



SAFETY DATA SHEET (1907/2006)

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ESCALOLÂ® 517

1. ES 1: Formulation; Formulation of cosmetic products

1.1. Title section

Environment	
CS 1: Formulation of preparations	ERC 2
Worker	
CS 2: Use in closed process, no likelihood of exposure	PROC 1
CS 3: Use in closed, continuous process with occasional controlled exposure	PROC 2
CS 4: Use in closed batch process (synthesis or formulation)	PROC 3
CS 5: Mixing or blending in batch processes for formulation of preparations and articles and/or significant contact	PROC 5 (multistage)
CS 6: Transfer of substance or preparation (charging/discharging) from/to vessels/large at non-dedicated facilities	PROC 8a containers
CS 7: Transfer of substance or preparation (charging/discharging) from/to vessels/large at dedicated facilities	PROC 8b containers
CS 8: Transfer of substance or preparation into small containers (dedicated filling line, weighing)	PROC 9 including
CS 9: Production of preparations or articles by tableting, compression, extrusion, pelletisation	PROC 14
CS 10: Use as laboratory reagent	PROC 15

1.2. Conditions of use affecting exposure

1.2.1. Control of environmental exposure: Formulation of preparations (ERC 2)

Amount used, frequency and duration of use (or from service life)
Daily amount per site <= 0.08 tonnes/day
Annual amount per site <= 24.0 tonnes/year
Technical and organisational conditions and measures
<i>physical-chemical treatment: yes (Water: 90%)</i>
Conditions and measures related to sewage treatment plant
Estimated substance removal from wastewater via municipal sewage treatment 79.0 %

Assumed domestic sewage treatment plant flow \geq 2000 m ³ /d
No application of sewage sludge to soil.
Conditions and measures related to treatment of waste (including article waste)
Dispose of waste or used sacks/containers according to local regulations.
Other conditions affecting environmental exposure
Receiving surface water flow \geq 18000 m ³ /d

1.2.2. Control of worker exposure: Use in closed process, no likelihood of exposure (PROC 1)

Product (article) characteristics
<i>Dustiness of material: High</i>
<i>Covers percentage substance in the product up to 100 %.</i>
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Use in closed process, no likelihood of exposure
<i>Advanced (industrial) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

1.2.3. Control of worker exposure: Use in closed, continuous process with occasional controlled exposure (PROC 2)

Product (article) characteristics
<i>Dustiness of material: High</i>
<i>Covers percentage substance in the product up to 100 %.</i>
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Use in closed, continuous process with occasional controlled exposure
<i>Advanced (industrial) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use

Covers use at ambient temperatures.

1.2.4. Control of worker exposure: Use in closed batch process (synthesis or formulation) (PROC 3)

Product (article) characteristics
<i>Dustiness of material: High</i>
<i>Covers percentage substance in the product up to 100 %.</i>
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Use in closed batch process (synthesis or formulation)
<i>Advanced (industrial) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

1.2.5. Control of worker exposure: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)

Product (article) characteristics
<i>Dustiness of material: High</i>
<i>Covers percentage substance in the product up to 100 %.</i>
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Local exhaust ventilation - efficiency of at least 90.0 %
<i>Local exhaust ventilation (for dermal): yes (Dermal: 90%)</i>
<i>Advanced (industrial) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

1.2.6. Control of worker exposure: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)

Product (article) characteristics
<i>Dustiness of material: High</i>
<i>Covers percentage substance in the product up to 100 %.</i>
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Local exhaust ventilation - efficiency of at least 90.0 %
<i>Local exhaust ventilation (for dermal): yes (Dermal: 90%)</i>
<i>Advanced (industrial) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

1.2.7. Control of worker exposure: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)

Product (article) characteristics
<i>Dustiness of material: High</i>
<i>Covers percentage substance in the product up to 100 %.</i>
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Use in semi-closed process with opportunity for exposure
Local exhaust ventilation - efficiency of at least 95.0 %
<i>Local exhaust ventilation: yes (Inhal: 95%)</i>
<i>Advanced (industrial) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

1.2.8. Control of worker exposure: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)

Product (article) characteristics
<i>Dustiness of material: High</i>

<i>Covers percentage substance in the product up to 100 %.</i>
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Use in semi-closed process with opportunity for exposure
Local exhaust ventilation - efficiency of at least 90.0 %
<i>Local exhaust ventilation (for dermal): yes (Dermal: 90%)</i>
<i>Advanced (industrial) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

1.2.9. Control of worker exposure: Production of preparations or articles by tableting, compression, extrusion, pelletisation (PROC 14)

Product (article) characteristics
<i>Dustiness of material: High</i>
<i>Covers percentage substance in the product up to 100 %.</i>
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
<i>Advanced (industrial) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

