

SAFETY DATA SHEET  
According to Regulation (EC) No 1907/2006 (REACH)



华阴市锦前程药业有限公司  
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## Annex

### Exposure Scenario – Table of Contents

ES1. Formulation & (re)packing of substances and mixtures (PC21, PC28, PC39)

ES2. Use as an intermediate at industrial sites (PC28, PC29, PC39)

ES3. Consumer use – Use in cosmetics (PC39)

SAFETY DATA SHEET  
According to Regulation (EC) No 1907/2006 (REACH)



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**SALICYLIC ACID SOLID**

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Revision: 3.0

## ES1: Formulation or re-packing - Formulation & (re)packing of substances and mixtures

### 1. Short title of ES 1: Formulation or re-packing - Formulation & (re)packing of substances and mixtures

Laboratory chemicals (PC21), Perfumes, fragrances (PC28), Cosmetics, personal care products (PC39)

#### Environment contributing scenario(s):

CS1: Formulation into mixture ERC 2

#### Worker contributing scenario(s):

CS2: Mixing or blending in batch processes PROC 5

CS3: Transfer of substance or mixture (charging and discharging) at dedicated facilities PROC 8b

CS4: Transfer of substance or mixture into small containers (dedicated filling line, including weighing) PROC 9

CS5: Use as laboratory reagent PROC 15

## 2. Conditions of use affecting exposure

### 2.1 CS1: Control of environmental exposure: Formulation into mixture (ERC 2)

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

Daily use amount at site:  $\leq 0.1$  tonnes/day

Daily use amount at site:  $\leq 150.0$  tonnes/year

#### Conditions and measures related to biological sewage treatment plant

Biological STP: Site specific [Effectiveness Water: 87.38%]

Discharge rate of STP:  $\geq 2000$  m<sup>3</sup>/day

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Application of the STP sludge on agricultural soil: Yes

Conditions and measures related to external treatment of waste (including article waste)

Particular considerations on the waste treatment operations: Other

“Explanation for the CSR” to be reported by each registrant on the specific conditions required for waste treatment: comply with the local and/or national regulations.

Other conditions affecting environmental exposure

Receiving surface water flow rate:  $\geq 18000 \text{ m}^3/\text{day}$

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply

Dilution factor to marine water:  $\leq 100.0$

2.2 CS2: Control of worker exposure: Mixing or blending in batch processes (PROC 5)

Product (article) characteristics

Percentage (w/w) of substance in mixture/article:  $\leq 5.0 \%$

Physical form of the used product: Solid (medium dusty form)

Amount used (or contained in articles), frequency and duration of use/exposure

Duration of activity:  $\leq 4.0 \text{ h/day}$

Technical and organisational conditions and measures

Occupational Health and Safety Management System: Advanced

General ventilation: Good general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%]

Local exhaust ventilation: Yes [Effectiveness Inhalation: 90%, Dermal: 0%]

Conditions and measures related to personal protection, hygiene and health evaluation

Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhalation: 90%]

Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate

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Revision: 3.0

dermal protection [Effectiveness Dermal: 80%]

Use of eye protection: Yes

Other conditions affecting workers exposure

Place of use: Indoor

Operating temperature:  $\leq 40.0$  °C

2.3 CS3: Control of worker exposure: Transfer of substance or mixture (charging and discharging) at dedicated facilities (PROC 8b)

Product (article) characteristics

Percentage (w/w) of substance in mixture/article:  $\leq 5.0$  %

Physical form of the used product: Solid (medium dusty form)

Amount used (or contained in articles), frequency and duration of use/exposure

Duration of activity:  $\leq 4.0$  h/day

Technical and organisational conditions and measures

Occupational Health and Safety Management System: Advanced

General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%]

Local exhaust ventilation: Yes [Effectiveness Inhalation: 95%, Dermal: 0%]

Conditions and measures related to personal protection, hygiene and health evaluation

Respiratory Protection: Yes (Respirator with APF of 20) [Effectiveness Inhalation: 95%]

Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate

dermal protection [Effectiveness Dermal: 80%]

Use of eye protection: Yes

Other conditions affecting workers exposure

Place of use: Indoor

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Operating temperature:  $\leq 40.0$  °C

2.4 CS4: Control of worker exposure: Transfer of substance or mixture into small containers  
(dedicated filling line, including weighing) (PROC 9)

Product (article) characteristics

Percentage (w/w) of substance in mixture/article:  $\leq 5.0$  %

Physical form of the used product: Solid (medium dusty form)

