

Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)



Revision date: 1/19/2022
Supercedes date: 4/19/2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier:

Product trade name: Kalama* Peach Lactone
Company product number: GUDL
REACH registration number: 01-2119959333-34-0005
Substance name: Undecan-4-olide
Substance identification number: EC 203-225-4
Other means of identification: 2(3H)-Furanone, 5-heptyldihydro-; 5-heptyloxolan-2-one

1.2. Relevant identified uses of the substance or mixture and uses advised against:

Uses: Fragrance ingredient. See Annex for covered uses. Odour agent.
Uses advised against: None identified

1.3. Details of the supplier of the safety data sheet:

Manufacturer/Supplier: Emerald Kalama Chemical Limited
 Dans Road
 Widnes, Cheshire WA8 0RF
 United Kingdom
 Telephone: +44 (0) 151 423 8000

EU Only Representative: Penman Consulting bvba
 Avenue des Arts 10
 B-1210 Brussels
 Belgium
 Telephone: +32 (0) 2 403 7239
 email: pcbvba10@penmanconsulting.com
 Email: product.compliance@emeraldmaterials.com

For further information about this SDS:

1.4. Emergency telephone number:

ChemTel (24 hours): 1-800-255-3924 (USA); +1-813-248-0585 (outside USA).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture:

Product classification according to Regulation (EC) 1272/2008 (CLP) as amended:

Hazardous to the aquatic environment, Chronic, category 3, H412
 See Section 2.2 for full text of H (Hazard) statements (EC 1272/2008).

2.2. Label elements:

Product labeling according to Regulation (EC) 1272/2008 (CLP) as amended:

Hazard pictogram(s): Not Applicable
Signal word: Not Applicable

Hazard statements:
 H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:
 P273 Avoid release to the environment.

Supplemental information: No Additional Information

Precautionary statements are listed according to the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) - Annex III and ECHA Guidance on Labelling and Packaging. Regulations in individual countries/regions may determine which statements are required on the product label. See product label for specifics.

2.3. Other hazards:

PBT/vPvB criteria: This product does not meet the PBT and vPvB classification criteria.
Endocrine disrupting properties: No specific information available.
Other hazards: No Additional Information

See Section 11 for toxicological information.

SECTION 3: Composition/information on ingredients

3.1. Substance:

<u>CAS-No.</u>	<u>Chemical Name</u>	<u>Weight%</u>	<u>Classification</u>	<u>H Statements</u>
0000104-67-6	Undecan-4-olide	100	Aquatic Chronic 3	H412
<u>CAS-No.</u>	<u>Chemical Name</u>	<u>REACH Registration No.</u>	<u>EC/List Number</u>	
0000104-67-6	Undecan-4-olide	01-2119959333-34-0005	203-225-4	
<u>CAS-No.</u>	<u>Chemical Name</u>	<u>M-factor</u>	<u>SCLs</u>	<u>ATE</u>
0000104-67-6	Undecan-4-olide	N/A	N/E	Not Available

See Section 16 for full text of H (Hazard) statements (EC 1272/2008).

Amounts specified are typical and do not represent a specification. Remaining components are proprietary, non-hazardous, and/or present at amounts below reportable limits.

SECTION 4: First aid measures

4.1. Description of first aid measures:

General: If irritation or other symptoms occur or persist from any route of exposure, remove the affected individual from the area: see a physician/get medical attention.

Following eye contact: Any material that contacts the eye should be washed out immediately with water. Get medical attention if symptoms occur.

Following skin contact: Wash the affected area thoroughly with plenty of soap and water. Get medical attention if symptoms occur.

Following inhalation: If affected, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Call a POISON CENTER or doctor/physician if you feel unwell.

Following ingestion: Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse out the mouth with water. Get medical attention immediately.

Protection of first aid responders: Wear proper personal protective clothing and equipment.

4.2. Most important symptoms and effects, both acute and delayed:

Irritation. Preexisting sensitization, skin and/or respiratory disorders or diseases may be aggravated. See section 11 for additional information.

4.3. Indication of any immediate medical attention and special treatment needed:

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media:

Suitable: Use water spray, ABC dry chemical, foam or carbon dioxide. Water or foam may cause frothing. Use water to keep fire-exposed containers cool. Water spray may be used to flush spills away from exposures.

Unsuitable: Do not use direct water stream. May spread fire.