1.2.10. Control of worker exposure: Use as laboratory reagent (PROC 15)

Product (article) characteristics
<i>Dustiness of material: High</i>
<i>Covers percentage substance in the product up to 100 %.</i>
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures

Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
<i>Advanced (industrial) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

1.3. Exposure estimation and reference to its source

1.3.1. Environmental release and exposure: Formulation of preparations (ERC 2)

Release route	Release rate	Release estimation method
Water	0.016 kg/day	SpERC based Cosmetics Europe / AISE 2.3c.v2 - Cosmetics Europe / AISE 2.3c.v2 Industrial use in formulation of solid cosmetic and home care products (small scale) - Formulation of solid cosmetic and home care products (small scale)
Air	0 kg/day	SpERC based same as above
Soil	0 kg/day	SpERC based same as above

Protection target	Exposure estimate (based on: EUSES 2.1.2)	RCR
Freshwater	2.042E-4 mg/L	< 0.01
Sediment (freshwater)	0.904 mg/kg dw	0.756
Marine water	2.059E-5 mg/L	< 0.01
Sediment (marine water)	0.091 mg/kg dw	0.076
Predator (freshwater)	0.201 mg/kg ww	< 0.01
Predator (marine water)	0.02 mg/kg ww	< 0.01
Top predator (marine water)	0.011 mg/kg ww	< 0.01
Sewage treatment plant	0.002 mg/L	< 0.01
Agricultural soil	0.028 mg/kg dw	0.119
Predator (terrestrial)	1.139 mg/kg ww	0.011

1.3.2. Worker exposure: Use in closed process, no likelihood of exposure (PROC 1)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Workers 3.0)	< 0.01

Inhalation, systemic, acute	0.04 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	0.034 mg/kg bw/day (TRA Workers 3.0)	< 0.01
Combined routes, systemic, long-term		< 0.01
Combined routes, systemic, acute		< 0.01

1.3.3. Worker exposure: Use in closed, continuous process with occasional controlled exposure (PROC 2)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	1 mg/m ³ (TRA Workers 3.0)	0.025
Inhalation, systemic, acute	4 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	1.37 mg/kg bw/day (TRA Workers 3.0)	0.211
Combined routes, systemic, long-term		0.237
Combined routes, systemic, acute		< 0.01

1.3.4. Worker exposure: Use in closed batch process (synthesis or formulation) (PROC 3)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	1 mg/m ³ (TRA Workers 3.0)	0.025
Inhalation, systemic, acute	4 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	0.69 mg/kg bw/day (TRA Workers 3.0)	0.106
Combined routes, systemic, long-term		0.132
Combined routes, systemic, acute		< 0.01

1.3.5. Worker exposure: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	2.5 mg/m ³ (TRA Workers 3.0)	0.063
Inhalation, systemic, acute	10 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	1.371 mg/kg bw/day (TRA Workers 3.0)	0.211
Combined routes, systemic, long-term		0.275
Combined routes, systemic, acute		< 0.01

1.3.6. Worker exposure: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	5 mg/m ³ (TRA Workers 3.0)	0.127
Inhalation, systemic, acute	20 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	1.371 mg/kg bw/day (TRA Workers 3.0)	0.211
Combined routes, systemic, long-term		0.338

Combined routes, systemic, acute	< 0.01
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1.3.7. Worker exposure: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	1.25 mg/m ³ (TRA Workers 3.0)	0.032
Inhalation, systemic, acute	5 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	0.685 mg/kg bw/day (TRA Workers 3.0)	0.106
Combined routes, systemic, long-term		0.137
Combined routes, systemic, acute		< 0.01

1.3.8. Worker exposure: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	2 mg/m ³ (TRA Workers 3.0)	0.051
Inhalation, systemic, acute	8 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	0.686 mg/kg bw/day (TRA Workers 3.0)	0.106
Combined routes, systemic, long-term		0.157
Combined routes, systemic, acute		< 0.01

1.3.9. Worker exposure: Production of preparations or articles by tableting, compression, extrusion, pelletisation (PROC 14)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	10 mg/m ³ (TRA Workers 3.0)	0.254
Inhalation, systemic, acute	40 mg/m ³ (TRA Workers 3.0)	0.016
Dermal, systemic, long-term	3.43 mg/kg bw/day (TRA Workers 3.0)	0.529
Combined routes, systemic, long-term		0.782
Combined routes, systemic, acute		0.016

1.3.10. Worker exposure: Use as laboratory reagent (PROC 15)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	5 mg/m ³ (TRA Workers 3.0)	0.127
Inhalation, systemic, acute	20 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	0.34 mg/kg bw/day (TRA Workers 3.0)	0.052
Combined routes, systemic, long-term		0.179
Combined routes, systemic, acute		< 0.01

