

gemäß Verordnung (EG) Nr. 1907/2006 (REACH)

## 0000 2157 Orangenöl süß italienisch

Nummer der Fassung: V 3.0 Überarbeitet am: 03.06.2019 Ersetzt Fassung vom: 17.10.2018 (V 2)

#### ABSCHNITT 1: Bezeichnung des Stoffs beziehungsweise des Gemischs und des Unternehmens

#### 1.1 Produktidentifikator

Bezeichnung des Stoffs Orangenöl süß italienisch

Registrierungsnummer (REACH) 01-2119493353-35-0024

EG-Nummer 232-433-8

CAS-Nummer 8028-48-6, 8008-57-9

Artikelnummer 0000 2157

# 1.2 Relevante identifizierte Verwendungen des Stoffs oder Gemischs und Verwendungen, von denen abgeraten wird

Relevante identifizierte Verwendungen Gewerbliche Verwendung

Verwendungen, von denen abgeraten wird Das Produkt ist nicht zur Verwendung durch Ver-

braucher vorgesehen.

#### 1.3 Einzelheiten zum Lieferanten, der das Sicherheitsdatenblatt bereitstellt

Joh. Vögele KG Bahnhofstraße 143 D-74348 Lauffen a.N. Deutschland

Telefon: +49 7133 9802 - 0 Telefax: +49 7133 9802 - 60

e-Mail: info@voegele-ingredients.de Webseite: www.voegele-ingredients.de

e-Mail (sachkundige Person) MSDS@voegele-ingredients.de

(Regulatory Affairs)

#### 1.4 Notrufnummer

Notfallinformationsdienst +49 (0) 700 24 112 112 (IVC)

#### Giftnotzentrale

Land	Name	Postleitzahl/Ort	Telefon
Österreich	Vergiftungsinformationszentrale (Poisons Information Centre)	1090 Wien	+43 1 406 43 43
Schweiz	Schweizerisches Toxikologisches Informations- zentrum	8032 Zürich	145 (CH) / +41 442515151 (≠CH)

#### **ABSCHNITT 2: Mögliche Gefahren**

#### 2.1 Einstufung des Stoffs oder Gemischs

Einstufung gemäß Verordnung (EG) Nr. 1272/2008 (CLP)

Abschnitt	Gefahrenklasse	Gefahrenklasse und - kategorie	Gefahrenhin- weis
2.6	entzündbare Flüssigkeiten	Flam. Liq. 3	H226
3.2	Ätz-/Reizwirkung auf die Haut	Skin Irrit. 2	H315
3.45	Sensibilisierung der Haut	Skin Sens. 1	H317

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Abschnitt	Gefahrenklasse	Gefahrenklasse und - kategorie	Gefahrenhin- weis
3.10	Aspirationsgefahr	Asp. Tox. 1	H304
4.1C	gewässergefährdend (chronische aquatische Toxizität)	Aquatic Chronic 2	H411

Voller Wortlaut der Abkürzungen in ABSCHNITT 16.

#### 2.2 Kennzeichnungselemente

Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008 (CLP)

- Signalwort Gefahr

- Piktogramme

GHS02, GHS07, GHS08, GHS09









#### - Gefahrenhinweise

H226 Flüssigkeit und Dampf entzündbar.

H304 Kann bei Verschlucken und Eindringen in die Atemwege tödlich sein.

H315 Verursacht Hautreizungen.

H317 Kann allergische Hautreaktionen verursachen.

H411 Giftig für Wasserorganismen, mit langfristiger Wirkung.

#### - Sicherheitshinweise

P210 Von Hitze, heißen Oberflächen, Funken, offenen Flammen sowie anderen Zündquellenarten

fernhalten. Nicht rauchen.

P280 Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen. P301+P310 BEI VERSCHLUCKEN: Sofort GIFTINFORMATIONSZENTRUM/Arzt anrufen.

P331 KEIN Erbrechen herbeiführen.

P370+P378 Bei Brand: Sand, Kohlendioxid oder Pulverlöschmittel zum Löschen verwenden.

P403+P235 An einem gut belüfteten Ort aufbewahren. Kühl halten.

#### 2.3 Sonstige Gefahren

ohne Bedeutung

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

#### 3.1 Stoffe

Stoffname Orangenöl süß italienisch (UVCB)

Identifikatoren

REACH Reg.-Nr. 01-2119493353-35-0024 CAS-Nr. 8028-48-6, 8008-57-9

EG-Nr. 232-433-8

#### Verunreinigungen und Zusatzstoffe, Einstufung gem. GHS

Stoffname	Identifikator	Gew%
d-Limonen	CAS-Nr. 5989-27-5 68606-81-5 EG-Nr. 227-813-5	≥90

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#### Verunreinigungen und Zusatzstoffe, Einstufung gem. GHS

Stoffname	Identifikator	Gew%
Myrcen	CAS-Nr. 123-35-3	1-<5
	EG-Nr. 204-622-5	
alpha-Pinen	CAS-Nr. 80-56-8	<1
	EG-Nr. 201-291-9	
Linalool	CAS-Nr. 78-70-6	<1
	EG-Nr. 201-134-4	

Voller Wortlaut der Abkürzungen in ABSCHNITT 16.

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

#### 4.1 Beschreibung der Erste-Hilfe-Maßnahmen

#### Allgemeine Anmerkungen

Betroffenen nicht unbeaufsichtigt lassen. Verunglückten aus der Gefahrenzone entfernen. Betroffenen ruhig lagern, zudecken und warm halten. Beschmutzte, getränkte Kleidung sofort ausziehen. Bei Auftreten von Beschwerden oder in Zweifelsfällen ärztlichen Rat einholen. Bei Bewusstlosigkeit stabile Seitenlage anwenden und nichts über den Mund verabreichen.

#### **Nach Inhalation**

Bei unregelmäßiger Atmung oder Atemstillstand sofort ärztlichen Beistand suchen und Erste-Hilfe-Maßnahmen einleiten. Bei Reizung der Atemwege Arzt aufsuchen. Für Frischluft sorgen.

#### Nach Kontakt mit der Haut

Mit viel Wasser und Seife waschen.

#### Nach Berührung mit den Augen

Eventuell vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter ausspülen. Augenlider geöffnet halten und mindestens 10 Minuten lang reichlich mit sauberem, fließendem Wasser spülen.

#### Nach Aufnahme durch Verschlucken

Mund mit Wasser ausspülen (nur wenn Verunfallter bei Bewusstsein ist). KEIN Erbrechen herbeiführen.

#### 4.2 Wichtigste akute und verzögert auftretende Symptome und Wirkungen

Bisher sind keine Symptome und Wirkungen bekannt.

#### 4.3 Hinweise auf ärztliche Soforthilfe oder Spezialbehandlung

keine

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#### ABSCHNITT 5: Maßnahmen zur Brandbekämpfung

#### 5.1 Löschmittel

#### Geeignete Löschmittel

Sprühwasser, Alkoholbeständiger Schaum, BC-Pulver, Kohlendioxid (CO2)

#### Ungeeignete Löschmittel

Wasser im Vollstrahl

#### 5.2 Besondere vom Stoff oder Gemisch ausgehende Gefahren

Bei unzureichender Belüftung und/oder bei Gebrauch Bildung explosionsfähiger/leichtentzündlicher Dampf-/Luft-Gemische möglich. Lösemitteldämpfe sind schwerer als Luft und breiten sich über dem Boden aus. Mit dem Vorhandensein von brennbaren Stoffen oder Gemischen ist in Bereichen zu rechnen, die von der Lüftung nicht erfasst sind, z.B. unbelüftete tief liegende Bereiche, wie Gruben, Kanäle, Keller und Schächte.

