%:</li> <li>*During spraying: Local exhaust ventilation - efficiency of at least [%]: 50%, or: Wear a half-mask respirator, selected in accordance with EN529 - efficiency of at least [%]: 50%.</li> <li>*During handling: Local exhaust ventilation - efficiency of at least [%]: 90%, or: Wear a half-mask respirator, selected in accordance with EN529 - efficiency of at least [%]: 90%.</li> <li>*Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).</li> </ul>
<i>For professional use concentration &lt;10%:</i> * Provide a good standard of general ventilation. Natural ventilation is from doors, windows etc. Controlled ventilation means air is supplied or removed by a powered fan.
<b>2.13 Control of workers exposure for</b> Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - liquid ( <b>PROC 8a</b> )
Product characteristics
Covers concentrations up to: 50%.
Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: Two hands (960 cm2).
Transfer of liquid products - falling liquids.

*Submerged loading. *For each use event, covers use amounts up to 100-1000 l/minute.
Handling that reduces contact between product and adjacent air.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
<b>2.14 Control of workers exposure for</b> Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid ( <b>PROC 8a</b> )
Product characteristics
Covers concentrations up to: 10%
Solid, medium dustiness.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Exposed skin surface assumed: Two hands (960 cm2).
Transfer of solid products - falling powders. *For each use event, covers use amounts up to 100-1000 kg/minute.
Handling that reduces contact between product and adjacent air.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
<b>2.15 Control of workers exposure for</b> Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid ( <b>PROC 8b</b> )
Product characteristics
Covers concentrations up to: 50%.
Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure

Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: Two hands face (480 cm2).
Transfer of liquid products - falling liquids. *Submerged loading. *For each use event, covers use amounts up to 100-1000 l/minute.
Handling that reduces contact between product and adjacent air.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
<b>2.16 Control of workers exposure for</b> Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid ( <b>PROC 8b</b> )
Product characteristics
Covers concentrations up to: 10%
Solid, medium dustiness.
Amount used, frequency and duration of use/exposure
Amount used, frequency and duration of use/exposure         Covers daily exposures up to 8 hours (unless stated differently).
Amount used, frequency and duration of use/exposure         Covers daily exposures up to 8 hours (unless stated differently).         Other operational conditions affecting workers exposure
Amount used, frequency and duration of use/exposure         Covers daily exposures up to 8 hours (unless stated differently).         Other operational conditions affecting workers exposure         Indoor use.
Amount used, frequency and duration of use/exposure         Covers daily exposures up to 8 hours (unless stated differently).         Other operational conditions affecting workers exposure         Indoor use.         Exposed skin surface assumed: Two hands face (480 cm2).
Amount used, frequency and duration of use/exposure         Covers daily exposures up to 8 hours (unless stated differently).         Other operational conditions affecting workers exposure         Indoor use.         Exposed skin surface assumed: Two hands face (480 cm2).         Transfer of solid products - falling powders.         *For each use event, covers use amounts up to 100-1000 kg/minute.
Amount used, frequency and duration of use/exposure         Covers daily exposures up to 8 hours (unless stated differently).         Other operational conditions affecting workers exposure         Indoor use.         Exposed skin surface assumed: Two hands face (480 cm2).         Transfer of solid products - falling powders.         *For each use event, covers use amounts up to 100-1000 kg/minute.         Handling that reduces contact between product and adjacent air.
Amount used, frequency and duration of use/exposure         Covers daily exposures up to 8 hours (unless stated differently).         Other operational conditions affecting workers exposure         Indoor use.         Exposed skin surface assumed: Two hands face (480 cm2). <i>Transfer of solid products - falling powders.</i> *For each use event, covers use amounts up to 100-1000 kg/minute.         Handling that reduces contact between product and adjacent air.         Technical and organisational conditions and measures
Amount used, frequency and duration of use/exposure         Covers daily exposures up to 8 hours (unless stated differently).         Other operational conditions affecting workers exposure         Indoor use.         Exposed skin surface assumed: Two hands face (480 cm2).         Transfer of solid products - falling powders.         *For each use event, covers use amounts up to 100-1000 kg/minute.         Handling that reduces contact between product and adjacent air.         Technical and organisational conditions and measures         Demonstrable and effective housekeeping practices are in place.
Amount used, frequency and duration of use/exposure         Covers daily exposures up to 8 hours (unless stated differently).         Other operational conditions affecting workers exposure         Indoor use.         Exposed skin surface assumed: Two hands face (480 cm2).         Transfer of solid products - falling powders.         *For each use event, covers use amounts up to 100-1000 kg/minute.         Handling that reduces contact between product and adjacent air.         Technical and organisational conditions and measures         Demonstrable and effective housekeeping practices are in place.         Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Amount used, frequency and duration of use/exposure         Covers daily exposures up to 8 hours (unless stated differently).         Other operational conditions affecting workers exposure         Indoor use.         Exposed skin surface assumed: Two hands face (480 cm2).         Transfer of solid products - falling powders.         *For each use event, covers use amounts up to 100-1000 kg/minute.         Handling that reduces contact between product and adjacent air.         Technical and organisational conditions and measures         Demonstrable and effective housekeeping practices are in place.         Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.         Use suitable eye protection.
Amount used, frequency and duration of use/exposure         Covers daily exposures up to 8 hours (unless stated differently).         Other operational conditions affecting workers exposure         Indoor use.         Exposed skin surface assumed: Two hands face (480 cm2).         Transfer of solid products - falling powders.         *For each use event, covers use amounts up to 100-1000 kg/minute.         Handling that reduces contact between product and adjacent air.         Technical and organisational conditions and measures         Demonstrable and effective housekeeping practices are in place.         Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.         Use suitable eye protection.         Wear suitable coveralls to prevent exposure to the skin.
Amount used, frequency and duration of use/exposure         Covers daily exposures up to 8 hours (unless stated differently).         Other operational conditions affecting workers exposure         Indoor use.         Exposed skin surface assumed: Two hands face (480 cm2). <i>Transfer of solid products - falling powders.</i> *For each use event, covers use amounts up to 100-1000 kg/minute. <i>Handling that reduces contact between product and adjacent air</i> .         Technical and organisational conditions and measures         Demonstrable and effective housekeeping practices are in place.         Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.         Use suitable eye protection.         Wear suitable coveralls to prevent exposure to the skin.         2.17 Control of workers exposure for Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (PROC 9)
Amount used, frequency and duration of use/exposure         Covers daily exposures up to 8 hours (unless stated differently).         Other operational conditions affecting workers exposure         Indoor use.         Exposed skin surface assumed: Two hands face (480 cm2).         Transfer of solid products - falling powders.         *For each use event, covers use amounts up to 100-1000 kg/minute.         Handling that reduces contact between product and adjacent air.         Technical and organisational conditions and measures         Demonstrable and effective housekeeping practices are in place.         Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.         Use suitable coveralls to prevent exposure to the skin.         2.17 Control of workers exposure for Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (PROC 9)         Product characteristics

Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: Two hands face (480 cm2).
Transfer of liquid products - falling liquids. *Splash loading. *For each use event, covers use amounts up to 10, 100 l/minute.
Technical and organisational conditions and measures
reclinical and of gainsational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
<b>2.18 Control of workers exposure for</b> Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid ( <b>PROC 9</b> )
Product characteristics
Covers concentrations up to: 10%
Solid, medium dustiness.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Exposed skin surface assumed: Two hands face (480 cm2).
<i>Transfer of solid products - falling powders.</i> *For each use event, covers use amounts up to 10-100 kg/minute.
Handling that reduces contact between product and adjacent air.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.
<b>2.19 Control of workers exposure for</b> Roller application or brushing - liquid ( <b>PROC 10</b> )
Product characteristics
Covers concentrations up to: 50%
Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: Two hands (960 cm2).
Spreading of liquid products (0.3-1.0 m <sup>2</sup> ) *Avoid carrying out operation for more than 4 hours
Handling of contaminated objects (0.3-1.0 m <sup>2</sup> ) - Contamination > 90 % of surface. *Avoid carrying out operation for more than 4 hours.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
Use above 5% concentration:
*Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).
(PROC 13)
Product characteristics
Covers concentrations up to: 50%.
Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: Two hands face (480 cm2).
Activities with open liquid surfaces or open reservoirs - activity with undisturbed surfaces (no aerosol formation).

\*Use above 25% concentration: Open surface 1-3 m<sup>2</sup> \*Open surface 0.3-1 m<sup>2</sup> \*Avoid carrying out operation for more than 4 hours. Handling of contaminated objects  $(0.3-1.0 \text{ m}^2)$  - Contamination > 90 % of surface. \*Avoid carrying out operation for more than 4 hours. Technical and organisational conditions and measures Demonstrable and effective housekeeping practices are in place. Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Use suitable eye protection. Wear suitable coveralls to prevent exposure to the skin. Use between 5- 25% concentration: \*Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour). Use above 25% concentration: \*Local exhaust ventilation - efficiency of at least [%]: 50. \*Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour). 2.21 Control of workers exposure for Production of preparations or articles by tabletting, compression, extrusion, pelletisation - solid (PROC 14) **Product characteristics** Covers concentrations up to: 10% Solid, low dustiness. Amount used, frequency and duration of use/exposure Covers daily exposures up to 8 hours (unless stated differently). Other operational conditions affecting workers exposure Indoor use. Exposed skin surface assumed: Two hands face (480 cm2). Tabletting, compression, extrusion or pelletisation. \*For each use event, covers use amounts up to 100-1000 kg/minute. Technical and organisational conditions and measures Demonstrable and effective housekeeping practices are in place. Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Use suitable eye protection. Wear suitable coveralls to prevent exposure to the skin. 2.22 Control of workers exposure for Use as laboratory reagent - liquid (PROC 15) **Product characteristics** Covers concentrations up to: 50%.

Liquid.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Assumes activities are at room temperature.
Exposed skin surface assumed: One hand face only (240 cm2).
Activities with open liquid surfaces or open reservoirs - activity with undisturbed surfaces (no aerosol formation). *Open surface < 0.1 m <sup>2</sup>
Transfer of liquid products - falling liquids. *Splash loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to 0.1-1 l/minute.
*Submerged loading. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to $<0.1$ l/minute. Handling that reduces contact between product and adjacent air.
Technical and organisational conditions and measures
Demonstrable and effective housekeeping practices are in place.
Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.
Use suitable eye protection.
Wear suitable coveralls to prevent exposure to the skin.
2.23 Control of workers exposure for Use as laboratory reagent - solid (PROC 15)
Product characteristics
Covers concentrations up to: 10%
Solid, medium dustiness.
Amount used, frequency and duration of use/exposure
Covers daily exposures up to 8 hours (unless stated differently).
Other operational conditions affecting workers exposure
Indoor use.
Exposed skin surface assumed: One hand face only (240 cm2).
Movement and open agitation of powders, granules or pelletised material - handling with high level of agitation. *For each use event, covers use amounts up to <10 gram/minute.
Transfer of solid products - falling powders. *Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to 10-100 gram/minute. *Carefully handle the substance to minimise releases. Ensure operatives are trained to minimise exposures. Avoid carrying out operation for more than 0.5 hour. For each use event, covers use amounts up to <10 gram/minute.

#### Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

**2.24 Control of workers exposure for** Hand-mixing with intimate contact and only PPE available - liquid (**PROC 19**)

Product characteristics

Covers concentrations up to: 50%.

Liquid.

Amount used, frequency and duration of use/exposure

Covers daily exposures up to 8 hours (unless stated differently).

#### Other operational conditions affecting workers exposure

Indoor use.

Assumes activities are above room temperature.

Exposed skin surface assumed: Two hands and forearms (1980 cm2).

Hand-mixing with intimate contact and only PPE available. \*For concentration >10% and large scale (1-3 m<sup>2</sup>): Assumes large workrooms. \*Small acade (0.2.1 m<sup>2</sup>)

\*Small scale  $(0.3-1 \text{ m}^2)$ .

Technical and organisational conditions and measures

Demonstrable and effective housekeeping practices are in place.

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls.

Use suitable eye protection.

Wear suitable coveralls to prevent exposure to the skin.

*For concentration* >10%:

\* Local exhaust ventilation - efficiency of at least [%]: 50%.

\* Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

3. Exposure esti	mation and reference to its source	
The environment Degradation in the	tal exposure estimates were calculate ne STP was calculated according to a	ed according to EUSES version 2.1.2. first-order kinetics.
<b>Environment</b> CEPE 15, 16a - 0	Other spray coating - Volatiles / Aba	itement including indoor point sources
Release route	Release rate (kg/day)	Release estimation method
Water	1.26	SPERC (CEPE 15, 16a)
Air	61.74	SPERC (CEPE 15, 16a)

Soil	0	SPERC
		(CEPE 15, 16a)

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.606
Freshwater (sediment)	0.802 mg/kg dw	0.617
Marine water (pelagic)	3.17E-4 mg/L	0.587
Marine water (sediment)	0.078 mg/kg dw	0.597
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

Environment CEPE 17a - Other spray coating, indoor use - point sources – Solids			
Release route	Release rate (kg/day)	Release estimation method	
Water	0	SPERC (CEPE 17a)	
Air	200.2	SPERC (CEPE 17a)	
Soil	0	SPERC (CEPE 17a)	

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	5.96E-4 mg/L	0.11
Freshwater (sediment)	0.146 mg/kg dw	0.112
Marine water (pelagic)	4.91E-5 mg/L	0.091
Marine water (sediment)	0.012 mg/kg dw	0.092
Effluent	0 mg/L	0
Agricultural soil	0.003 mg/kg dw	0.012

Environment ESVOC 11 - Industrial use of solvents in oil field drilling and production operations			
Release route         Release rate (kg/day)         Release estimation method			
Water	1.267	Other method	
Air	0.5	Other method	
Soil	0	Other method	

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.62
Freshwater (sediment)	0.819 mg/kg dw	0.63
Marine water (pelagic)	3.23E-4 mg/L	0.598
Marine water (sediment)	0.079 mg/kg dw	0.608
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

## Environment

ESVOC 13 - Industrial use of formulated lubricants			
Release route	Release rate (kg/day)	Release estimation method	
Water	1.266	SPERC (ESVOC 13)	
Air	63.3	SPERC (ESVOC 13)	
Soil	0	SPERC (ESVOC 13)	

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.609
Freshwater (sediment)	0.805 mg/kg dw	0.619
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.599
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

<b>Environment</b> ESVOC 38 - Use of the substance within laboratory setting, including pilot plants			
Release route	Release rate (kg/day)     Release estimation method		
Water	1.264	SPERC (ESVOC 38)	
Air	1.58	SPERC (ESVOC 38)	
Soil	0	SPERC (ESVOC 38)	

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.607
Freshwater (sediment)	0.804 mg/kg dw	0.618
Marine water (pelagic)	3.18E-4 mg/L	0.589
Marine water (sediment)	0.078 mg/kg dw	0.598
Effluent	0.027 mg/L	0.013
Agricultural soil	0.261 mg/kg dw	1

## Environment

FEICA 6,7 - Industrial Use of Substances other than Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others

Release route	Release rate (kg/day)	Release estimation method
Water	0	SPERC (FEICA 6, 7)
Air	212.5	SPERC (FEICA 6, 7)
Soil	0	SPERC (FEICA 6, 7)

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	5.96E-4 mg/L	0.11
Freshwater (sediment)	0.146 mg/kg dw	0.112
Marine water (pelagic)	4.91E-5 mg/L	0.091
Marine water (sediment)	0.012 mg/kg dw	0.092
Effluent	0 mg/L	0
Agricultural soil	0.003 mg/kg dw	0.013

#### Environment

FEICA 8, 9 - Industrial Use of Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others adhesives

Release route	Release rate (kg/day)	Release estimation method
Water	0	SPERC (FEICA 8, 9)
Air	250	SPERC (FEICA 8, 9)
Soil	0	SPERC (FEICA 8, 9)