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

Human

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL for workers (given that the processes and activities in question are covered by the PROCs listed above) as given below:

Route	Type of effect	Hazard conclusion
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level): 39.38 mg/m ³
Inhalation	Systemic effects - Acute	DNEL (Derived No Effect Level): 2520 mg/m ³
Inhalation	Local effects - Long-term	No hazard identified
Inhalation	Local effects - Acute	No hazard identified
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level): 6.49 mg/kg bw/day
Dermal	Systemic effects - Acute	No hazard identified
Dermal	Local effects - Long-term	No hazard identified
Dermal	Local effects - Acute	No hazard identified
Route	Type of effect	Hazard conclusion
Eyes	Local effects	No hazard identified

If measured data are not available, the DU may make use of an appropriate scaling tool such as Chesar to estimate the associated exposure.

Environment

For Environmental exposure, if the operation conditions described above in the contributing scenario are met, and risk management measures are already carried out, it can be regarded the use of DU or their customers has been covered by this exposure scenario, and the risk is controlled.

If the OC and RMM is not well matched with what described above in the contributing scenario, DU can make use of an appropriate scaling tool such as Chesar by use of the assessment method given at the beginning of contributing scenario.

Compartment	Hazard conclusion
Freshwater	PNEC aqua (freshwater): 0.027 mg/L
Marine water	PNEC aqua (marine water): 0.027 mg/L
Intermittent releases to water	PNEC aqua (intermittent releases): 0.027 mg/L
Sediments (freshwater)	PNEC sediment (freshwater): 11.96 mg/kg sediment dw
Sediments (marine water)	PNEC sediment (marine water): 11.96 mg/kg sediment dw
Sewage treatment plant	PNEC STP: 100 mg/L
Soil	PNEC soil: 2.384 mg/kg soil dw

Air	No hazard identified:
Secondary poisoning	PNEC oral: 100 mg/kg food

2. ES 2: Use at industrial site; Use as cosmetics Intermediate

2.1. Title section

Environment	
CS 1: Industrial use resulting in manufacture of another substance (use of intermediates) ERC 6a	
Worker	
CS 2: Use in closed batch process (synthesis or formulation)	PROC 3
CS 3: Use in batch and other process (synthesis) where opportunity for exposure arises	PROC 4
CS 4: Mixing or blending in batch processes for formulation of preparations and articles PROC 5 (multistage and/or significant contact)	

2.2. Conditions of use affecting exposure

2.2.1. Control of environmental exposure: Industrial use resulting in manufacture of another substance (use of intermediates) (ERC 6a)

Amount used, frequency and duration of use (or from service life)
Daily amount per site <= 0.008 tonnes/day
Annual amount per site <= 2.4 tonnes/year
Technical and organisational conditions and measures
<i>physical-chemical treatment: yes (Water: 90%)</i>
Conditions and measures related to sewage treatment plant
Estimated substance removal from wastewater via municipal sewage treatment 79.0 %
Assumed domestic sewage treatment plant flow >= 2000 m3/d
No application of sewage sludge to soil.
Conditions and measures related to treatment of waste (including article waste)
Dispose of waste or used sacks/containers according to local regulations.
Other conditions affecting environmental exposure
Receiving surface water flow >= 18000 m3/d

2.2.2. Control of worker exposure: Use in closed batch process (synthesis or formulation) (PROC 3)

Product (article) characteristics
<i>Dustiness of material: High</i>
<i>Covers percentage substance in the product up to 100 %.</i>

Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Use in closed batch process (synthesis or formulation)
<i>Advanced (industrial) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

2.2.3. Control of worker exposure: Use in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)

Product (article) characteristics
<i>Dustiness of material: High</i>
<i>Covers percentage substance in the product up to 100 %.</i>
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Use in semi-closed process with opportunity for exposure
Local exhaust ventilation - efficiency of at least 90.0 %
<i>Local exhaust ventilation (for dermal): yes (Dermal: 90%)</i>
<i>Advanced (industrial) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

2.2.4. Control of worker exposure: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)

Product (article) characteristics
<i>Dustiness of material: High</i>
<i>Covers percentage substance in the product up to 100 %.</i>
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>

Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Local exhaust ventilation - efficiency of at least 90.0 %
<i>Local exhaust ventilation (for dermal): yes (Dermal: 90%)</i>
<i>Advanced (industrial) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

2.3. Exposure estimation and reference to its source

2.3.1. Environmental release and exposure: Industrial use resulting in manufacture of another substance (use of intermediates) (ERC 6a)

Release route	Release rate	Release estimation method
Water	0.016 kg/day	ERC based
Air	8E-5 kg/day	Release factor
Release route	Release rate	Release estimation method
Soil	8E-4 kg/day	Release factor