Amount used (or contained in articles), frequency and duration of use/exposure

Duration of activity:  $\leq 8.0$  h/day

Technical and organisational conditions and measures

Occupational Health and Safety Management System: Advanced

General ventilation: Good general ventilation (1-3 air changes per hour) [Effectiveness Inhalation:  
0%]

Local exhaust ventilation: Yes [Effectiveness Inhalation: 90%, Dermal: 0%]

Conditions and measures related to personal protection, hygiene and health evaluation

Respiratory Protection: Yes (Respirator with APF of 20) [Effectiveness Inhalation: 95%]

Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate  
dermal protection [Effectiveness Dermal: 80%]

Other conditions affecting workers exposure

Place of use: Indoor

Operating temperature:  $\leq 40.0$  °C

2.5 CS5: Control of worker exposure: Use as laboratories (PROC 15)

Product (article) characteristics

SAFETY DATA SHEET  
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Percentage (w/w) of substance in mixture/article:  $\leq 5.0\%$

Physical form of the used product: Solid (medium dusty form)

Amount used (or contained in articles), frequency and duration of use/exposure

Duration of activity:  $\leq 0.1$  h/day

Technical and organisational conditions and measures

Occupational Health and Safety Management System: Advanced

General ventilation: Good general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%]

Local exhaust ventilation: Yes [Effectiveness Inhalation: 90%, Dermal: 0%]

Conditions and measures related to personal protection, hygiene and health evaluation

Respiratory Protection: Yes (Respirator with APF of 20) [Effectiveness Inhalation: 95%]

Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with specific activity training) and (other) appropriate dermal protection [Effectiveness Dermal: 95%]

Use of eye protection: Yes

Other conditions affecting workers exposure

Place of use: Indoor

Operating temperature:  $\leq 40.0$  °C

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

3.1 CS1: Environmental release and exposure: Formulation into mixture (ERC 2)

Release route	Release rate	Release estimation method
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**SALICYLIC ACID SOLID**

Issuing date: 03/08/2020

Revision: 3.0

Water	Release factor before on site RMM: 2%	ERC
	Release factor after on site RMM: 2%	
	Local release rate: 20 kg/day	
Air	Release factor before on site RMM: 2.5%	ERC
	Release factor after on site RMM: 2.5%	
	Local release rate: 25 kg/day	
Non agricultural soil	Release factor after on site RMM: 0.01%	ERC
Protection target	Exposure concentration	RCR
Freshwater	Local PEC: 0.126 mg/L	RCR = 0.631
Sediment (freshwater)	Local PEC: 0.897 mg/kg dw	RCR = 0.631
Marine water	Local PEC: 0.013 mg/L	RCR = 0.631
Sediment (marine water)	Local PEC: 0.09 mg/kg dw	RCR = 0.631
Sewage treatment plant	Local PEC: 1.262 mg/L	RCR < 0.01
Agricultural soil	Local PEC: 0.099 mg/kg dw	RCR = 0.594
Man via Environment - inhalation	Concentration in air: 2.86E-3 mg/m <sup>3</sup>	RCR < 0.01
Man via Environemnt - oral	Exposure via food consumption: 0.237 mg/kg bw/day	RCR = 0.237
Man via Environemnt- combined routes		RCR = 0.237

**3.2 CS2: Worker exposure: Mixing or blending in batch processes (PROC 5)**

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systematic, long-term	0.006 mg/m <sup>3</sup>	RCR < 0.01

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Revision: 3.0

Inhalation, local, long term	0.006 mg/m <sup>3</sup>	RCR < 0.01
Dermal, systemic, long term	0.548 mg/kg bw/day	RCR = 0.238
Combined routes, systemic, long-term		RCR = 0.24

**3.3 CS3: Worker exposure: Transfer of substance or mixture (charging and discharging) at dedicated facilities (PROC 8b)**

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systematic, long-term	0.0003 mg/m <sup>3</sup>	RCR < 0.01
Inhalation, local, long-term	0.0003 mg/m <sup>3</sup>	RCR < 0.01
Dermal, systemic, long term	0.548 mg/kg bw/day	RCR = 0.238
Combined routes, systemic, long-term		RCR = 0.239

**3.4 CS4: Worker exposure: Transfer of substance or mixture into small containers (dedicated filling line, including weighing) (PROC 9)**