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	5.96E-4 mg/L	0.11
Freshwater (sediment)	0.146 mg/kg dw	0.112
Marine water (pelagic)	4.91E-5 mg/L	0.091
Marine water (sediment)	0.012 mg/kg dw	0.092
Effluent	0 mg/L	0
Agricultural soil	0.004 mg/kg dw	0.015

Risk characterisation for man via the environment

CEPE 15, 16a - Other spray coating - Volatiles / Abatement including indoor point sources

Inhalation: RCR = 0.001

Oral: RCR = 8.639E-4

**Risk characterisation for man via the environment** CEPE 17a - Other spray coating, indoor use - point sources – Solids

Inhalation: RCR = 0.004

Oral: RCR = 2.19E-4

**Risk characterisation for man via the environment** ESVOC 11 - Industrial use of solvents in oil field drilling and production operations

Inhalation: RCR = 6.723E-5

Oral: RCR = 5.278E-4

**Risk characterisation for man via the environment** ESVOC 13 - Industrial use of formulated lubricants Inhalation: RCR = 1.813E-4

Oral: RCR = 4.989E-4

**Risk characterisation for man via the environment** ESVOC 38 - Use of the substance within laboratory setting, including pilot plants

Inhalation: RCR = 6.819E-5

Oral: RCR = 4.95E-4

#### Risk characterisation for man via the environment

FEICA 6,7 - Industrial Use of Substances other than Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others

Inhalation: RCR = 0.004

Oral: RCR = 2.236E-4

#### Risk characterisation for man via the environment

FEICA 8,9 - Industrial Use of Solvents in Paper, Board and related Products/ Woodworking and joinery/Footwear and Leather/Textile/Transportation (Automotive/aircraft/rail vehicles)/Industrial Building Construction Adhesives/Others adhesives

Inhalation: RCR = 0.005

Oral: RCR = 2.38E-4

Worker exposure						
Long-term, systemic						
Contributing scenario	Inhalation	Dermal	Combined routes	Exposure estimation Method		
Use in closed process, no likelihood of exposure - liquid (PROC 1)	Exposure: 0.44 mg/m <sup>3</sup> RCR: 0.014	Exposure: 0.003 mg/kg bw/day RCR: 3.857E-4	RCR: 0.015	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: High level containment) Derm: Extended TRA workers		
Use in closed process, no likelihood of exposure - solid (PROC 1)	Exposure: 0.032 mg/m <sup>3</sup> RCR: 0.001	Exposure: 6.857E-4 mg/kg bw/day RCR: 7.713E- 5	RCR: 0.001	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: High level containment) Derm: Extended TRA workers		
Use in closed, continuous process with occasional controlled exposure - liquid (PROC 2)	Exposure: 0.69 mg/m <sup>3</sup> RCR: 0.022	Exposure: 0.014 mg/kg bw/day RCR: 0.002	RCR: 0.024	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: High level		

				containment)
				Derm: Extended TRA workers
Use in closed, continuous process with occasional controlled exposure - solid (PROC 2)	Exposure: 0.036 mg/m <sup>3</sup> RCR: 0.001	Exposure: 0.003 mg/kg bw/day RCR: 3.085E- 4	RCR: 0.001	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: High level containment)
				Derm: Extended TRA workers
Use in closed batch process - liquid (PROC 3)	Exposure: 4.3 mg/m <sup>3</sup> RCR: 0.138	Exposure: 0.003 mg/kg bw/day RCR: 3.857E- 4	RCR: 0.139	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: Medium level containment) Derm: Extended TRA workers
Use in closed batch process - solid (PROC 3)	Exposure: 0.32 mg/m <sup>3</sup> RCR: 0.01	Exposure: 6.857E-4 mg/kg bw/day RCR: 7.713E- 5	RCR: 0.01	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: Medium level containment) Derm: Extended TRA workers
Use in batch and other process where opportunity for exposure arises - liquid (PROC 4)	Exposure: 4.4 mg/m <sup>3</sup> RCR: 0.142	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.149	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: Low level containment) Derm: Extended TRA workers
Use in batch and other process where opportunity for exposure arises - solid (PROC 4)	Exposure: 3 mg/m <sup>3</sup> RCR: 0.096	Exposure: 0.014 mg/kg bw/day RCR: 0.002	RCR: 0.098	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: Low level containment) Derm: Extended TRA workers
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant	Exposure: 4.4 mg/m <sup>3</sup> RCR: 0.142	Exposure: 0.137 mg/kg bw/day	RCR: 0.157	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%.

contact) - liquid (PROC 5)		RCR: 0.015		RMM: Low level containment)
				Derm: Extended TRA workers
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid (PROC 5)	Exposure: 3 mg/m <sup>3</sup> RCR: 0.096	Exposure: 0.027 mg/kg bw/day RCR: 0.003	RCR: 0.1	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. RMM: Low level containment)
				Derm: Extended TRA workers
Industrial and non-industrial spraying - liquid (PROC 7 and 11)	Exposure: 1.5 mg/m <sup>3</sup> RCR: 0.048	Exposure: 0.214 mg/kg bw/day RCR: 0.024	RCR: 0.072	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 5%. No RMM) Derm: Extended TRA
				workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non- dedicated facilities - liquid (RPOC Se)	Exposure: 13 mg/m <sup>3</sup> RCR: 0.418	Exposure: 0.137 mg/kg bw/day RCR: 0.015	RCR: 0.433	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM)
(rroc sa)				Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non- dedicated facilities - solid	Exposure: 3.2 mg/m <sup>3</sup> RCR: 0.103	Exposure: 0.027 mg/kg bw/day RCR: 0.003	RCR: 0.106	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM)
				Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid	Exposure: 13 mg/m <sup>3</sup> RCR: 0.418	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.426	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM)
(PROC 80)				Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid (PROC 8b)	Exposure: 3.2 mg/m <sup>3</sup> RCR: 0.103	Exposure: 0.014 mg/kg bw/day RCR: 0.002	RCR: 0.104	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA

				workers
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (PROC 9)	Exposure: 13 mg/m <sup>3</sup> RCR: 0.418	Exposure: 0.069 mg/kg bw/day RCR: 0.008	RCR: 0.426	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM)
				Derm: Extended TRA workers
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid (PROC 9)	Exposure: 0.96 mg/m <sup>3</sup> RCR: 0.031	Exposure: 0.014 mg/kg bw/day RCR: 0.002	RCR: 0.032	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM)
				Derm: Extended TRA workers
Roller application or brushing - liquid (PROC 10)	Exposure: 16 mg/m <sup>3</sup> RCR: 0.515	Exposure: 0.137 mg/kg bw/day RCR: 0.031	RCR: 0.546	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 5%. No RMM)
				Derm: Extended TRA workers
Roller application or brushing - liquid (PROC 10)	Exposure: 4 mg/m <sup>3</sup> RCR: 0.129	Exposure: 0.137 mg/kg bw/day RCR: 0.031	RCR: 0.16	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 5%. No RMM)
				Derm: Extended TRA workers
Treatment of articles by dipping and pouring - liquid (PROC 13)	Exposure: 12 mg/m <sup>3</sup> RCR: 0.386	Exposure: 0.069 mg/kg bw/day RCR: 0.015	RCR: 0.401	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. RMM: LEV, general ventilation)
				Derm: Extended TRA workers
Treatment of articles by dipping and pouring - liquid (PROC 13)	Exposure: 15 mg/m <sup>3</sup> RCR: 0.482	Exposure: 0.069 mg/kg bw/day RCR: 0.015	RCR: 0.497	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 25%. RMM: General ventilation)
				Derm: Extended TRA workers
Treatment of articles by dipping and pouring - liquid (PROC 13)	Exposure: 2.2 mg/m <sup>3</sup>	Exposure: 0.069 mg/kg	RCR: 0.086	Inhal: External exposure estimation tool (Advanced

	RCR: 0.071	bw/day RCR: 0.015		REACH Tool. OC: Concentration up to 5%. No RMM) Derm: Extended TRA workers
Production of preparations or articles by tabletting, compression, extrusion, pelletisation - solid (PROC 14)	Exposure: 0.32 mg/m <sup>3</sup> RCR: 0.01	Exposure: 0.007 mg/kg bw/day RCR: 7.713E- 4	RCR: 0.011	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Use as laboratory reagent - liquid (PROC 15)	Exposure: 4.2 mg/m <sup>3</sup> RCR: 0.135	Exposure: 0.003 mg/kg bw/day RCR: 3.857E- 4	RCR: 0.135	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 50%. No RMM) Derm: Extended TRA workers
Use as laboratory reagent - solid (PROC 15)	Exposure: 0.092 mg/m <sup>3</sup> RCR: 0.003	Exposure: 6.857E-4 mg/kg bw/day RCR: 7.713E- 5	RCR: 0.003	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Hand-mixing with intimate contact and only PPE available - liquid (PROC 19)	Exposure: 14 mg/m <sup>3</sup> RCR: 0.45	Exposure: 1.414 mg/kg bw/day RCR: 0.159	RCR: 0.609	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Hand-mixing with intimate contact and only PPE available - liquid (PROC 19)	Exposure: 9.1 mg/m <sup>3</sup> RCR: 0.293	Exposure: 1.414 mg/kg bw/day RCR: 0.159	RCR: 0.452	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA workers
Hand-mixing with intimate contact and only PPE available - liquid (PROC 19)	Exposure: 3.6 mg/m <sup>3</sup> RCR: 0.116	Exposure: 1.414 mg/kg bw/day RCR: 0.159	RCR: 0.275	Inhal: External exposure estimation tool (Advanced REACH Tool. OC: Concentration up to 10%. No RMM) Derm: Extended TRA

#### workers

## Acute systemic

Not required as no hazard identified

## Local effects via inhalation route

Not required as no hazard identified

#### Local effects via dermal route

A qualitative approach was used to assess the risk of sensitization in accordance with REACH Guidance R.8 (moderate hazard level). The use of gloves and generic organisational measures were proposed as Risk Management Measures to control the risk. Residual exposure was quantitatively estimated and assessed.