5.2. Special hazards arising from the substance or mixture:

Unusual fire/explosion hazards: Product is not considered a fire hazard, but will burn if ignited. Closed container may rupture (due to build up in pressure) when exposed to extreme heat.

Hazardous combustion products: Irritating or toxic substances may be emitted upon burning, combustion or decomposition. See section 10 (10.6 Hazardous decomposition products) for additional information.

5.3. Advice for firefighters:

Wear self-contained breathing apparatus (SCBA) equipped with a full facepiece and operated in a pressure-demand mode (or other positive pressure mode) and approved protective clothing. Personnel without suitable respiratory protection must leave the area to prevent significant exposure to hazardous gases from combustion, burning or decomposition. In an enclosed or poorly ventilated area, wear SCBA during cleanup immediately after a fire as well as during the attack phase of firefighting operations.

See section 9 for additional information.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:

See Section 8 for recommendations on the use of personal protective equipment. If spilled in an enclosed area, ventilate. Eliminate ignition sources.

6.2. Environmental precautions:

Do not flush liquid into public sewer, water systems or surface waters.

6.3. Methods and material for containment and cleaning up:

Contain by diking with sand, earth or other non-combustible material. Wear proper personal protective clothing and equipment. Absorb spill with an inert material. Place into labeled, closed container; store in safe location to await disposal. Change contaminated clothing and laundry before reuse.

6.4. References to other sections:

See Section 8 for recommendations on the use of personal protection and Section 13 for waste disposal.

SECTION 7: Handling and storage

7.1. Precautions for safe handling:

As with any chemical product, use good laboratory/workplace procedures. Do not cut, puncture, or weld on or near the container. Wash thoroughly after handling this product. Always wash up before eating, smoking or using the facilities. Use under well-ventilated conditions. Avoid eye contact. Avoid repeated or prolonged skin contact. Avoid inhalation of aerosol, mist, spray, fume or vapor. Avoid drinking, tasting, swallowing or ingesting this product. Wash contaminated clothing before reuse. Provide eyewash fountains and safety showers in the work area.

7.2. Conditions for safe storage, including any incompatibilities:

Store cool and dry, under well-ventilated conditions. Store this material away from incompatible substances (see section 10). Do not store in open, unlabeled or mislabeled containers. Keep container closed when not in use. Do not reuse empty container without commercial cleaning or reconditioning. Empty container contains residual product which may exhibit hazards of product.

7.3. Specific end use(s):

Further information concerning special risk management measures: see annex of this safety data sheet (exposure scenarios).

SECTION 8: Exposure controls / personal protection

8.1. Control parameters:

Occupational exposure limits (OEL):

<u>Chemical Name</u>	<u>EU OELV</u>	<u>EU IOELV</u>	<u>ACGIH - TWA/Ceiling</u>	<u>ACGIH - STEL</u>
Undecan-4-olide	N/E	N/E	N/E	N/E
<u>Chemical Name</u>	<u>UK WEL</u>	<u>Ireland OEL</u>		
Undecan-4-olide	N/E	N/E		

N/E=Not established (no exposure limits established for the listed substances for listed country/region/organization).

Derived No Effect Levels (DNELs):

Undecan-4-olide

<u>Population</u>	<u>Route</u>	<u>Acute (local)</u>	<u>Acute (systemic)</u>	<u>Long Term (local)</u>	<u>Long Term (systemic)</u>
Workers	Inhalation	N/E	N/E	N/E	19 mg/m ³
Workers	Dermal	N/E	N/E	N/E	5,38 mg/kg bw/day
General population	Inhalation	N/E	N/E	N/E	4,68 mg/m ³
General population	Dermal	N/E	N/E	N/E	2,7 mg/kg bw/day
General population	Oral	N/E	N/E	N/E	2,7 mg/kg bw/day
Human via the environment	Inhalation	N/E	N/E	N/E	4,68 mg/m ³
Human via the environment	Oral	N/E	N/E	N/E	2,7 mg/kg bw/day

Predicted No Effect Concentration (PNECs):

Undecan-4-olide

<u>Compartment</u>	<u>PNEC</u>
Freshwater	17,52 µg/L
Freshwater sediment	1,882 mg/kg dw
Marine water	1,75 µg/L
Marine water sediment	0,188 mg/kg dw
Intermittent releases	58,5 µg/L
Soil	0,366 mg/kg dw
STP	80 mg/L
Oral	66,7 mg/kg food

8.2. Exposure controls:

Appropriate engineering controls: Always provide effective general and, when necessary, local exhaust ventilation to draw spray, aerosol, fume, mist and vapor away from workers to prevent routine inhalation. Ventilation must be adequate to maintain the ambient workplace atmosphere below the exposure limit(s) outlined in the SDS.