#### Gefährliche Verbrennungsprodukte

Stickoxide (NOx), Kohlenmonoxid (CO), Kohlendioxid (CO2)

#### 5.3 Hinweise für die Brandbekämpfung

Explosions- und Brandgase nicht einatmen. Löschmaßnahmen auf die Umgebung abstimmen. Löschwasser nicht in Kanäle und Gewässer gelangen lassen. Kontaminiertes Löschwasser getrennt sammeln. Brandbekämpfung mit üblichen Vorsichtsmaßnahmen aus angemessener Entfernung.

#### ABSCHNITT 6: Maßnahmen bei unbeabsichtigter Freisetzung

# 6.1 Personenbezogene Vorsichtsmaßnahmen, Schutzausrüstungen und in Notfällen anzuwendende Verfahren

Nicht für Notfälle geschultes Personal

Personen in Sicherheit bringen.

Einsatzkräfte

Bei Einwirkungen von Dämpfen, Stäuben, Aerosolen und Gasen ist ein Atemschutzgerät zu tragen.

#### 6.2 Umweltschutzmaßnahmen

Das Eindringen in die Kanalisation oder in Oberflächen- und Grundwasser verhindern. Verunreinigtes Waschwasser zurückhalten und entsorgen. Falls der Stoff in offenes Gewässer oder Kanalisation gelangt, zuständige Behörde benachrichtigen.

#### 6.3 Methoden und Material für Rückhaltung und Reinigung

Hinweise wie verschüttete Materialien an der Ausbreitung gehindert werden können

Abdecken der Kanalisationen

Hinweise wie die Reinigung im Fall von Verschütten erfolgen kann

Mit saugfähigem Material (z.B. Lappen, Vlies) aufwischen. Verschüttete Mengen aufnehmen: Sägemehl, Kieselgur (Diatomit), Sand, Universalbinder

#### Geeignete Rückhaltetechniken

Einsatz adsorbierender Materialien.

#### Weitere Angaben betreffend Verschütten und Freisetzung

In geeigneten Behältern zur Entsorgung bringen. Den betroffenen Bereich belüften.

#### 6.4 Verweis auf andere Abschnitte

Gefährliche Verbrennungsprodukte: siehe Abschnitt 5. Persönliche Schutzausrüstung: siehe Abschnitt 8. Unverträgliche Materialien: siehe Abschnitt 10. Angaben zur Entsorgung: siehe Abschnitt 13.

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#### **ABSCHNITT 7: Handhabung und Lagerung**

#### 7.1 Schutzmaßnahmen zur sicheren Handhabung

#### Empfehlungen

- Maßnahmen zur Verhinderung von Bränden sowie von Aerosol- und Staubbildung

Verwendung einer örtlichen und generellen Lüftung. Vermeiden von Zündquellen. Von Zündquellen fernhalten - Nicht rauchen. Maßnahmen gegen elektrostatische Entladungen treffen. Nur in gut gelüfteten Bereichen verwenden. Wegen Explosionsgefahr Eindringen der Dämpfe in Keller, Kanalisation und Gruben verhindern. Behälter und zu befüllende Anlage erden. Explosionsgeschützte elektrische Geräte/Lüftungsanlagen/Beleuchtungsanlagen verwenden. Nur funkenfreies Werkzeug verwenden.

- Spezifische Hinweise/Angaben

Mit dem Vorhandensein von brennbaren Stoffen oder Gemischen ist in Bereichen zu rechnen, die von der Lüftung nicht erfasst sind, z.B. unbelüftete tief liegende Bereiche, wie Gruben, Kanäle, Keller und Schächte. Dämpfe sind schwerer als Luft, breiten sich am Boden aus und bilden mit Luft ein explosionsfähiges Gemisch. Dämpfe können zusammen mit Luft ein explosives Gemisch bilden.

#### Hinweise zur allgemeinen Hygiene am Arbeitsplatz

Nach Gebrauch die Hände waschen. In Bereichen, in denen gearbeitet wird, nicht essen, trinken und rauchen. Vor dem Betreten von Bereichen, in denen gegessen wird, kontaminierte Kleidung und Schutzausrüstung ablegen. Bewahren Sie Speisen und Getränke nicht zusammen mit Chemikalien auf. Benutzen Sie für Chemikalien keine Gefäße, die üblicherweise für die Aufnahme von Lebensmitteln bestimmt sind. Von Nahrungsmitteln, Getränken und Futtermitteln fernhalten.

#### 7.2 Bedingungen zur sicheren Lagerung unter Berücksichtigung von Unverträglichkeiten

Begegnung von Risiken nachstehender Art

- Explosionsfähige Atmosphären

Behälter dicht geschlossen an einem gut gelüfteten Ort aufbewahren. Verwendung einer örtlichen und generellen Lüftung. Kühl halten. Vor Sonnenbestrahlung schützen.

- Durch Entzündbarkeit bedingte Gefahren

Von Zündquellen fernhalten - Nicht rauchen. Von Hitze, heißen Oberflächen, Funken, offenen Flammen sowie anderen Zündquellenarten fernhalten. Nicht rauchen. Maßnahmen gegen elektrostatische Entladungen treffen. Vor Sonnenbestrahlung schützen.

- Anforderungen an die Belüftung

Verwendung einer örtlichen und generellen Lüftung. Behälter und zu befüllende Anlage erden.

Geeignete Verpackung

Es dürfen nur zugelassene Verpackungen (z.B. gemäß ADR) verwendet werden.

#### 7.3 Spezifische Endanwendungen

Für einen allgemeinen Überblick siehe Abschnitt 16.

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

#### 8.1 Zu überwachende Parameter

## Grenzwerte für die berufsbedingte Exposition (Arbeitsplatzgrenzwerte)

Land	Arbeitsstoff	CAS-Nr.	Iden tifi- ka- tor	SMW [ppm]	SMW [mg/ m³]	KZW [ppm]	KZW [mg/ m³]	Mow [ppm]	Mow [mg/ m³]	Hin- weis	Quel- le
AT	Kohlenwasser- stoffdämpfe (Aromatenge- halt ≤ 25%, n- Hexan < 1%)	5989-27- 5	MAK	70		140 (30 min)					GKV

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#### Grenzwerte für die berufsbedingte Exposition (Arbeitsplatzgrenzwerte)

Land	Arbeitsstoff	CAS-Nr.	Iden tifi- ka- tor	SMW [ppm]	SMW [mg/ m³]	KZW [ppm]	KZW [mg/ m³]	Mow [ppm]	Mow [mg/ m³]	Hin- weis	Quel- le
AT	Kohlenwasser- stoffdämpfe (Aromatenge- halt < 1%, n-Hex- an < 5%, Cyclo-/ Isohexane ≥25%)	80-56-8	MAK	170		340 (30 min)					GKV
СН	D-Limonen	5989-27- 5	MAK	7	40	14	80				SUVA
СН	α-Pinen	80-56-8	MAK	20	112	40	224				SUVA
DE	(R)-p-Mentha- 1,8-dien	5989-27- 5	AGW	5	28	20	112				TRGS 900
DE	D-Limonen	5989-27- 5	MAK	5	28	20	112				DFG