Protection target	Exposure estimate (based on: EUSES 2.1.2)	RCR
Freshwater	2.042E-4 mg/L	< 0.01
Sediment (freshwater)	0.904 mg/kg dw	0.756
Marine water	2.059E-5 mg/L	< 0.01
Sediment (marine water)	0.091 mg/kg dw	0.076
Predator (freshwater)	0.201 mg/kg ww	< 0.01
Predator (marine water)	0.02 mg/kg ww	< 0.01
Top predator (marine water)	0.011 mg/kg ww	< 0.01
Sewage treatment plant	0.002 mg/L	< 0.01
Agricultural soil	0.028 mg/kg dw	0.119
Predator (terrestrial)	1.139 mg/kg ww	0.011

2.3.2. Worker exposure: Use in closed batch process (synthesis or formulation) (PROC 3)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	1 mg/m ³ (TRA Workers 3.0)	0.025
Inhalation, systemic, acute	4 mg/m ³ (TRA Workers 3.0)	< 0.01

Dermal, systemic, long-term	0.69 mg/kg bw/day (TRA Workers 3.0)	0.106
Combined routes, systemic, long-term		0.132
Combined routes, systemic, acute		< 0.01

2.3.3. Worker exposure: Use in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	2.5 mg/m ³ (TRA Workers 3.0)	0.063
Inhalation, systemic, acute	10 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	0.686 mg/kg bw/day (TRA Workers 3.0)	0.106
Combined routes, systemic, long-term		0.169
Combined routes, systemic, acute		< 0.01

2.3.4. Worker exposure: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	2.5 mg/m ³ (TRA Workers 3.0)	0.063
Inhalation, systemic, acute	10 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	1.371 mg/kg bw/day (TRA Workers 3.0)	0.211
Combined routes, systemic, long-term		0.275
Combined routes, systemic, acute		< 0.01

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

Human

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL for workers (given that the processes and activities in question are covered by the PROCs listed above) as given below:

Route	Type of effect	Hazard conclusion
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level): 39.38 mg/m ³
Inhalation	Systemic effects - Acute	DNEL (Derived No Effect Level): 2520 mg/m ³
Inhalation	Local effects - Long-term	No hazard identified
Inhalation	Local effects - Acute	No hazard identified
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level): 6.49 mg/kg bw/day
Dermal	Systemic effects - Acute	No hazard identified
Dermal	Local effects - Long-term	No hazard identified

Dermal	Local effects - Acute	No hazard identified
Eyes	Local effects	No hazard identified

If measured data are not available, the DU may make use of an appropriate scaling tool such as Chesar to estimate the associated exposure.

Environment

For Environmental exposure, if the operation conditions described above in the contributing scenario are met, and risk management measures are already carried out, it can be regarded the use of DU or their customers has been covered by this exposure scenario, and the risk is controlled.

If the OC and RMM is not well matched with what described above in the contributing scenario, DU can make use of an appropriate scaling tool such as Chesar by use of the assessment method given at the beginning of contributing scenario.

Compartment	Hazard conclusion
Freshwater	PNEC aqua (freshwater): 0.027 mg/L
Marine water	PNEC aqua (marine water): 0.027 mg/L
Intermittent releases to water	PNEC aqua (intermittent releases): 0.027 mg/L
Sediments (freshwater)	PNEC sediment (freshwater): 11.96 mg/kg sediment dw
Sediments (marine water)	PNEC sediment (marine water): 11.96 mg/kg sediment dw
Sewage treatment plant	PNEC STP: 100 mg/L
Soil	PNEC soil: 2.384 mg/kg soil dw
Air	No hazard identified:
Secondary poisoning	PNEC oral: 100 mg/kg food

3. ES 3: Use by professional worker; cosmetics application

3.1. Title section

Environment	
CS 1: Wide dispersive indoor use of substances in closed systems	ERC 9a
Worker	
CS 2: Mixing or blending in batch processes for formulation of preparations and articles PROC 5 (multistage and/or significant contact)	

3.2. Conditions of use affecting exposure

3.2.1. Control of environmental exposure: Wide dispersive indoor use of substances in closed systems (ERC 9a)

Conditions and measures related to treatment of waste (including article waste)
Dispose of waste or used sacks/containers according to local regulations.