Individual protection measures, such as personal protective equipment:

Eye/face protection: Wear eye protection.

Hand protection: Avoid skin contact when mixing or handling the material by wearing impervious and chemical resistant gloves. In case of prolonged immersion or frequently repeated contact, gloves with breakthrough times greater than 240 minutes (protection class 5 or greater) are recommended. For brief contact or splash applications, gloves with breakthrough times of 10 minutes or greater are recommended (protection class 1 or greater). The protective gloves to be used must comply with the specifications of the Regulation (EU) 2016/425 and the resultant standard EN 374. Suitability and durability of a glove is dependent on usage (e.g. frequency and duration of contact, other chemicals which may be handled, chemical resistance of glove material and dexterity). Always seek advice of the glove supplier as to the most suitable glove material.

Skin and body protection: Use good laboratory/workplace procedures including personal protective clothing: labcoat, safety glasses and protective gloves.

Respiratory protection: Respiratory protection is not needed with proper ventilation. Wear an approved respirator (e.g., an organic vapor respirator, a full face air purifying respirator for organic vapors, or a self-contained breathing apparatus) whenever exposure to aerosol, mist, spray, fume or vapor exceed the applicable exposure limit(s) of any chemical substance listed in this SDS.

Further information: Eyewash fountains and safety showers are recommended in the work area.

Environmental exposure controls: See Sections 6 and 12.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties:**

Physical state:	Liquid
Colour:	Clear to pale yellow
Odour:	Peach
Odour threshold:	Not Available
Melting point/Freezing point:	-9.5 °C (15 °F)
Boiling point °C:	297-299 °C
Boiling point °F:	567-570 °F
Flammability:	Not flammable
Lower and upper explosion limit:	LEL: Not Available UEL: Not Available
Flash point:	145 °C (293 °F) ASTM D6450-99
Auto-ignition temperature:	>256 °C (>493 °F) (similar materials)
Decomposition temperature:	Not Available
pH:	Not Available
Kinematic viscosity:	<10.6 mm ² /s (<10 mPa.s) at 20°C
Solubility in water:	0.158 g/L @ 20°C
Partition coefficient n-octanol/water (log value):	3.6 (OECD 117)
Vapour pressure:	0.27 Pa @ 25°C (estimated)
Density and/or relative density:	0.941-0.947
Relative vapour density:	Not Available
Particle characteristics:	Not Applicable
% Volatile by weight:	Not Available
VOC:	Not Available

Amounts specified are typical and do not represent a specification.

9.2. Other information:**Information with regard to physical hazard classes:**

Explosive properties: Not explosive

Oxidising properties: Not oxidizing

Other safety characteristics:

Evaporation rate: Not Available

SECTION 10: Stability and reactivity

10.1. Reactivity:

None known.

10.2. Chemical stability:

This product is stable.

10.3. Possibility of hazardous reactions:

Hazardous polymerization will not occur.

10.4. Conditions to avoid:

Excessive heat and ignition sources.

10.5. Incompatible materials:

Avoid strong bases and oxidizing agents.

10.6. Hazardous decomposition products:

Carbon dioxide, carbon monoxide and hydrocarbons.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**Acute toxicity:** Not classified (based on available data, the classification criteria are not met).

<u>Chemical Name</u>	<u>Inhalation LC50</u>	<u>Species</u>	<u>Oral LD50</u>	<u>Species</u>	<u>Dermal LD50</u>	<u>Species</u>
Undecan-4-olide	N/E	N/E	>2000 mg/kg	Rat/ adult	>2000 mg/kg	Rat/ adult

Skin corrosion/irritation: Not classified (based on available data, the classification criteria are not met).

<u>Chemical Name</u>	<u>Skin irritation</u>	<u>Species</u>
Undecan-4-olide	Mild-slight irritant	Human

Serious eye damage/irritation: Not classified (based on available data, the classification criteria are not met).