Hinweis

KZW Kurzzeitwert (Grenzwert für Kurzzeitexposition): Grenzwert der nicht überschritten werden soll, auf eine Dauer von 15 Mi-

nuten bezogen (soweit nicht anders angegeben)

Mow Momentanwert ist der Grenzwert, der nicht überschritten werden soll (ceiling value)

SMW Schichtmittelwert (Grenzwert für Langzeitexposition): Zeitlich gewichteter Mittelwert, gemessen oder berechnet für einen

Bezugszeitraum von acht Stunden (soweit nicht anders angegeben)

#### Für die menschliche Gesundheit maßgebliche Werte

#### Relevante DNEL- und andere Schwellenwerte

Endpunkt	Schwellen- wert	Schutzziel, Expositi- onsweg	Verwendung in	Expositionsdauer
DNEL	31,1 mg/m³	Mensch, inhalativ	Arbeitnehmer (Industrie)	chronisch - systemische Wir- kungen
DNEL	8,89 mg/kg KG/ Tag	Mensch, dermal	Arbeitnehmer (Industrie)	chronisch - systemische Wir- kungen
DNEL	185,8 μg/cm²	Mensch, dermal	Arbeitnehmer (Industrie)	akut - lokale Wirkungen

#### Relevante DNEL von Bestandteilen der Mischung

Stoffname	CAS-Nr.	End- punkt	Schwel- lenwert	Schutzziel, Expo- sitionsweg	Verwendung in	Expositions- dauer
d-Limonen	5989-27-5 68606-81-5	DNEL	66,7 mg/m <sup>3</sup>	Mensch, inhalativ	Arbeitnehmer (Industrie)	chronisch - sy- stemische Wir- kungen
d-Limonen	5989-27-5 68606-81-5	DNEL	9,5 mg/kg KG/Tag	Mensch, dermal	Arbeitnehmer (Industrie)	chronisch - sy- stemische Wir- kungen
alpha-Pinen	80-56-8	DNEL	3,8 mg/m <sup>3</sup>	Mensch, inhalativ	Arbeitnehmer (Industrie)	chronisch - sy- stemische Wir- kungen
alpha-Pinen	80-56-8	DNEL	0,54 mg/kg KG/Tag	Mensch, dermal	Arbeitnehmer (Industrie)	chronisch - sy- stemische Wir- kungen

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#### Relevante DNEL von Bestandteilen der Mischung

Stoffname	CAS-Nr.	End- punkt	Schwel- lenwert	Schutzziel, Expo- sitionsweg	Verwendung in	Expositions- dauer
Linalool	78-70-6	DNEL	2,8 mg/m³	Mensch, inhalativ	Arbeitnehmer (Industrie)	chronisch - sy- stemische Wir- kungen
Linalool	78-70-6	DNEL	16,5 mg/m³	Mensch, inhalativ	Arbeitnehmer (Industrie)	akut - systemi- sche Wirkungen
Linalool	78-70-6	DNEL	2,5 mg/kg KG/Tag	Mensch, dermal	Arbeitnehmer (Industrie)	chronisch - sy- stemische Wir- kungen
Linalool	78-70-6	DNEL	5 mg/kg KG/Tag	Mensch, dermal	Arbeitnehmer (Industrie)	akut - systemi- sche Wirkungen

#### Für die Umwelt maßgebliche Werte

#### Relevante PNEC- und andere Schwellenwerte

End- punkt	Schwellen- wert	Organismus	Umweltkompartiment	Expositionsdauer
PNEC	5,4 <sup>µg</sup> / <sub>l</sub>	Wasserorganismen	Süßwasser	kurzzeitig (einmalig)
PNEC	0,54 <sup>µg</sup> / <sub>l</sub>	Wasserorganismen	Meerwasser	kurzzeitig (einmalig)
PNEC	2,1 <sup>mg</sup> / <sub>l</sub>	Wasserorganismen	Kläranlage (STP)	kurzzeitig (einmalig)
PNEC	1,3 <sup>mg</sup> / <sub>kg</sub>	Wasserorganismen	Süßwassersediment	kurzzeitig (einmalig)
PNEC	0,13 <sup>mg</sup> / <sub>kg</sub>	Wasserorganismen	Meeressediment	kurzzeitig (einmalig)
PNEC	0,261 <sup>mg</sup> / <sub>kg</sub>	terrestrische Organismen	Boden	kurzzeitig (einmalig)

## Relevante PNEC von Bestandteilen der Mischung

Stoffname	CAS-Nr.	End- punkt	Schwel- lenwert	Organismus	Umweltkom- partiment	Expositions- dauer
d-Limonen	5989-27-5 68606-81-5	PNEC	14 <sup>µg</sup> / <sub>l</sub>	Wasserorganismen	Süßwasser	kurzzeitig (ein- malig)
d-Limonen	5989-27-5 68606-81-5	PNEC	1,4 <sup>µg</sup> / <sub>I</sub>	Wasserorganismen	Meerwasser	kurzzeitig (ein- malig)
d-Limonen	5989-27-5 68606-81-5	PNEC	1,8 <sup>mg</sup> / <sub>l</sub>	Wasserorganismen	Kläranlage (STP)	kurzzeitig (ein- malig)
d-Limonen	5989-27-5 68606-81-5	PNEC	3,85 <sup>mg</sup> / <sub>kg</sub>	Wasserorganismen	Süßwassersedi- ment	kurzzeitig (ein- malig)
d-Limonen	5989-27-5 68606-81-5	PNEC	0,385 <sup>mg</sup> / <sub>kg</sub>	Wasserorganismen	Meeressediment	kurzzeitig (ein- malig)
d-Limonen	5989-27-5 68606-81-5	PNEC	0,763 <sup>mg</sup> / <sub>kg</sub>	terrestrische Orga- nismen	Boden	kurzzeitig (ein- malig)
alpha-Pinen	80-56-8	PNEC	0,606 <sup>µg</sup> / <sub>I</sub>	Wasserorganismen	Süßwasser	kurzzeitig (ein- malig)
alpha-Pinen	80-56-8	PNEC	0,061 <sup>µg</sup> / <sub>l</sub>	Wasserorganismen	Meerwasser	kurzzeitig (ein- malig)
alpha-Pinen	80-56-8	PNEC	0,2 <sup>mg</sup> / <sub>l</sub>	Wasserorganismen	Kläranlage (STP)	kurzzeitig (ein- malig)

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#### Relevante PNEC von Bestandteilen der Mischung