3.2.2. Control of worker exposure: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)

Product (article) characteristics
<i>Dustiness of material: High</i>
Limit the substance content in the product to 5 %.
Covers solid products only.
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
<i>Basic (professional) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

3.3. Exposure estimation and reference to its source

3.3.1. Environmental release and exposure: Wide dispersive indoor use of substances in closed systems (ERC 9a)

Release route	Release rate	Release estimation method
Water	2.2E-4 kg/day	ERC based
Air	2.2E-4 kg/day	ERC based
Soil	0 kg/day	ERC based

Protection target	Exposure estimate (based on: EUSES 2.1.2)	RCR
Freshwater	4.883E-5 mg/L	< 0.01
Sediment (freshwater)	0.216 mg/kg dw	0.181
Marine water	5.057E-6 mg/L	< 0.01
Sediment (marine water)	0.022 mg/kg dw	0.019
Predator (freshwater)	0.086 mg/kg ww	< 0.01
Predator (marine water)	0.009 mg/kg ww	< 0.01

Top predator (marine water)	0.009 mg/kg ww	< 0.01
Sewage treatment plant	2.31E-5 mg/L	< 0.01
Agricultural soil	0.032 mg/kg dw	0.134
Predator (terrestrial)	1.167 mg/kg ww	0.012

3.3.2. Worker exposure: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	10 mg/m ³ (TRA Workers 3.0)	0.254
Inhalation, systemic, acute	40 mg/m ³ (TRA Workers 3.0)	0.016
Dermal, systemic, long-term	2.742 mg/kg bw/day (TRA Workers 3.0)	0.423
Combined routes, systemic, long-term		0.676
Combined routes, systemic, acute		0.016

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

Human

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL for workers (given that the processes and activities in question are covered by the PROCs listed above) as given below:

Route	Type of effect	Hazard conclusion
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level): 39.38 mg/m ³
Inhalation	Systemic effects - Acute	DNEL (Derived No Effect Level): 2520 mg/m ³
Inhalation	Local effects - Long-term	No hazard identified
Inhalation	Local effects - Acute	No hazard identified
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level): 6.49 mg/kg bw/day
Dermal	Systemic effects - Acute	No hazard identified
Dermal	Local effects - Long-term	No hazard identified
Dermal	Local effects - Acute	No hazard identified
Eyes	Local effects	No hazard identified

If measured data are not available, the DU may make use of an appropriate scaling tool such as Chesar to estimate the associated exposure.

Environment

For Environmental exposure, if the operation conditions described above in the contributing scenario are met, and risk management measures are already carried out, it can be regarded the use of DU or their customers has been covered by this exposure scenario, and the risk is controlled.

If the OC and RMM is not well matched with what described above in the contributing scenario, DU can make use of an appropriate scaling tool such as Chesar by use of the assessment method given at the beginning of contributing scenario.

Compartment	Hazard conclusion
Freshwater	PNEC aqua (freshwater): 0.027 mg/L
Marine water	PNEC aqua (marine water): 0.027 mg/L
Intermittent releases to water	PNEC aqua (intermittent releases): 0.027 mg/L
Sediments (freshwater)	PNEC sediment (freshwater): 11.96 mg/kg sediment dw
Sediments (marine water)	PNEC sediment (marine water): 11.96 mg/kg sediment dw
Sewage treatment plant	PNEC STP: 100 mg/L
Soil	PNEC soil: 2.384 mg/kg soil dw
Air	No hazard identified:
Secondary poisoning	PNEC oral: 100 mg/kg food

4. ES 4: Use by professional worker; Professional use of cosmetic products

4.1. Title section

Environment	
CS 1: Wide dispersive outdoor use of processing aids in open systems	ERC 8d, ERC 8a
Worker	
CS 2: Use in closed process, no likelihood of exposure	PROC 1
CS 3: Use in closed, continuous process with occasional controlled exposure	PROC 2
CS 4: Use in closed batch process (synthesis or formulation)	PROC 3
CS 5: Use in batch and other process (synthesis) where opportunity for exposure arises	PROC 4
CS 6: Mixing or blending in batch processes for formulation of preparations and articles and/or significant contact	PROC 5 (multistage)
CS 7: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	PROC 8a
CS 8: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	PROC 8b
CS 9: Transfer of substance or preparation into small containers (dedicated filling line, weighing)	PROC 9 including
CS 10: Roller application or brushing	PROC 10
CS 11: Production of preparations or articles by tableting, compression, extrusion, pelletisation	PROC 14

4.2. Conditions of use affecting exposure

4.2.1. Control of environmental exposure: Wide dispersive outdoor use of processing aids in open systems (ERC 8d)

Conditions and measures related to treatment of waste (including article waste)
Dispose of waste or used sacks/containers according to local regulations.