<u>Chemical Name</u>	<u>Eye irritation</u>	<u>Species</u>
Undecan-4-olide	Non-irritant (OECD 405)	Rabbit/ adult

Respiratory or skin sensitization: Not classified (based on available data, the classification criteria are not met).

<u>Chemical Name</u>	<u>Skin sensitisation</u>	<u>Species</u>
Undecan-4-olide	Non-sensitizer	Guinea pig and Human

Carcinogenicity: Not classified (no relevant information found).**Germ cell mutagenicity:** Not classified (based on available data, the classification criteria are not met). UNDECAN-4-OLIDE: Mutagenic assays were negative for both in vivo and in vitro assays.**Reproductive toxicity:** Not classified (based on available data, the classification criteria are not met). UNDECAN-4-OLIDE - READ-ACROSS: Developmental toxicity oral study, rat: NOAEL (no-observed-adverse-effect level), maternal toxicity=1000 mg/kg bw/day; NOAEL, developmental toxicity=1000 mg/kg bw/day.**Specific target organ toxicity (STOT) - single exposure:** Not classified (based on available data, the classification criteria are not met).**Specific target organ toxicity (STOT) - repeated exposure:** Not classified (based on available data, the classification criteria are not met). UNDECAN-4-OLIDE - READ-ACROSS: Repeated dose study, oral, rats: NOAEL (no-observed-adverse-effect-level) = 1000 mg/kg/day.**Aspiration hazard:** Not classified (no relevant information found).**Other toxicity information:** No additional information available.**Information on likely routes of exposure:****General:** Caution must be exercised through the prudent use of protective equipment and handling procedures to minimize exposure.**Eyes:** May cause eye irritation.**Skin:** May cause mild skin irritation.**Inhalation:** High airborne concentrations of vapors resulting from heating, misting or spraying may cause irritation of the respiratory tract and mucous membranes.**Ingestion:** Ingestion may cause irritation.

11.2. Information on other hazards**Endocrine disrupting properties:** No specific information available.**Other information:** No additional information available.**SECTION 12: Ecological information****12.1. Toxicity:**

<u>Chemical Name</u>	<u>Species</u>	<u>Acute</u>	<u>Acute</u>	<u>Chronic</u>
Undecan-4-olide	Fish	LC50 21.5 mg/L (96 hours) (similar materials)	LC50 6.13 mg/L(96 hours) (calculated)	N/E
Undecan-4-olide	Invertebrates	EC50 5.85 mg/L (48 hours)	N/E	EC10 1.02 mg/L (21 days) (geometric mean measured)
Undecan-4-olide	Algae	EC50 5.94 mg/L (48 hours) (geometric mean measured)	N/E	EC10 0.876 mg/L(48 hours) (geometric mean measured)
Undecan-4-olide	Micro-organisms	EC50 800 mg/L (30 minutes) (similar materials)		

12.2. Persistence and degradability:

Expected to readily biodegrade, based on similar material(s).

<u>Chemical Name</u>	<u>Biodegradation</u>
Undecan-4-olide	Readily biodegradable (OECD 301F, read-across)

12.3. Bioaccumulative potential:

Not expected to bioaccumulate.

<u>Chemical Name</u>	<u>Bioconcentration Factor (BCF)</u>	<u>Log Kow</u>
Undecan-4-olide	421 L/kg (calculated)	3.6 (OECD 117)

12.4. Mobility in soil:

No specific information available.

<u>Chemical Name</u>	<u>Mobility in soil (Koc/Kow)</u>
Undecan-4-olide	398.5-709.2 L/kg (calculated)

12.5. Results of PBT and vPvB assessment:

This product does not meet the PBT and vPvB classification criteria.

12.6. Endocrine disrupting properties:

No specific information available.

12.7. Other adverse effects:

No additional information available.

SECTION 13: Disposal considerations**13.1. Waste treatment methods:**

Dispose of unused contents (incineration) in accordance with national and local regulations. Dispose of container in accordance with national and local regulations. Ensure the use of properly authorized waste management companies, where appropriate.

See Section 8 for recommendations on the use of personal protective equipment.

SECTION 14: Transport information

The information below is provided to assist in documentation. It may supplement the information on the package. The package in your possession may carry a different version of the label depending on the date of manufacture. Depending on inner packaging quantities and packaging instructions, it may be subject to specific regulatory exceptions.