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systematic, long-term	0.005 mg/m <sup>3</sup>	RCR < 0.01
Inhalation, local, long term	0.005 mg/m <sup>3</sup>	RCR < 0.01
Dermal, systemic, long term	0.274 mg/kg bw/day	RCR = 0.119
Combined routes, systemic, long-term		RCR = 0.12

**3.5 CS5: Worker exposure: Use as laboratory reagent (PROC 15)**

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systematic, long-term	0.00005 mg/m <sup>3</sup>	RCR < 0.01
Inhalation, local, long term	0.00005 mg/m <sup>3</sup>	RCR < 0.01
Dermal, systemic, long term	0.014 mg/kg bw/day	RCR < 0.01



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Revision: 3.0

Combined routes, systemic, long-term

RCR < 0.01

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

Guidance is based on assumed operating conditions which may not be applicable to all sites. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

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**SALICYLIC ACID SOLID**

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## ES2: Use as an Intermediate at Industrial sites

### 1. Short title of ES2: Use as an Intermediate at Industrial sites

Perfumes, fragrances (PC28), Pharmaceuticals (PC29), Cosmetics, personal care products (PC39)

#### Environment contributing scenario(s):

CS1: Use of intermediate ERC 6a

#### Worker contributing scenario(s):

CS2: Chemical Production or refinery in closed continuous process with occasional PROC 2

controlled exposure or processes with equivalent containment conditions

CS3: Manufacture or formulation in the chemical industry in closed batch processes with PROC 3

occasional controlled exposure or processes with equivalent containment conditions

CS4: Transfer of substance or mixture (charging and discharging) at dedicated facilities PROC 8b

CS5: Transfer of substance or mixture into small containers (dedicated filling line, PROC 9

including weighing)

CS6: Use as laboratory reagent PROC 15

### 2. Conditions of use affecting exposure

#### 2.1 CS1: Control of environmental exposure: Use of intermediate (ERC 6a)

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

Daily use amount at site:  $\leq 1.0$  tonnes/day

Daily use amount at site:  $\leq 200.0$  tonnes/year

##### Conditions and measures related to biological sewage treatment plant

Biological STP: Site specific [Effectiveness Water: 87.38%]

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Discharge rate of STP:  $\geq 2000 \text{ m}^3/\text{day}$

Application of the STP sludge on agricultural soil: Yes

Conditions and measures related to external treatment of waste (including article waste)

Particular considerations on the waste treatment operations: Other

“Explanation for the CSR” to be reported by each registrant on the specific conditions required for waste treatment: comply with the local and/or national regulations.

Other conditions affecting environmental exposure

Receiving surface water flow rate:  $\geq 18000 \text{ m}^3/\text{day}$

2.2 CS2: Control of worker exposure: Chemical Production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions (PROC 2)

Product (article) characteristics

Percentage (w/w) of substance in mixture/article:  $\leq 5.0 \%$

Physical form of the used product: Solid (medium dusty form)

Amount used (or contained in articles), frequency and duration of use/exposure

Duration of activity:  $\leq 8.0 \text{ h/day}$

Technical and organisational conditions and measures

Occupational Health and Safety Management System: Advanced

General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%]

Local exhaust ventilation: Yes [Effectiveness Inhalation: 90%, Dermal: 0%]

Conditions and measures related to personal protection, hygiene and health evaluation

Respiratory Protection: Yes (Respirator with APF of 20) [Effectiveness Inhalation: 95%]

Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%]

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Issuing date: 03/08/2020

Revision: 3.0

Use of eye protection: Yes

Other conditions affecting workers exposure

Place of use: Indoor

Operating temperature:  $\leq 40.0$  °C

2.3 CS3: Control of worker exposure: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions (PROC 3)

Product (article) characteristics

Percentage (w/w) of substance in mixture/article:  $\leq 5.0$  %

Physical form of the used product: Solid (medium dusty form)

Amount used (or contained in articles), frequency and duration of use/exposure

Duration of activity:  $\leq 8.0$  h/day

Technical and organisational conditions and measures

Occupational Health and Safety Management System: Advanced

General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%]

Local exhaust ventilation: Yes [Effectiveness Inhalation: 90%, Dermal: 0%]

Conditions and measures related to personal protection, hygiene and health evaluation

Respiratory Protection: Yes (Respirator with APF of 20) [Effectiveness Inhalation: 95%]

Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%]

Use of eye protection: Yes

Other conditions affecting workers exposure

Place of use: Indoor

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**SALICYLIC ACID SOLID**

Issuing date: 03/08/2020

Revision: 3.0

Operating temperature:  $\leq 40.0$  °C

2.4 CS4: Control of worker exposure: Transfer of substance or mixture (charging and discharging) at dedicated facilities (PROC 8b)