4.2.2. Control of worker exposure: Use in closed process, no likelihood of exposure (PROC 1)

Product (article) characteristics
<i>Dustiness of material: High</i>
Limit the substance content in the product to 5 %.
Covers solid products only.
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Use in closed process, no likelihood of exposure

<i>Basic (professional) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

4.2.3. Control of worker exposure: Use in closed, continuous process with occasional controlled exposure (PROC 2)

Product (article) characteristics
<i>Dustiness of material: High</i>
Limit the substance content in the product to 5 %.
Covers solid products only.
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Use in closed, continuous process with occasional controlled exposure
<i>Basic (professional) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

4.2.4. Control of worker exposure: Use in closed batch process (synthesis or formulation) (PROC 3)

Product (article) characteristics
<i>Dustiness of material: High</i>
Limit the substance content in the product to 5 %.
Covers solid products only.
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Use in closed batch process (synthesis or formulation)
<i>Basic (professional) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use

Covers use at ambient temperatures.

4.2.5. Control of worker exposure: Use in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)

Product (article) characteristics
<i>Dustiness of material: High</i>
Limit the substance content in the product to 5 %.
Covers solid products only.
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Use in semi-closed process with opportunity for exposure
<i>Basic (professional) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

4.2.6. Control of worker exposure: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)

Product (article) characteristics
<i>Dustiness of material: High</i>
Limit the substance content in the product to 5 %.
Covers solid products only.
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
<i>Basic (professional) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

4.2.7. Control of worker exposure: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)

Product (article) characteristics
<i>Dustiness of material: High</i>
Limit the substance content in the product to 5 %.
Covers solid products only.
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
<i>Basic (professional) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

4.2.8. Control of worker exposure: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)

Product (article) characteristics
<i>Dustiness of material: High</i>
Limit the substance content in the product to 5 %.
Covers solid products only.
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Use in semi-closed process with opportunity for exposure
<i>Basic (professional) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

4.2.9. Control of worker exposure: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)

Product (article) characteristics
<i>Dustiness of material: High</i>
Limit the substance content in the product to 5 %.
Covers solid products only.

Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
Use in semi-closed process with opportunity for exposure
<i>Basic (professional) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

4.2.10. Control of worker exposure: Roller application or brushing (PROC 10)

Product (article) characteristics
<i>Dustiness of material: High</i>
Limit the substance content in the product to 5 %.
Covers solid products only.
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .
<i>Basic (professional) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

4.2.11. Control of worker exposure: Production of preparations or articles by tableting, compression, extrusion, pelletisation (PROC 14)

Product (article) characteristics
<i>Dustiness of material: High</i>
Limit the substance content in the product to 5 %.
Covers solid products only.
Amount used (or contained in articles), frequency and duration of use/exposure
<i>Covers daily exposures up to 8 hours.</i>
Technical and organisational conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour) .

<i>Basic (professional) exposure controls assumed.</i>
Other conditions affecting workers exposure
Indoor use
Covers use at ambient temperatures.

4.3. Exposure estimation and reference to its source

4.3.1. Environmental release and exposure: Wide dispersive outdoor use of processing aids in open systems (ERC 8d)

Release route	Release rate	Release estimation method
Water	0.004 kg/day	ERC based
Air	0.004 kg/day	ERC based
Soil	8.8E-4 kg/day	ERC based

Protection target	Exposure estimate (based on: EUSES 2.1.2)	RCR
Freshwater	8.999E-5 mg/L	< 0.01
Sediment (freshwater)	0.399 mg/kg dw	0.333
Marine water	9.173E-6 mg/L	< 0.01
Sediment (marine water)	0.041 mg/kg dw	0.034
Predator (freshwater)	0.124 mg/kg ww	< 0.01
Predator (marine water)	0.013 mg/kg ww	< 0.01
Top predator (marine water)	0.01 mg/kg ww	< 0.01
Sewage treatment plant	4.62E-4 mg/L	< 0.01
Agricultural soil	0.101 mg/kg dw	0.425
Predator (terrestrial)	1.702 mg/kg ww	0.017

4.3.2. Worker exposure: Use in closed process, no likelihood of exposure (PROC 1)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	0.02 mg/m ³ (TRA Workers 3.0)	< 0.01
Inhalation, systemic, acute	0.08 mg/m ³ (TRA Workers 3.0)	< 0.01
Route of exposure and type of effects	Exposure estimate	RCR
Dermal, systemic, long-term	0.007 mg/kg bw/day (TRA Workers 3.0)	< 0.01
Combined routes, systemic, long-term		< 0.01
Combined routes, systemic, acute		< 0.01

4.3.3. Worker exposure: Use in closed, continuous process with occasional controlled exposure (PROC 2)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	1 mg/m ³ (TRA Workers 3.0)	0.025
Inhalation, systemic, acute	4 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	0.274 mg/kg bw/day (TRA Workers 3.0)	0.042
Combined routes, systemic, long-term		0.068
Combined routes, systemic, acute		< 0.01