Stoffname	CAS-Nr.	End- punkt	Schwel- lenwert	Organismus	Umweltkom- partiment	Expositions- dauer
alpha-Pinen	80-56-8	PNEC	157 <sup>µg</sup> / <sub>kg</sub>	Wasserorganismen	Süßwassersedi- ment	kurzzeitig (ein- malig)
alpha-Pinen	80-56-8	PNEC	15,7 <sup>µg</sup> / <sub>kg</sub>	Wasserorganismen	Meeressediment	kurzzeitig (ein- malig)
alpha-Pinen	80-56-8	PNEC	31,7 <sup>µg</sup> / <sub>kg</sub>	terrestrische Orga- nismen	Boden	kurzzeitig (ein- malig)
Linalool	78-70-6	PNEC	0,2 <sup>mg</sup> / <sub>l</sub>	Wasserorganismen	Süßwasser	kurzzeitig (ein- malig)
Linalool	78-70-6	PNEC	0,02 <sup>mg</sup> / <sub>l</sub>	Wasserorganismen	Meerwasser	kurzzeitig (ein- malig)
Linalool	78-70-6	PNEC	10 <sup>mg</sup> / <sub>l</sub>	Wasserorganismen	Kläranlage (STP)	kurzzeitig (ein- malig)
Linalool	78-70-6	PNEC	2,22 <sup>mg</sup> / <sub>kg</sub>	Wasserorganismen	Süßwassersedi- ment	kurzzeitig (ein- malig)
Linalool	78-70-6	PNEC	0,222 <sup>mg</sup> / <sub>kg</sub>	Wasserorganismen	Meeressediment	kurzzeitig (ein- malig)
Linalool	78-70-6	PNEC	0,327 <sup>mg</sup> / <sub>kg</sub>	terrestrische Orga- nismen	Boden	kurzzeitig (ein- malig)

## 8.2 Begrenzung und Überwachung der Exposition

Geeignete technische Steuerungseinrichtungen

Generelle Lüftung.

Individuelle Schutzmaßnahmen (persönliche Schutzausrüstung)

#### Augen-/Gesichtsschutz

Schutzbrille/Gesichtsschutz tragen.

#### Hautschutz

- Handschutz

Geeignete Schutzhandschuhe tragen. Geeignet ist ein nach EN 374 geprüfter Chemikalienschutzhandschuh. Vor Gebrauch auf Dichtheit/Undurchlässigkeit überprüfen. Bei beabsichtigter Wiederverwendung Handschuhe vor dem Ausziehen reinigen und danach gut durchlüften. Es wird empfohlen, die Chemikalienbeständigkeit der oben genannten Schutzhandschuhe für spezielle Anwendungen mit dem Handschuhhersteller abzuklären.

- Art des Materials

NBR: Acrylnitril-Butadien-Kautschuk

- Materialstärke
  - > 0,7 mm
- Durchbruchszeit des Handschuhmaterials
  - >10 Minuten (Permeationslevel: 1)
- Sonstige Schutzmaßnahmen

Erholungsphasen zur Regeneration der Haut einlegen. Vorbeugender Hautschutz (Schutzcremes/Salben) wird empfohlen. Nach Gebrauch Hände gründlich waschen.

#### Atemschutz

Bei unzureichender Belüftung Atemschutz tragen.

Filtrierende Halbmaske (EN 149). Typ: A (gegen organische Gase und Dämpfe mit Siedepunkt > 65 °C, Kennfarbe: Braun).

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#### Begrenzung und Überwachung der Umweltexposition

Zur Vermeidung einer Kontamination der Umwelt geeigneten Behälter verwenden. Das Eindringen in die Kanalisation oder in Oberflächen- und Grundwasser verhindern.

#### **ABSCHNITT 9: Physikalische und chemische Eigenschaften**

# 9.1 Angaben zu den grundlegenden physikalischen und chemischen Eigenschaften Aussehen

Aggregatzustand	flüssig
Farbe	gelbbraun
Geruch	charakteristisch

#### Weitere sicherheitstechnische Kenngrößen

pH-Wert	nicht bestimmt
Schmelzpunkt/Gefrierpunkt	<-25 °C
Siedebeginn und Siedebereich	nicht bestimmt
Flammpunkt	51 °C
Verdampfungsgeschwindigkeit	nicht bestimmt
Entzündbarkeit (fest, gasförmig)	nicht relevant, (Flüssigkeit)
Explosionsgrenzen	nicht bestimmt
Dampfdruck	186,4 Pa bei 25 °C
Dichte	0,846 <sup>g</sup> / <sub>cm³</sub> bei 20 °C
Dampfdichte	keine Information verfügbar

#### Löslichkeit(en)

- Wasserlöslichkeit	<1.767 <sup>mg</sup> / <sub>l</sub> bei 25 °C
---------------------	---

#### Verteilungskoeffizient

- n-Octanol/Wasser (log KOW)	2,78 – 4,88 (ECHA)
Selbstentzündungstemperatur	235 °C bei 1.016 hPa (ECHA)

#### Viskosität

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- Kinematische Viskosität	1,17 <sup>mm²</sup> / <sub>s</sub> bei 20 °C
- Dynamische Viskosität	0,99 mPa s bei 20 °C
Explosive Eigenschaften	keine
Oxidierende Eigenschaften	keine

#### 9.2 Sonstige Angaben

` ,	T3 (maximal zulässige Oberflächentemperatur der Betriebsmittel: 200°C)
į	tel. 200 C)

#### **ABSCHNITT 10: Stabilität und Reaktivität**

#### 10.1 Reaktivität

Bezüglich Unverträglichkeiten: siehe unten "Zu vermeidende Bedingungen" und "Unverträgliche Materialien". Es handelt sich um einen reaktiven Stoff. Das Gemisch enthält reaktive(n) Stoff(e). Entzündungsgefahr.

Bei Erwärmung:

Entzündungsgefahr

#### 10.2 Chemische Stabilität

Siehe unten "Zu vermeidende Bedingungen".

#### 10.3 Möglichkeit gefährlicher Reaktionen

Es sind keine gefährlichen Reaktionen bekannt.

#### 10.4 Zu vermeidende Bedingungen

Von Hitze, heißen Oberflächen, Funken, offenen Flammen sowie anderen Zündquellenarten fernhalten. Nicht rauchen

Hinweise wie Brände oder Explosionen vermieden werden können

Explosionsgeschützte elektrische Geräte/Lüftungsanlagen/Beleuchtungsanlagen verwenden. Nur funkenfreies Werkzeug verwenden. Maßnahmen gegen elektrostatische Entladungen treffen.

#### 10.5 Unverträgliche Materialien

Oxidationsmittel

#### 10.6 Gefährliche Zersetzungsprodukte

Vernünftigerweise zu erwartende, gefährliche Zersetzungsprodukte, die bei Verwendung, Lagerung, Verschütten und Erwärmung entstehen, sind nicht bekannt. Gefährliche Verbrennungsprodukte: siehe Abschnitt 5.

#### **ABSCHNITT 11: Toxikologische Angaben**

#### 11.1 Angaben zu toxikologischen Wirkungen

#### Einstufung gemäß GHS (1272/2008/EG, CLP)

Akute Toxizität

Die Kriterien für die Einstufung in diese Gefahrenklassen sind nicht erfüllt.

Ätz-/Reizwirkung auf die Haut

Verursacht Hautreizungen.

#### Schwere Augenschädigung/Augenreizung

Die Kriterien für die Einstufung in diese Gefahrenklasse sind nicht erfüllt.

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#### Sensibilisierung der Atemwege oder der Haut

Kann allergische Hautreaktionen verursachen.

#### Keimzellmutagenität

Die Kriterien für die Einstufung in diese Gefahrenklasse sind nicht erfüllt.

#### Karzinogenität

Die Kriterien für die Einstufung in diese Gefahrenklasse sind nicht erfüllt.

#### Reproduktionstoxizität

Die Kriterien für die Einstufung in diese Gefahrenklasse sind nicht erfüllt.