Contributing scenario	Acute	Long term	Exposure estimation Method
Use in closed process, no likelihood of exposure - liquid (PROC 1)	Exposure: 0.002 mg/cm <sup>2</sup> RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in closed process, no likelihood of exposure - solid (PROC 1)	Exposure: 1.99E-4 mg/cm <sup>2</sup> RCR: 0.001	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in closed, continuous process with occasional controlled exposure - liquid (PROC 2)	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in closed, continuous process with occasional controlled exposure - solid (PROC 2)	Exposure: 8.75E-4 mg/cm <sup>2</sup> RCR: 0.005	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in closed batch process - liquid (PROC 3)	Exposure: 0.002 mg/cm <sup>2</sup> RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in closed batch process - solid (PROC 3)	Exposure: 3.99E-4 mg/cm <sup>2</sup> RCR: 0.002	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in batch and other process where opportunity for exposure arises - liquid (PROC 4)	Exposure: 0.02 mg/cm <sup>2</sup> RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use in batch and other process where opportunity for exposure arises - solid (PROC 4)	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)

Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - liquid (PROC 5)	Exposure: 0.04 mg/cm <sup>2</sup> RCR: 0.215	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) - solid (PROC 5)	Exposure: 0.008 mg/cm <sup>2</sup> RCR: 0.043	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Industrial and non-industrial spraying - liquid (PROC 7 and 11)	Exposure: 0.02 mg/cm <sup>2</sup> RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - liquid (PROC 8a)	Exposure: 0.002 mg/cm <sup>2</sup> RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid (PROC 8a)	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid (PROC 8b)	Exposure: 0.02 mg/cm <sup>2</sup> RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - solid (PROC 8b)	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (PROC 9)	Exposure: 0.02 mg/cm <sup>2</sup> RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - solid (PROC 9)	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Roller application or brushing - liquid (PROC 10)*	Exposure: 0.02 mg/cm <sup>2</sup> RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Treatment of articles by dipping and pouring - liquid (PROC 13)*	Exposure: 0.02 mg/cm <sup>2</sup> RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Production of preparations or articles by tabletting, compression, extrusion,	Exposure: 0.002 mg/cm <sup>2</sup>	N/A	Acute: External exposure estimation tool (Quantitative

pelletisation - solid (PROC 14)	RCR: 0.011		assessment of residual exposure)
Use as laboratory reagent - liquid (PROC 15)	Exposure: 0.002 mg/cm <sup>2</sup> RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Use as laboratory reagent - solid (PROC 15)	Exposure: 3.99E-4 mg/cm <sup>2</sup> RCR: 0.002	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
Hand-mixing with intimate contact and only PPE available - liquid (PROC 19)*	Exposure: 0.05 mg/cm <sup>2</sup> RCR: 0.269	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)

\*Exposure estimation and risk characterisation was based on long term systemic dermal exposure value and therefore this value is identical for all estimated concentrations/scenarios.

## 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

#### Environment

The daily amount per site as mentioned in section 2.1 is the maximum amount (kg/day) that may be safely used, taking into account the default operational conditions as specified in section 2.1 and the release fractions as specified in section 3. This amount is defined as  $M_{Safe}$ .

To evaluate the compliance of specific formulation, the site-specific substance use rate ( $M_{Site}$ ) and days emitting ( $T_{Emission, Site}$ ), onsite and offsite emission controls and subsequent total substance emission Reduction Efficiency ( $RE_{Total, Site} = 1 - [(1 - RE_{Onsite, Site}) \times (1 - RE_{Offsite, Site})]$ ), sewage treatment plant effluent flow rate ( $G_{Effluent, Site}$ ) and receiving water dilution factor ( $q_{Site}$ ) need to be known.

It is simpler and thus may be preferable to some users to compare  $M_{Site}$  with  $M_{Safe}$ . Adequate control of risk exists if the following conditions are met: [RE<sub>Total, Site</sub>  $\geq$  RE<sub>Total, SpERC</sub>, G<sub>Effluent, Site</sub>  $\geq$  G<sub>Effluent, SpERC</sub>, and q<sub>Site</sub>  $\geq$  q<sub>SpERC</sub>] and  $M_{Safe} \geq M_{Site}$ .

In case the above comparison does not show safe use, the following scaling possibilities are advised:

- The risk is driven by soil for a number of industrial use contributing scenarios. As a default it is assumed that STP sludge is applied on agricultural soil. However this may not always be the case. If the STP sludge is not applied to soil, the RCR for agricultural soil will decrease significantly and therefore the amount that may be used will increase.
- When STP sludge is not applied to soil, the risk will be driven by surface water and sediment. The RCR for these protection targets is lower and therefore the volume can be increased with a factor of approximately 1.7 assuming all other conditions stay equal. If the volume is then not yet high enough, scaling based on municipal STP discharge rate and receiving river flow rate is advised.
- As mentioned in section 3, degradation in the STP has been calculated according to first-order kinetics in the model EUSES. This implies that the concentration in the effluent is proportional to the concentration in the influent and so the predicted concentration in effluent depends on the use volume. An alternative approach is to use Monod kinetics in EUSES. This can be applied for readily biodegradable substances in case: a) the release to the WWTP/STP is more or less continuous so the specific bacteria responsible for biodegradation will be able to maintain themselves in the system and b) the total COD load remains within the specifications of the WWTP/STP. When this approach is applied, the substance concentration in the STP effluent is independent of the concentration in the influent and therefore the use volume, and will remain below 50 µg/l. This implies that under these circumstances M<sub>safe</sub> is theoretically unlimited.