Product (article) characteristics

Percentage (w/w) of substance in mixture/article:  $\leq 5.0$  %

Physical form of the used product: Solid (medium dusty form)

Amount used (or contained in articles), frequency and duration of use/exposure

Duration of activity:  $\leq 8.0$  h/day

Technical and organisational conditions and measures

Occupational Health and Safety Management System: Advanced

General ventilation: Good general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%]

Local exhaust ventilation: Yes [Effectiveness Inhalation: 95%, Dermal: 0%]

Conditions and measures related to personal protection, hygiene and health evaluation

Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhalation: 90%]

Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%]

Other conditions affecting workers exposure

Place of use: Indoor

Operating temperature:  $\leq 40.0$  °C

2.5 CS5: Control of worker exposure: Transfer of substance or mixture into small containers (dedicated filling line, including weighing) (PROC 9)

SAFETY DATA SHEET  
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Revision: 3.0

Product (article) characteristics

Percentage (w/w) of substance in mixture/article:  $\leq 5.0 \%$

Physical form of the used product: Solid (medium dusty form)

Amount used (or contained in articles), frequency and duration of use/exposure

Duration of activity:  $\leq 8$  h/day

Technical and organisational conditions and measures

Occupational Health and Safety Management System: Advanced

General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%]

Local exhaust ventilation: Yes [Effectiveness Inhalation: 90%, Dermal: 0%]

Conditions and measures related to personal protection, hygiene and health evaluation

Respiratory Protection: Yes (Respirator with APF of 20) [Effectiveness Inhalation: 95%]

Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate

dermal protection [Effectiveness Dermal: 80%]

Use of eye protection: Yes

Other conditions affecting workers exposure

Place of use: Indoor

Operating temperature:  $\leq 40.0$  °C

2.6 CS6: Control of worker exposure: Use as laboratory reagent (PROC 15)

Product (article) characteristics

Percentage (w/w) of substance in mixture/article:  $\leq 5.0 \%$

Physical form of the used product: Solid (medium dusty form)

Amount used (or contained in articles), frequency and duration of use/exposure

Duration of activity:  $\leq 0.2$  h/day

SAFETY DATA SHEET  
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**SALICYLIC ACID SOLID**

Issuing date: 03/08/2020

Revision: 3.0

**Technical and organisational conditions and measures**

Occupational Health and Safety Management System: Advanced

General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%]

Local exhaust ventilation: Yes [Effectiveness Inhalation: 90%, Dermal: 0%]

**Conditions and measures related to personal protection, hygiene and health evaluation**

Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhalation: 90%]

Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%]

**Other conditions affecting workers exposure**

Place of use: Indoor

Operating temperature: <= 40.0 °C

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

**3.1 CS1: Environmental release and exposure: Use of intermediate (ERC 6a)**

Release route	Release rate	Release estimation method
Water	Release factor before on site RMM: 2%	ERC
	Release factor after on site RMM: 2%	
	Local release rate: 20 kg/day	
Air	Release factor before on site RMM: 5%	ERC
	Release factor after on site RMM: 5%	
	Local release rate: 50 kg/day	

SAFETY DATA SHEET  
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**SALICYLIC ACID SOLID**

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Revision: 3.0

Non agricultural soil	Release factor after on site RMM: 0.1%	ERC
Protection target	Exposure concentration	RCR
Freshwater	Local PEC: 0.126 mg/L	RCR = 0.631
Sediment (freshwater)	Local PEC: 0.896 mg/kg dw	RCR = 0.631
Marine water	Local PEC: 0.013 mg/L	RCR = 0.631
Sediment (marine water)	Local PEC: 0.09 mg/kg dw	RCR = 0.631
Sewage treatment plant	Local PEC: 1.262 mg/L	RCR < 0.01
Agricultural soil	Local PEC: 0.1 mg/kg dw	RCR = 0.601
Man via Environment - inhalation	Concentration in air: 7.62E-3 mg/m <sup>3</sup>	RCR < 0.01
Man via Environemnt - oral	Exposure via food consumption: 0.618 mg/kg bw/day	RCR = 0.618
Man via Environemnt- combined routes		RCR = 0.62