#### Spezifische Zielorgan-Toxizität bei einmaliger Exposition

Die Kriterien für die Einstufung in diese Gefahrenklasse sind nicht erfüllt.

#### Spezifische Zielorgan-Toxizität bei wiederholter Exposition

Die Kriterien für die Einstufung in diese Gefahrenklasse sind nicht erfüllt.

#### Aspirationsgefahr

Kann bei Verschlucken und Eindringen in die Atemwege tödlich sein.

#### **ABSCHNITT 12: Umweltbezogene Angaben**

#### 12.1 Toxizität

Gemäß 1272/2008/EG: Giftig für Wasserorganismen, mit langfristiger Wirkung. Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV): WGK 3, stark wassergefährdend (Deutschland)

#### (Akute) aquatische Toxizität

Endpunkt	Wert	Spezies	Expositionsdau- er	
LL50	5,65 <sup>mg</sup> / <sub>l</sub>	Fisch	96 h	
EL50	1,4 <sup>mg</sup> / <sub>l</sub>	wirbellose Wasserlebewesen	24 h	

#### 12.2 Persistenz und Abbaubarkeit

#### Abbaubarkeit von Bestandteilen der Mischung

Stoffname	CAS-Nr.	Prozess	Abbaurate	Zeit	Methode	Quelle
Linalool	78-70-6	Sauerstoffver- brauch	40,9 %	5 d		ECHA

#### 12.3 Bioakkumulationspotenzial

Es sind keine Daten verfügbar.

n-Octanol/Wasser (log KOW)	2,78 – 4,88 (ECHA)
BCF	32 – 156 (ECHA)

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#### Bioakkumulationspotenzial von Bestandteilen der Mischung

Stoffname	CAS-Nr.	BCF	Log KOW	BSB5/CSB
d-Limonen	5989-27-5 68606-81-5		4,38 (pH-Wert: 7,2, 37 °C)	
Myrcen	123-35-3		4,82 (pH-Wert: ~6,5, 30 °C)	
Linalool	78-70-6		2,9 (pH-Wert: 7, 20 °C)	

#### 12.4 Mobilität im Boden

Es sind keine Daten verfügbar.

#### 12.5 Ergebnisse der PBT- und vPvB-Beurteilung

Es sind keine Daten verfügbar.

#### 12.6 Andere schädliche Wirkungen

Potenzial zur Störung der endokrinen Systeme Nicht gelistet.

#### **ABSCHNITT 13: Hinweise zur Entsorgung**

#### 13.1 Verfahren der Abfallbehandlung

Für die Abfallbehandlung relevante Angaben

Rückgewinnung/Regenerierung von Lösemitteln.

#### Für die Entsorgung über Abwasser relevante Angaben

Nicht in die Kanalisation gelangen lassen. Freisetzung in die Umwelt vermeiden. Besondere Anweisungen einholen/ Sicherheitsdatenblatt zu Rate ziehen.

#### Abfallbehandlung von Behältern/Verpackungen

Es handelt sich um einen gefährlichen Abfall; es dürfen nur zugelassene Verpackungen (z.B. gemäß ADR) verwendet werden. Vollständig entleerte Verpackungen können einer Verwertung zugeführt werden. Kontaminierte Verpackungen sind wie der Stoff zu behandeln.

#### Einschlägige Rechtsvorschriften über Abfall

Entscheidung 2000/532/EG über ein Abfallverzeichnis

Produkt, Produktreste: 07 06 99 Abfälle a. n. g.

Verpackungen: 15 01 10x Verpackungen, die Rückstände gefährlicher Stoffe enthalten oder durch gefährliche Stoffe verunreinigt sind.

Vollständig entleerte Verpackungen können einer Verwertung zugeführt werden.

#### **Anmerkungen**

Bitte beachten Sie die einschlägigen nationalen oder regionalen Bestimmungen. Abfall ist so zu trennen, dass er von den kommunalen oder nationalen Abfallentsorgungseinrichtungen getrennt behandelt werden kann.

#### **ABSCHNITT 14: Angaben zum Transport**

**14.1 UN-Nummer** 1169

**14.2 Ordnungsgemäße UN-Versandbezeichnung** EXTRAKTE, AROMATISCH, FLÜSSIG

14.3 Transportgefahrenklassen

Klasse 3 (entzündbare flüssige Stoffe) (umweltgefährdend)

**14.4 Verpackungsgruppe** III (Stoff mit geringer Gefahr)

**14.5 Umweltgefahren** gewässergefährdend

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#### Besondere Vorsichtsmaßnahmen für den Verwender

Die Vorschriften für gefährliche Güter (ADR) sind auch innerhalb des Betriebsgeländes zu beachten.

#### Massengutbeförderung gemäß Anhang II des MARPOL-Übereinkommens und gemäß IBC-Code

Die Fracht wird nicht als Massengut befördert.

#### Angaben nach den einzelnen UN-Modellvorschriften

#### Beförderung gefährlicher Güter auf Straße, Schiene oder Binnenwasserstraßen (ADR/RID/ADN)

**UN-Nummer** 1169

Offizielle Benennung für die Beförderung EXTRAKTE, AROMATISCH, FLÜSSIG

Vermerke im Beförderungspapier UN1169, EXTRAKTE, AROMATISCH, FLÜSSIG, 3, III,

(D/E), umweltgefährdend

Klasse 3 Klassifizierungscode F1 Verpackungsgruppe III

Gefahrzettel 3, Fisch und Baum



Umweltgefahren ja (gewässergefährdend)

Sondervorschriften (SV) 601 Freigestellte Mengen (EQ) E1 Begrenzte Mengen (LQ) 5 L Beförderungskategorie (BK) 3 Tunnelbeschränkungscode (TBC) D/E Nummer zur Kennzeichnung der Gefahr 30

#### Internationaler Code für die Beförderung gefährlicher Güter mit Seeschiffen (IMDG)

**UN-Nummer** 1169

Offizielle Benennung für die Beförderung EXTRAKTE, AROMATISCH, FLÜSSIG

Angaben im Beförderungsdokument (shipper's UN1169, EXTRAKTE, AROMATISCH, FLÜSSIG, 3, III, 51°C c.c., MEERESSCHADSTOFF

declaration)

3 Klasse

Meeresschadstoff (Marine Pollutant) ja (gewässergefährdend)

Verpackungsgruppe TTT

Gefahrzettel 3, Fisch und Baum



223, 955 Sondervorschriften (SV) Freigestellte Mengen (EQ) E1 Begrenzte Mengen (LQ) 5 L F-E. S-D **EmS** Staukategorie (stowage category) Α

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#### Internationale Zivilluftfahrt-Organisation (ICAO-IATA/DGR)

UN-Nummer 1169

Offizielle Benennung für die Beförderung Extrakte, aromatisch, flüssig

Angaben im Beförderungsdokument (shipper's

declaration)

UN1169, Extrakte, aromatisch, flüssig, 3, III

Klasse 3

Umweltgefahren ja (gewässergefährdend)

Verpackungsgruppe III Gefahrzettel 3



Sondervorschriften (SV)

Freigestellte Mengen (EQ)

Begrenzte Mengen (LQ)

10 L

#### **ABSCHNITT 15: Rechtsvorschriften**

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

Einschlägige Bestimmungen der Europäischen Union (EU)

Verzeichnis der zulassungspflichtigen Stoffe (REACH, Anhang XIV) / SVHC - Kandidatenliste nicht gelistet