<u>Human health</u>

A DU works within the boundaries of this ES if he fulfills the conditions of use set in section 2. Table 4.1 provides an overview of the assumed effectiveness for the different RMM. The DU can use this effectiveness estimation in order to assess if any deviating RMM will also provide safe use. This is done by multiplying the relevant RCR with the effectiveness of the RMM implemented at the workplace and dividing it by the effectiveness of the RMM listed in section 2. If the shift duration is greater than 8 hours per day, the long term systemic DNELs have to be adapted with the using the following equation, derived from the Brief and Scala model: DNEL Reduction Factor =  $(8 \text{ x hours worked in shift}) \times ((24 - \text{hours worked in shift}) / 16)$ . This equation can not be used to adapt a DNEL for a shift duration shorter than 8 hours. With the adapted DNEL, the DU can recalculate the RCR by dividing the exposure estimation in section 3 with the adapted DNEL. If the RCR is smaller than 0.725 (1 - 0.275 or 1 - (Sum of all man through environment and generic consumer exposure), the downstreamuser works within the boundaries set by the ES.

Risk management measure	Assumed effectiveness <sup>4</sup>		Source of effectiveness	
_	Inhalatory	Dermal		
High level containment - Process fully enclosed (air tight) and the integrity of the enclosure is monitored at least once a month (containment is not breached).	99.9%	99.9%	Advanced REACH tool (www.advancedreachtool.com).	
Medium level containment - Undertake operation under enclosed conditions.	99%	33%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.	
Low level containment - Put lids on containers immediately after use.	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.	
Working outdoor / natural ventilation	30%	-	Advanced REACH tool (www.advancedreachtool.com)	
General ventilation (mechanical)	50%	-	Advanced REACH tool (www.advancedreachtool.com).	
Local exhaust ventilation, fixed capturing hood	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.	
Local exhaust ventilation, other system	50%	17%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.	
Laminar flow booth	90%	30%	Advanced REACH tool (www.advancedreachtool.com) for the inhalatory effectiveness, the dermal effectiveness is assumed to be 1/3 of the inhalatory effectiveness.	
Respirator (Wear a full face respirator conforming to EN140 with Type A / P2 filter or better. APF >20))	95%	Not applicable	Advanced REACH tool (www.advancedreachtool.com).	
Respirator (Wear a respirator (half face mask) conforming to EN140 with Type A filter / P2 filter or better. APF >10)	90%	Not applicable	Advanced REACH tool (www.advancedreachtool.com).	
Reduction of duration of exposure			ECETOC TRA (http://www.ecetoc.org/tra) for the	
> 60 and <= 240 minutes per shift	40%	40%	inhalatory effectiveness, expert judgment for dermal	
> 15 and <= 60 minutes per shift	80%	80%	effectiveness.	
<= 15 minutes per shift	90%	80%		
Concentration of substance in mixture			ECETOC TRA (http://www.ecetoc.org/tra) for the	
> 5% and <= 25%	40%	75%	inhalatory effectiveness, expert judgment for dermal	
> 1% and <= 5%	80%	95%	effectiveness.	
<= 1%	90%	99%		

Table 4.1 Effectiveness	of risk management measures	(RMM)
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<sup>&</sup>lt;sup>4</sup> All effectiveness's listed are only valid if the RMM is properly designed, installed (if applicable), used and maintained.

## 5. ES 5: Professional end-use (SU 22); Professional use

1. Title of Exposure scenario	
Environment	
Environmental assessment see Consumer use.	
Worker	
Worker assessment see Industrial use.	

2. Conditions of use affecting exposure

2.1 Control of environmental exposure

Environmental assessment see Consumer use.

2.2 Control of workers exposure

Worker assessment see Industrial use.

#### **3. Exposure estimation and reference to its source**

Environment

Environmental assessment see Consumer use.

Risk characterisation for man via the environment

Man through environment assessment see Consumer use.

Worker exposure

Worker assessment see Industrial use.

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Environment See Consumer use.

<u>Human health</u> See Industrial use.

## 6. ES 6: Consumer end-use (SU 21); Consumer use

1. Title of Exposure scenario	
Environment:	ERC 8a,
* Professional and consumer use of fragrances, cosmetics, detergents/maintenance products and	8c, 8d, 8f,
laboratory agents	9a, 9b,
* Professional and consumer use of coatings/inks, lubricants and construction chemicals	10a, 11a
* Professional and consumer use resulting in and after inclusion into / onto a matrix	
Consumer	

GES4\_C Covers general exposures to consumers arising from the use of household products sold as washing and cleaning products, aerosols, coatings, de-icers, lubricants and air care products

#### 2. Conditions of use affecting exposure

#### 2.1 Control of environmental exposure:

Professional and consumer use of fragrances, cosmetics, detergents/maintenance products and laboratory agents

Professional and consumer use of coatings/inks, lubricants and construction chemicals

Professional and consumer use resulting in and after inclusion into / onto a matrix

**2.1.1 Control of environmental exposure:** Professional and consumer use of fragrances, cosmetics, detergents/maintenance products and laboratory agents

Amounts used

Daily wide dispersive use = 0.001 tonnes/day

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m3/d}$ 

STP sludge is applied on agricultural soil

**2.1.2 Control of environmental exposure:** Professional and consumer use of coatings/inks, lubricants and construction chemicals

Amounts used

Daily wide dispersive use = 0.003 tonnes/day

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate  $\geq 2E3 \text{ m}3/\text{d}$ 

STP sludge is applied on agricultural soil

2.1.3 Control of environmental exposure: Professional and consumer use resulting in and after inclusion into

/ onto a matrix

Amounts used

Daily wide dispersive use = 0.003 tonnes/day

Other given operational conditions affecting environmental exposure

Receiving river flow rate  $\geq 1.8E4 \text{ m}3/d$ 

Conditions and measures related to municipal sewage treatment plant

Wastewater is to be treated by a municipal STP (assumed removal efficiency from water phase 95.74%).