**3.2 CS2: Worker exposure: Chemical Production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions (PROC 2)**

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systematic, long-term	5E-4 mg/m <sup>3</sup>	RCR < 0.01
Inhalation, local, long term	5E-4 mg/m <sup>3</sup>	RCR < 0.01
Dermal, systemic, long term	0.055 mg/kg bw/day	RCR = 0.024
Combined routes, systemic, long-term		RCR = 0.024

**3.3 CS3: Worker exposure: Manufacture or formulation in the chemical industry in closed batch**



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**SALICYLIC ACID SOLID**

Issuing date: 03/08/2020

Revision: 3.0

processes with occasional controlled exposure or processes with equivalent containment conditions (PROC 3)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systematic, long-term	0.001 mg/m <sup>3</sup>	RCR < 0.01
Inhalation, local, long-term	0.001 mg/m <sup>3</sup>	RCR < 0.01
Dermal, systemic, long term	0.028 mg/kg bw/day	RCR = 0.012
Combined routes, systemic, long-term		RCR = 0.012

3.4 CS4: Worker exposure: Transfer of substance or mixture (charging and discharging) at dedicated facilities (PROC 8b)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systematic, long-term	0.001 mg/m <sup>3</sup>	RCR < 0.01
Inhalation, local, long term	0.01 mg/m <sup>3</sup>	RCR < 0.01
Dermal, systemic, long term	0.548 mg/kg bw/day	RCR = 0.238
Combined routes, systemic, long-term		RCR = 0.239

3.5 CS5: Worker exposure: Transfer of substance or mixture into small containers (dedicated filling line, including weighing) (PROC 9)

Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systematic, long-term	0.005 mg/m <sup>3</sup>	RCR < 0.01
Inhalation, local, long term	0.005 mg/m <sup>3</sup>	RCR < 0.01
Dermal, systemic, long term	0.274 mg/kg bw/day	RCR = 0.119
Combined routes, systemic, long-term		RCR = 0.12

3.6 CS6: Worker exposure: Use as laboratory reagent (PROC 15)

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Route of exposure and type of effects	Exposure estimate	RCR
Inhalation, systematic, long-term	0.0001 mg/m <sup>3</sup>	RCR < 0.01
Inhalation, local, long term	0.0001 mg/m <sup>3</sup>	RCR < 0.01
Dermal, systemic, long term	0.014 mg/kg bw/day	RCR < 0.01
Combined routes, systemic, long-term		RCR < 0.01

**4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the ES**

Guidance is based on assumed operating conditions which may not be applicable to all sites. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

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### ES3: Consumer use – Use in cosmetics

#### 1. Short title of ES 1: Consumer use – Use in cosmetics

Cosmetics, personal care products (PC39)

Environment contributing scenario(s):

CS1: Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor) ERC 8a

#### 2. Conditions of use affecting exposure

2.1 CS1: Control of environmental exposure: Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor) (ERC 8a)

Amount used, frequency and duration of use

Daily local widespread use amount:  $\leq 0.028$  kg/day

Conditions and measures related to external treatment of waste (including article waste)

Particular considerations on the waste treatment operations

Other conditions affecting environmental exposure

Biological STP: Standard [Effectiveness Water: 87.38%]

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

3.1 CS1: Environmental release and exposure: Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor) (ERC 8a)

Release route	Release rate	Release estimation method
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Water	Release factor before on site RMM: 100%	ERC
	Release factor after on site RMM: 100%	
	Local release rate: 0.028 kg/day	
Air	Release factor before on site RMM: 100%	ERC
	Release factor after on site RMM: 100%	
Non agricultural soil	Release factor after on site RMM: 0%	ERC
Protection target	Exposure concentration	RCR
Freshwater	Local PEC: 2.48E-4 mg/L	RCR < 0.01
Sediment (freshwater)	Local PEC: 1.76E-3 mg/kg dw	RCR < 0.01
Marine water	Local PEC: 2.47E-5 mg/L	RCR < 0.01
Sediment (marine water)	Local PEC: 1.76E-3 mg/kg dw	RCR < 0.01
Sewage treatment plant	Local PEC: 1.74E-3 mg/kg	RCR < 0.01
Agricultural soil	Local PEC: 5.4E-4 mg/kg dw	RCR < 0.01
Man via Environment - inhalation	Concentration in air: 1.27E-7 mg/m <sup>3</sup>	RCR < 0.01
Man via Environemnt - oral	Exposure via food consumption: 1.12E-4 mg/kg bw/day	RCR < 0.01
Man via Environemnt- combined routes		RCR < 0.01

**4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the ES**

Guidance is based on assumed operating conditions which may not be applicable to all sites. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.