## Seveso Richtlinie

2012/	2012/18/EU (Seveso III)					
Nr.	Gefährlicher Stoff/Gefahrenkategorien	Mengenschwelle (in 1 wendung in Betriebe oberen k	n der unteren und	Anm.		
E2	Umweltgefahren (gewässergefährdend, Kat. 2)	200	500	57)		

#### Hinweis

#### Nationale Vorschriften (Österreich)

Verordnung über brennbare Flüssigkeiten (VbF)

VbF (Gruppe und Gefahrenklasse) AII (brennbare Flüssigkeiten der Gruppe A, Gefahrenklasse II)

#### **Nationale Vorschriften (Deutschland)**

#### Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV)

Wassergefährdungsklasse (WGK) 3 stark wassergefährdend

Kennnummer 3824

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<sup>57)</sup> gewässergefährdend, Gefahrenkategorie Chronisch 2



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#### Technische Anleitung zur Reinhaltung der Luft (Deutschland)

Nummer	Stoffgruppe	Klasse	Konz.	Massenstrom	Massenkon- zentration	Hinweis
5.2.5	organische Stoffe	Klasse I	≥ 25 Gew %	0,1 <sup>kg</sup> / <sub>h</sub>	20 <sup>mg</sup> / <sub>m³</sub>	3)

#### Hinweis

#### Lagerung von Gefahrstoffen in ortsbeweglichen Behältern (TRGS 510) (Deutschland)

Lagerklasse (LGK)

3 (entzündliche Flüssigkeiten)

#### **Nationale Verzeichnisse**

Land	Verzeichnis	Status
AU	AICS	Stoff ist gelistet
CA	DSL	Stoff ist gelistet
CN	IECSC	Stoff ist gelistet
EU	ECSI	Stoff ist gelistet
EU	REACH Reg.	Stoff ist gelistet
KR	KECI	Stoff ist gelistet
MX	INSQ	Stoff ist gelistet
NZ	NZIoC	Stoff ist gelistet
PH	PICCS	Stoff ist gelistet
TR	CICR	Stoff ist gelistet
TW	TCSI	Stoff ist gelistet
US	TSCA	Stoff ist gelistet

Legende

Australian Inventory of Chemical Substances Chemical Inventory and Control Regulation Domestic Substances List (DSL) EG Stoffverzeichnis (EINECS, ELINCS, NLP) Inventory of Existing Chemical Substances Produced or Imported in China AICS CICR DSL

ECSI IECSC

National Inventory of Chemical Substances
Korea Existing Chemicals Inventory
New Zealand Inventory of Chemicals
Philippine Inventory of Chemicals and Chemical Substances INSQ KECI NZIoC

REACH Reg. REACH registrierte Stoffe

Taiwan Chemical Substance Inventory

**TSCA Toxic Substance Control Act** 

## Stoffsicherheitsbeurteilung

Eine Stoffsicherheitsbeurteilung wurde für diesen Stoff durchgeführt.

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der Massenstrom 0,50 kg/h oder die Massenkonzentration 50 mg/m³ darf, jeweils angegeben als Gesamtkohlenstoff, insgesamt nicht überschritten werden (ausgenommen staubförmige organische Stoffe)



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## **ABSCHNITT 16: Sonstige Angaben**

## Vorgenommene Änderungen (überarbeitetes Sicherheitsdatenblatt)

Abschnitt	Ehemaliger Eintrag (Text/Wert)	Aktueller Eintrag (Text/Wert)	Sicher- heitsre- levant
2.3	Sonstige Gefahren	Sonstige Gefahren: ohne Bedeutung	ja
2.3	Ergebnisse der PBT- und vPvB-Beurteilung: Nach den Ergebnissen seiner Bewertung ist die- ser Stoff weder ein PBT- noch ein vPvB-Stoff.		ja
3.1	Stoffname: Orangenöl süß italienisch	Stoffname: Orangenöl süß italienisch (UVCB)	ja
8.1		Grenzwerte für die berufsbedingte Exposition (Arbeitsplatzgrenzwerte): Änderung in der Auflistung (Tabelle)	ja
12.1		(Akute) aquatische Toxizität: Änderung in der Auflistung (Tabelle)	ja
14.3	Klasse: 3 (entzündbare flüssige Stoffe)	Klasse: 3 (entzündbare flüssige Stoffe) (umweltgefährdend)	ja
15.1	VbF (Gruppe und Gefahrenklasse): AII (brennbare Flüssigkkeiten der Gruppe A, Ge- fahrenklasse II)	VbF (Gruppe und Gefahrenklasse): AII (brennbare Flüssigkeiten der Gruppe A, Ge- fahrenklasse II)	ja
15.1		Technische Anleitung zur Reinhaltung der Luft (Deutschland): Änderung in der Auflistung (Tabelle)	ja

#### Abkürzungen und Akronyme

Abk.	Beschreibungen der verwendeten Abkürzungen
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigati- on intérieures (Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf Binnenwasserstraßen)
ADR	Accord européen relatif au transport international des marchandises dangereuses par route (Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf der Straße)
AGW	Arbeitsplatzgrenzwert
BCF	Bioconcentration factor (Biokonzentrationsfaktor)
BSB	Biochemischer Sauerstoffbedarf
CAS	Chemical Abstracts Service (Datenbank von chemischen Verbindungen und deren eindeutigem Schlüssel, der CAS Registry Number)
CLP	Verordnung (EG) Nr. 1272/2008 über die Einstufung, Kennzeichnung und Verpackung (Classification, Labelling and Packaging) von Stoffen und Gemischen
CSB	Chemischer Sauerstoffbedarf
DFG	Deutsche Forschungsgemeinschaft MAK-und BAT-Werte-Liste, Senatskommission zur Prüfung gesund- heitsschädlicher Arbeitsstoffe, Wiley-VCH, Weinheim
DGR	Dangerous Goods Regulations (Gefahrgutvorschriften) Regelwerk für den Transport gefährlicher Güter, siehe IATA/DGR
DNEL	Derived No-Effect Level (abgeleitete Expositionshöhe ohne Beeinträchtigung)
EG-Nr.	Das EG-Verzeichnis (EINECS, ELINCS und das NLP-Verzeichnis) ist die Quelle für die siebenstellige EC- Nummer als Kennzahl für Stoffe in der EU (Europäische Union)