4.3.4. Worker exposure: Use in closed batch process (synthesis or formulation) (PROC 3)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	1 mg/m ³ (TRA Workers 3.0)	0.025
Inhalation, systemic, acute	4 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	0.138 mg/kg bw/day (TRA Workers 3.0)	0.021
Combined routes, systemic, long-term		0.047
Combined routes, systemic, acute		< 0.01

4.3.5. Worker exposure: Use in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	10 mg/m ³ (TRA Workers 3.0)	0.254
Inhalation, systemic, acute	40 mg/m ³ (TRA Workers 3.0)	0.016
Dermal, systemic, long-term	1.372 mg/kg bw/day (TRA Workers 3.0)	0.211
Combined routes, systemic, long-term		0.465
Combined routes, systemic, acute		0.016

4.3.6. Worker exposure: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	10 mg/m ³ (TRA Workers 3.0)	0.254
Inhalation, systemic, acute	40 mg/m ³ (TRA Workers 3.0)	0.016
Dermal, systemic, long-term	2.742 mg/kg bw/day (TRA Workers 3.0)	0.423
Combined routes, systemic, long-term		0.676
Combined routes, systemic, acute		0.016

4.3.7. Worker exposure: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)

Route of exposure and type of effects	Exposure estimate	RCR
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Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	10 mg/m ³ (TRA Workers 3.0)	0.254
Inhalation, systemic, acute	40 mg/m ³ (TRA Workers 3.0)	0.016
Dermal, systemic, long-term	2.742 mg/kg bw/day (TRA Workers 3.0)	0.423
Combined routes, systemic, long-term		0.676
Combined routes, systemic, acute		0.016

4.3.8. Worker exposure: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	10 mg/m ³ (TRA Workers 3.0)	0.254
Inhalation, systemic, acute	40 mg/m ³ (TRA Workers 3.0)	0.016
Dermal, systemic, long-term	2.742 mg/kg bw/day (TRA Workers 3.0)	0.423
Combined routes, systemic, long-term		0.676
Combined routes, systemic, acute		0.016

4.3.9. Worker exposure: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	4 mg/m ³ (TRA Workers 3.0)	0.102
Inhalation, systemic, acute	16 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	1.372 mg/kg bw/day (TRA Workers 3.0)	0.211
Combined routes, systemic, long-term		0.313
Combined routes, systemic, acute		< 0.01

4.3.10. Worker exposure: Roller application or brushing (PROC 10)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	2 mg/m ³ (TRA Workers 3.0)	0.051
Inhalation, systemic, acute	8 mg/m ³ (TRA Workers 3.0)	< 0.01
Dermal, systemic, long-term	5.486 mg/kg bw/day (TRA Workers 3.0)	0.845
Combined routes, systemic, long-term		0.896
Combined routes, systemic, acute		< 0.01

4.3.11. Worker exposure: Production of preparations or articles by tableting, compression, extrusion, pelletisation (PROC 14)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systemic, long-term	10 mg/m ³ (TRA Workers 3.0)	0.254
Inhalation, systemic, acute	40 mg/m ³ (TRA Workers 3.0)	0.016

Dermal, systemic, long-term	0.686 mg/kg bw/day (TRA Workers 3.0)	0.106
Combined routes, systemic, long-term		0.36
Combined routes, systemic, acute		0.016

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

Human

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL for workers (given that the processes and activities in question are covered by the PROCs listed above) as given below:

Route	Type of effect	Hazard conclusion
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level): 39.38 mg/m ³
Inhalation	Systemic effects - Acute	DNEL (Derived No Effect Level): 2520 mg/m ³
Inhalation	Local effects - Long-term	No hazard identified
Inhalation	Local effects - Acute	No hazard identified
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level): 6.49 mg/kg bw/day
Dermal	Systemic effects - Acute	No hazard identified
Dermal	Local effects - Long-term	No hazard identified
Dermal	Local effects - Acute	No hazard identified
Eyes	Local effects	No hazard identified

If measured data are not available, the DU may make use of an appropriate scaling tool such as Chesar to estimate the associated exposure.

Environment

For Environmental exposure, if the operation conditions described above in the contributing scenario are met, and risk management measures are already carried out, it can be regarded the use of DU or their customers has been covered by this exposure scenario, and the risk is controlled.

If the OC and RMM is not well matched with what described above in the contributing scenario, DU can make use of an appropriate scaling tool such as Chesar by use of the assessment method given at the beginning of contributing scenario.