Municipal STP discharge rate >= 2E3 m3/d

STP sludge is applied on agricultural soil

**2.2 Control of consumers exposure for** GES4\_C Covers general exposures to consumers arising from the use of household products sold as washing and cleaning products, aerosols, coatings, de-icers, lubricants and air care products

3. Exposure estimation and reference to its source

The environmental exposure estimates were calculated according to EUSES version 2.1.2. Degradation in the STP was calculated according to first-order kinetics.

#### Environment

Professional and consumer use of fragrances, cosmetics, detergents/maintenance products and laboratory agents

Release route	Release rate (kg/day)	Release estimation method
Water	1	ERC (ERC 8d)
Air	0	ERC (ERC 8d)
Soil	0.2	ERC (ERC 8d)

Protection target	Exposure estimate (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	0.003 mg/L	0.504
Freshwater (sediment)	0.667 mg/kg dw	0.513
Marine water (pelagic)	2.62E-4 mg/L	0.485
Marine water (sediment)	0.064 mg/kg dw	0.493
Effluent	0.021 mg/L	0.01
Agricultural soil	0.206 mg/kg dw	0.789

<b>Environment</b> Professional and consumer use of coatings/inks, lubricants and construction chemicals				
Release route	Release rate (kg/day)	Release estimation method		
Water	0.138	SPERC (Wide dispersive use coatings/inks, lubricants, construction chemicals)		
Air	0.003	SPERC (Wide dispersive use coatings/inks, lubricants, construction chemicals)		
Soil		SPERC		
0.15	(Wide dispersive use coatings/inks, lubricants,			
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	construction chemicals)			

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	8.88E-4 mg/L	0.164
Freshwater (sediment)	0.218 mg/kg dw	0.168
Marine water (pelagic)	7.84E-5 mg/L	0.145
Marine water (sediment)	0.019 mg/kg dw	0.148
Effluent	0.003 mg/L	0.001
Agricultural soil	0.028 mg/kg dw	0.109

<b>Environment</b> Professional and consumer use resulting in and after inclusion into / onto a matrix			
Release route	Release rate (kg/day)	Release estimation method	
Water	0.088	SPERC (Wide dispersive use inclusion into/onto matrix)	
Air	0.003	SPERC (Wide dispersive use inclusion into/onto matrix)	
Soil	0	SPERC (Wide dispersive use inclusion into/onto matrix)	

Protection target	<b>Exposure estimate</b> (based on: EUSES 2.0)	RCR
Freshwater (pelagic)	7.83E-4 mg/L	0.145
Freshwater (sediment)	0.192 mg/kg dw	0.148
Marine water (pelagic)	6.78E-5 mg/L	0.126
Marine water (sediment)	0.017 mg/kg dw	0.128
Effluent	0.002 mg/L	8.952E-4
Agricultural soil	0.018 mg/kg dw	0.07

Risk characterisation for man via the environment

Inhalation: RCR = 8.055E-5

Oral: RCR = 8.94E-4

Risk characterisation for man via the environment

Inhalation: RCR = 6.747E-5

Oral: RCR = 2.459E-4

Risk characterisation for man via the environment

Inhalation: RCR = 6.663E-5

Oral: RCR = 2.087E-4

Consumer exposure	
Type of product	Maximum concentration of Orange oil allowed in
	consumer products (% w/w)

Laundry & aerosol cleaning spray	2%
Dishwashing product	5%
Aerosol air fresheners	15%
Biocidal products	6%
Fuels (not as main component)	5%
Paints	6%
Paint removers	50%
Coatings and paints, thinners	10%
Non-metal-surface treatment products	0.5%
Polishes	13%

#### Long-term, systemic

Contributing scenario	Inhalation	Dermal	Oral	Combined routes	Exposure estimation Method
GES4_C Covers general exposures to consumers arising from the use of household products sold as washing and cleaning products, aerosols, coatings, de-icers, lubricants and air care products	Exposure: 1.94 mg/m <sup>3</sup> RCR: 0.249	Exposure: 0.024 mg/kg bw/day RCR: 0.005	Exposure: 0.02 mg/kg bw/day RCR: 0.005	RCR: 0.259	Values derived from IFRA's final report on "REACH Exposure Scenario's for fragrance substances (03/02/2010, page 19 and 20)".

#### Risk characterisation for acute systemic

Not required as no hazard identified

## Local effects via inhalation route

Not required as no hazard identified

### Local effects via dermal route

A qualitative approach was used to assess the risk of sensitization in accordance with REACH Guidance R.8 (moderate hazard level). The maximum final concentration in the product is 1% (IFRA's final report on "REACH Exposure Scenario's for fragrance substances, 03/02/2010) and the product should be labelled according to the Detergents Regulation to inform consumers on the intrinsic properties. Sensitizing substances in detergents exceeding 0.01% by weight must be listed using the INCI nomenclature according to the regulation.

<b>Contributing scenario</b>	Acute	Long term	<b>Exposure estimation Method</b>
GES4_C Covers general exposures to consumers arising from the use of household products sold as washing and cleaning products, aerosols, coatings, de- icers, lubricants and air care products	Exposure: 9.6E-4 mg/cm <sup>2</sup> RCR: 0.01	N/A	Acute: IFRA report.

# 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

<u>Environment</u> Not applicable for consumer uses.

Human health

Not applicable for consumer uses.