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Abk.	Beschreibungen der verwendeten Abkürzungen
EINECS	European Inventory of Existing Commercial Chemical Substances (europäisches Verzeichnis der auf dem Markt vorhandenen chemischen Stoffe)
ELINCS	European List of Notified Chemical Substances (europäische Liste der angemeldeten chemischen Stoffe)
EmS	Emergency Schedule (Notfall Zeitplan)
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" "Global harmonisiertes System zur Einstufung und Kennzeichnung von Chemikalien", das die Vereinten Nationen entwickelt haben
GKV	Grenzwerteverordnung
IATA	International Air Transport Association (Internationale Flug-Transport-Vereinigung)
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA) (Regelwerk für den Transport gefährli- cher Güter im Luftverkehr)
ICAO	International Civil Aviation Organization (internationale Zivilluftfahrt-Organisation)
IMDG	International Maritime Dangerous Goods Code (internationaler Code für die Beförderung gefährlicher Güter mit Seeschiffen)
KZW	Kurzzeitwert
LGK	Lagerklasse gemäß TRGS 510, Deutschland
log KOW	n-Octanol/Wasser
MARPOL	Internationales Übereinkommen zur Verhütung der Meeresverschmutzung durch Schiffe (Abk. von "Marine Pollutant")
Mow	Momentanwert
NLP	No-Longer Polymer (nicht-länger-Polymer)
PBT	Persistent, Bioakkumulierbar und Toxisch
PNEC	Predicted No-Effect Concentration (abgeschätzte Nicht-Effekt-Konzentration)
ppm	Parts per million (Teile pro Million)
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Registrierung, Bewertung, Zulassung und Beschränkung chemischer Stoffe)
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Ordnung für die internationale Eisenbahnbeförderung gefährlicher Güter)
SMW	Schichtmittelwert
SUVA	Grenzwerte am Arbeitsplatz, Suva
SVHC	Substance of Very High Concern (besonders besorgniserregender Stoff)
TRGS	Technische Regeln für GefahrStoffe (Deutschland)
TRGS 900	Arbeitsplatzgrenzwerte (TRGS 900)
VbF	Verordnung über brennbare Flüssigkeiten (Österreich)
vPvB	Very Persistent and very Bioaccumulative (sehr persistent und sehr bioakkumulierbar)

## Wichtige Literatur und Datenquellen

Verordnung (EG) Nr. 1272/2008 über die Einstufung, Kennzeichnung und Verpackung (Classification, Labelling and Packaging) von Stoffen und Gemischen. Verordnung (EG) Nr. 1907/2006 (REACH), geändert mit 2015/830/EU.

Beförderung gefährlicher Güter auf Straße, Schiene oder Binnenwasserstraßen (ADR/RID/ADN). Internationaler Code für die Beförderung gefährlicher Güter mit Seeschiffen (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA) (Regelwerk für den Transport gefährlicher Güter im Luftverkehr).

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#### Liste der einschlägigen Sätze (Code und Wortlaut wie in Kapitel 2 und 3 angegeben)

Code	Text
H226	Flüssigkeit und Dampf entzündbar.
H304	Kann bei Verschlucken und Eindringen in die Atemwege tödlich sein.
H315	Verursacht Hautreizungen.
H317	Kann allergische Hautreaktionen verursachen.
H411	Giftig für Wasserorganismen, mit langfristiger Wirkung.

## Haftungsausschluss

Die vorliegenden Informationen beruhen auf unserem gegenwärtigen Kenntnisstand. Dieses SDB wurde ausschließlich für dieses Produkt zusammengestellt und ist ausschließlich für dieses vorgesehen.

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# **ES FOR COMMUNICATION**

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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 dedicated facilities	PROC 8b
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 >= 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

#### 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 >= 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

#### 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 >= 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

#### 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 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**

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

Environment 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	Exposure estimate (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
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Environment ENV2 Further refinement of essential oils				
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	Exposure estimate (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

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				
Contributing scenario	Inhalation	Dermal	Combined routes	Exposure estimation Method
Manufacture in closed process, no likelihood of exposure (PROC 1)	Exposure: 1.5 mg/m³ 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/m³ 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/m³ RCR: 0.482	Exposure: 0.007 mg/kg bw/day RCR: 7.713E-	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/m³ 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/m³ 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/m³ 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.

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)
Manufacture in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)	Exposure: 0.04 mg/cm <sup>2</sup> RCR: 0.215	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 (PROC 8b)	Exposure: 0.04 mg/cm <sup>2</sup> RCR: 0.215	N/A	Acute: External exposure estimation tool (Quantitative 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 ( $g_{Site}$ ) 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. 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 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.
		•	

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

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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%	

## 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

#### 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 >= 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

# 2.1.2 Control of environmental exposure: Compounding of fragrance oils (generic large/medium sites) (ERC 2)

#### Amounts used

Daily amount per site <= 0.632 tonnes/day

Annual amount per site <= 158 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

#### 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

# **2.2 Control of workers exposure for** Formulation and distribution / compounding in closed system, 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** 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 1/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** Formulation and distribution / compounding in closed batch process (synthesis or formulation) (PROC 3)

#### **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** Formulation and distribution / compounding 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>.

#### 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.
- \*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.

**2.8 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.

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)

Liauid

## 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**

Environment

Blending of mixtures and distribution

Release route	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	Exposure estimate (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

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)			
	1.7.0	CDED C			

Air 15.8 SPERC

(Compounding of fragrance oils - Compounding of fragrance oils medium/large compounder)

Soil 0.063 SPERC

(Compounding of fragrance oils - Compounding of fragrance oils medium/large compounder)

Protection target	Exposure estimate (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> Compounding o	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	Exposure estimate (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					
Formulation and distribution / compounding in closed system, no likelihood of exposure (PROC 1)	Exposure: 1.5 mg/m³ 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/m³ 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/m³ 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/m³ 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 TRA	

				workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)	Exposure: 18 mg/m³ 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/m³ 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/m³ 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/m³ 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.

Contributing scenario	Acute	Long term	<b>Exposure estimation Method</b>
Formulation and distribution / compounding in closed system, no likelihood of exposure (PROC 1)			Acute: External exposure estimation tool (Quantitative assessment of residual exposure)

Formulation and distribution / compounding 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)
Formulation and distribution / compounding 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)
Formulation and distribution / compounding in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)		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) (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/cm <sup>2</sup> RCR: 0.215	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
(charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)	Exposure: 0.04 mg/cm <sup>2</sup> RCR: 0.215	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) (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)
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 ( $g_{Site}$ ) 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. 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 =  $(8 \text{ x hours worked in shift}) \times ((24 - \text{hours worked in shift}) / 16)$ . 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  $0.725 (1 - 0.275 \text{ or } 1 - (\text{Sum of all man through environment and generic consumer exposure), the downstreamuser works within the boundaries set by the ES.$ 

Table 4.1 Effectiveness of risk management measures (RMM).

Risk management measure	Assumed effectiveness <sup>2</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.

<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.

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<= 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, 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)	
Worker	DD C C 1
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 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
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 <= 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 >= 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

## 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 >= 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

#### 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 <= 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 >= 2E3 m3/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 >= 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

#### 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 >= 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

## 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 >= 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

## 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 >= 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

#### 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 >= 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

#### 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 <= 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 >= 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

## 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 <= 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 >= 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

## 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 >= 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

#### 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 >= 2E3 m3/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 >= 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

#### 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 >= 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

## 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 >= 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

# **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.

# 2.3 Control of workers exposure for Formulation 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** 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 1/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.

*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.

<sup>\*</sup>Undertake operation under enclosed conditions.

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.

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

#### **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.

**2.12 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).

Transfer of solid products - falling powders.

\*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).

\*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

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 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).