Compartment	Hazard conclusion
Freshwater	PNEC aqua (freshwater): 0.027 mg/L
Marine water	PNEC aqua (marine water): 0.027 mg/L
Intermittent releases to water	PNEC aqua (intermittent releases): 0.027 mg/L

Sediments (freshwater)	PNEC sediment (freshwater): 11.96 mg/kg sediment dw
Sediments (marine water)	PNEC sediment (marine water): 11.96 mg/kg sediment dw
Sewage treatment plant	PNEC STP: 100 mg/L
Soil	PNEC soil: 2.384 mg/kg soil dw
Air	No hazard identified:
Secondary poisoning	PNEC oral: 100 mg/kg food

5. ES 5: Consumer Use; Consumer end-use of cosmetic products

5.1. Title section

Environment	
CS 1: Wide dispersive indoor use of processing aids in open systems	ERC 8a
Consumer	
CS 2: Perfumes, fragrances	PC 28
CS 3: Cosmetics, personal care products	PC 39

5.2. Conditions of use affecting exposure

5.2.1. Control of environmental exposure: Wide dispersive indoor use of processing aids in open systems (ERC 8a)

Conditions and measures related to treatment of waste (including article waste)
Dispose of waste or used sacks/containers according to local regulations.

5.2.2. Control of consumer exposure: Perfumes, fragrances (PC 28)

REACH regulation Article 14(5) text: The chemical safety report need not include consideration of the risks to human health from the following end uses:

(a) in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food; (b) in cosmetic products within the scope of Directive 76/768/EEC.

According to REACH regulations article 14, the chemical safety report of substance A need not include consideration of the risks to human health in cosmetic products within the scope of Directive 76/768/EEC.

5.2.3. Control of consumer exposure: Cosmetics, personal care products (PC 39)

REACH regulation Article 14(5) text: The chemical safety report need not include consideration of the risks to human health from the following end uses:

(a) in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food; (b) in cosmetic products within the scope of Directive 76/768/EEC.

According to REACH regulations article 14, the chemical safety report of substance A need not include consideration of the risks to human health in cosmetic products within the scope of Directive 76/768/EEC.

5.3. Exposure estimation and reference to its source

5.3.1. Environmental release and exposure: Wide dispersive indoor use of processing aids in open systems (ERC 8a)

Release route	Release rate	Release estimation method
Water	0.005 kg/day	ERC based
Air	0.005 kg/day	ERC based
Soil	0 kg/day	ERC based

Protection target	Exposure estimate (based on: EUSES 2.1.2)	RCR
Freshwater	1.008E-4 mg/L	< 0.01
Sediment (freshwater)	0.446 mg/kg dw	0.373
Marine water	1.026E-5 mg/L	< 0.01
Sediment (marine water)	0.045 mg/kg dw	0.038
Predator (freshwater)	0.133 mg/kg ww	< 0.01
Predator (marine water)	0.014 mg/kg ww	< 0.01
Top predator (marine water)	0.01 mg/kg ww	< 0.01
Sewage treatment plant	5.775E-4 mg/L	< 0.01
Agricultural soil	0.12 mg/kg dw	0.502
Predator (terrestrial)	1.843 mg/kg ww	0.018

5.3.2. Consumer exposure: Perfumes, fragrances (PC 28)

REACH regulation Article 14(5) text: The chemical safety report need not include consideration of the risks to human health from the following end uses:

(a) in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food; (b) in cosmetic products within the scope of Directive 76/768/EEC.

According to REACH regulations article 14, the chemical safety report of substance A need not include consideration of the risks to human health in cosmetic products within the scope of Directive 76/768/EEC.

5.3.3. Consumer exposure: Cosmetics, personal care products (PC 39)

REACH regulation Article 14(5) text: The chemical safety report need not include consideration of the risks to human health from the following end uses:

(a) in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food; (b) in cosmetic products within the scope of Directive 76/768/EEC.

According to REACH regulations article 14, the chemical safety report of substance A need not include consideration of the risks to human health in cosmetic products within the scope of Directive 76/768/EEC.

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

Environment

For Environmental exposure, if the operation conditions described above in the contributing scenario are met, and risk management measures are already carried out, it can be regarded the use of DU or their customers has been covered by this exposure scenario, and the risk is controlled.

If the OC and RMM is not well matched with what described above in the contributing scenario, DU can make use of an appropriate scaling tool such as Chesar by use of the assessment method given at the beginning of contributing scenario.

Compartment	Hazard conclusion
Freshwater	PNEC aqua (freshwater): 0.027 mg/L
Marine water	PNEC aqua (marine water): 0.027 mg/L
Intermittent releases to water	PNEC aqua (intermittent releases): 0.027 mg/L
Sediments (freshwater)	PNEC sediment (freshwater): 11.96 mg/kg sediment dw
Sediments (marine water)	PNEC sediment (marine water): 11.96 mg/kg sediment dw
Compartment	Hazard conclusion
Sewage treatment plant	PNEC STP: 100 mg/L
Soil	PNEC soil: 2.384 mg/kg soil dw
Air	No hazard identified:
Secondary poisoning	PNEC oral: 100 mg/kg food