2.20 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	Exposure estimate (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)

8	Exposure estimate (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		SPERC (AISE and COLIPA SpERCs for formulation - Formulation AISE 3, 9 and 11 and COLIPA 2 and 16)

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

	Exposure estimate (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	Exposure estimate (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	SPERC (AISE and COLIPA SpERCs for formulation - Formulation COLIPA 6 and 8)

Protection target	Exposure estimate (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)

	Exposure estimate (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	Exposure estimate (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	Exposure estimate (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 5 - Formulation of Cosmetics: Fine Fragrances - Cleaning with Water (small scale)				
Release route	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)		

8	Exposure estimate (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)

	Exposure estimate (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

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	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

# 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 route	Release rate (kg/day)	Release estimation method
Water	1.26	SPERC (ESVOC 4)
Air	63	SPERC (ESVOC 4)
Soil	0	SPERC (ESVOC 4)

	Exposure estimate (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 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)

9	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	0.004 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	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

#### 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	Long-term, systemic					
Contributing scenario	Inhalation	Dermal	Combined routes	Exposure estimation Method		
Formulation 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		
Formulation 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. Concentration up to 10%. RMM: High level containment)  Derm: Extended TRA workers		
Formulation in closed, continuous process with occasional controlled exposure - liquid (PROC 2)	Exposure: 0.69 mg/m³ 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		

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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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)
(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		
(synthesis) where opportunity for exposure	Exposure: 0.02 mg/cm <sup>2</sup>	N/A	Acute: External exposure estimation tool (Quantitative
arises - liquid (PROC 4)	RCR: 0.108		assessment of residual exposure)
	Exposure: 0.004 mg/cm <sup>2</sup>	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
arises - soriu (1 ROC 4)	RCR: 0.022		assessment of residual exposure)
	Exposure: 0.04 mg/cm <sup>2</sup>	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
	RCR: 0.215		assessment of residual exposure)
	Exposure: 0.008 mg/cm <sup>2</sup>	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
solid (PROC 5)	RCR: 0.043		assessment of residual exposure)
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities - liquid		N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
	RCR: 0.054		
(charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid	Exposure: 0.004 mg/cm <sup>2</sup> RCR: 0.022	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
(charging/discharging) from/to vessels/large containers at dedicated facilities - liquid	Exposure: 0.02 mg/cm <sup>2</sup> RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
(PROC 86)	KCK. 0.100		
	Exposure: 0.004 mg/cm <sup>2</sup>	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
	RCR: 0.022		1)
	Exposure: 0.02 mg/cm <sup>2</sup>	N/A	Acute: External exposure estimation tool (Quantitative exposure of residual exposure)
morading moraling) inquia (11000)	RCR: 0.108		onposure of residual exposure)
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)

(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)
	Exposure: 0.02 mg/cm <sup>2</sup> RCR: 0.108	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
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)
15)	Exposure: 0.002 mg/cm <sup>2</sup> RCR: 0.011	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
	Exposure: 3.99E-4 mg/cm <sup>2</sup> RCR: 0.002	N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)

<sup>\*</sup>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  $M_{\text{Safe}}$ .

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 ( $g_{Site}$ ) 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  $M_{safe}$  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  $0.725 (1 - 0.275 \text{ or } 1 - (\text{Sum of all man through environment and generic consumer exposure), the downstreamuser works within the boundaries set by the ES.$ 

Table 4.1 Effectiveness of risk management measures (RMM).

Risk management measure	Assumed effectiveness <sup>3</sup>		Source of effectiveness		
	Inhalatory	Dermal	1		
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%	ECETOC TRACLE //		
Concentration of substance in mixture	400/	7.50/	ECETOC TRA (http://www.ecetoc.org/tra) for the		
> 5% and <= 25%	40%	75%	inhalatory effectiveness, expert judgment for dermal effectiveness.		
> 1% and <= 5%	80%	95%	effectiveness.		
<= 1%	90%	99%			

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<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  * CEPE 15, 16 - Other products - Valetiles / Abstract including index proint sources.	
* 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	
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

PROC 19

#### 2. Conditions of use affecting exposure

Control of environmental exposure for Industrial use of fragranced products is included under Chapter 6.

#### 2.1 Control of environmental exposure:

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

**2.1.1** Control of environmental exposure: 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 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

# **2.1.2 Control of environmental exposure:** 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 >= 2E3 m3/d

STP sludge is applied on agricultural soil

# **2.1.3** Control of environmental exposure: 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 >= 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

## 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 >= 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

# **2.1.5 Control of environmental exposure:** 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 >= 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

**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 >= 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

**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 >= 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

## 2.2 Control of workers exposure for Use 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.

# 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 1/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.

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

#### **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.

### 2.12 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  $m^2$ ) - 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%.

For professional use concentration >10%:

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

For professional use concentration <10%:

- \* 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.
- **2.13 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.

**2.14 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.

**2.15 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.

**2.16 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.

**2.17 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.

**2.18 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).

Transfer of solid products - falling powders.

\*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.

# 2.19 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>)

\*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).

# **2.20 Control of workers exposure for** Treatment of articles by dipping and pouring - liquid (PROC 13) (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 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 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 1/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 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 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**

CEPE 15, 16a - Other spray coating - Volatiles / Abatement 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
İ		(CEPE 15, 16a)

Protection target	Exposure estimate (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	lease 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	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	0.012

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	Exposure estimate (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

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)

	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

Environment ESVOC 38 - Use of the substance within laboratory setting, including pilot plants			
Release route	elease 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	Exposure estimate (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

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	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	0.013

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	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	0.004 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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	Exposure: 13 mg/m³ 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)
(PROC 8a)				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/m³ 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)
(PROC 8a)				Derm: Extended TRA workers
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities - liquid	Exposure: 13 mg/m³ 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 8b)				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/m³ 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
				Z Entended 1101

				workers
Transfer of substance or preparation into small containers (dedicated filling line, including weighing) - liquid (PROC 9)	Exposure: 13 mg/m³ 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/m³ 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/m³ 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/m³ 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/m³ 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
Use as laboratory reagent - liquid (PROC 15)	Exposure: 4.2 mg/m³ 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/m³ 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/m³ 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/m³ 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	
		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	<b>Exposure estimation Method</b>
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)

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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)
(charging/discharging) from/to vessels/large containers at non-dedicated facilities - liquid		N/A	Acute: External exposure estimation tool (Quantitative assessment of residual exposure)
(charging/discharging) from/to vessels/large containers at non-dedicated facilities - solid	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)
(charging/discharging) from/to vessels/large containers at dedicated facilities - solid	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)
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)

<sup>\*</sup>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 ( $g_{Site}$ ) 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 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.

#### 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 measures (RMM).

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%	

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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.

Human health

See Industrial use.

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

# 1. Title of Exposure scenario

#### **Environment:**

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

ERC 8a, 8c, 8d, 8f, 9a, 9b, 10a, 11a

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

\* 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 >= 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

**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 >= 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

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 >= 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

**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

# Environment Professional and consumer use of coatings/inks, lubricants and construction chemicals Release route Release rate (kg/day) Release estimation method SPERC (Wide dispersive use coatings/inks, lubricants, construction chemicals) Air 0.003 SPERC (Wide dispersive use coatings/inks, lubricants, construction chemicals) SPERC SPERC SPERC SPERC SPERC SPERC

0.15	(Wide dispersive use coatings/inks, lubricants,
	construction chemicals)

Protection target	Exposure estimate (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

Environment Professional and consumer use resulting in and after inclusion into / onto a matrix				
Release route	ute 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	Exposure estimate (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	RCR: 0.249	mg/kg	Exposure: 0.02 mg/kg bw/day RCR: 0.005		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.

Contributing scenario	Acute	Long term	Exposure estimation Method
cleaning products, aerosols, coatings, de-	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

**Environment** 

Not applicable for consumer uses.

Human health

Not applicable for consumer uses.