14.1. UN number or ID number: N/A**14.2. UN proper shipping name:**

Not regulated - See Bill of Lading for Details

14.3. Transport hazard class(es):

U.S. DOT hazard class: N/A
Canada TDG hazard class: N/A
Europe ADR/RID/ADN hazard class: N/A
IMDG Code (ocean) hazard class: N/A
ICAO/IATA (air) hazard class: N/A

SDS Name: Kalama* Peach Lactone

A "N/A" listing for the hazard class indicates the product is not regulated for transport by that regulation.

14.4. Packing group: N/A

14.5. Environmental hazards:

Marine pollutant: Not Applicable

Hazardous substance (USA): Not Applicable

14.6. Special precautions for user:

Not Applicable

14.7. Maritime transport in bulk according to IMO instruments

Not Applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Europe REACH (EC) 1907/2006: Applicable components are registered, exempt or otherwise compliant. EU REACH is only relevant to substances either manufactured or imported into the EU. Emerald Kalama Chemical has met its obligations under the EU REACH regulation. EU REACH information regarding this product is provided for informational purposes only. Each Legal Entity may have differing EU REACH obligations, depending on their place in the supply chain. Emerald's compliance with EU REACH does not imply automatic coverage for Downstream Users located in the EU. For material manufactured outside of the EU, the importer of record must understand and meet their specific obligations under the regulation.

EU Authorizations and/or restrictions on use: Not Applicable

Other EU information: No Additional Information

National regulations: No Additional Information

Chemical inventories:

<u>Regulation</u>	<u>Status</u>
Australian Inventory of Industrial Chemicals (AIIC):	Y
Canadian Domestic Substances List (DSL):	Y
Canadian Non-Domestic Substances List (NDSL):	N
China Inventory of Existing Chemical Substances (IECSC):	Y
European EC Inventory (EINECS, ELINCS, NLP):	Y
Japan Existing and New Chemical Substances (ENCS):	Y
Japan Industrial Safety and Health Law (ISHL):	Y
Korean Existing and Evaluated Chemical Substances (KECL):	Y
New Zealand Inventory of Chemicals (NZIoC):	Y
Philippines Inventory of Chemicals and Chemical Substances (PICCS):	Y
Taiwan Inventory of Existing Chemicals:	Y
U.S. Toxic Substances Control Act (TSCA) (Active):	Y

A "Y" listing indicates all intentionally added components are either listed or are otherwise compliant with the regulation. A "N" listing indicates that for one or more components: 1) there is no listing on the public inventory (or is not on the ACTIVE inventory for U.S. TSCA); 2) no information is available; or 3) the component has not been reviewed. A "Y" for New Zealand may mean that a qualified group standard may exist for the components in this product.

UK REACH: As the UK has formally left the European Union, EU REACH [(EC) 1907/2006] is no longer directly applicable within the UK. Please see UK REACH formatted SDS for information related to UK REACH compliance.

15.2. Chemical safety assessment:

A chemical safety assessment has been carried out for the substance or mixture.

SECTION 16: Other information

Hazard (H) Statements in the Composition section (Section 3):

H412 Harmful to aquatic life with long lasting effects.

Reason for revision: Changes in Section(s): 1

Evaluation method for classification of mixtures: Not Applicable (substance)

Legend:

* : Trademark owned by Emerald Kalama Chemical, LLC.

ACGIH: American Conference of Governmental Industrial Hygienists

ATE: Acute toxicity estimate

EU OELV: European Union Occupational Exposure Limit Value

EU IOELV: European Union Indicative Occupational Exposure Limit Value

N/A: Not Applicable

N/E: None Established

SCL: Specific concentration limit

SDS Name: Kalama* Peach Lactone

STEL: Short Term Exposure Limit
TWA: Time Weighted Average (exposure for 8-hour workday)

Users Responsibility/Disclaimer of Liability:

The information set forth herein is based on our current knowledge, and is intended to describe the product solely with respect to health, safety and the environment. As such, it must not be interpreted as a guarantee of any specific property of the product. As a result, the customer shall be solely responsible for deciding whether said information is suitable and beneficial.

Safety Data Sheet Preparer:
Product Compliance Department
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Annex

Exposure Scenarios

Substance information:

Name of substance: Undecan-4-olide.
EC# 203-225-4 / CAS# 104-67-6
REACH Registration number: 01-2119959333-34-0005

List of exposure scenarios:

ES1: Formulation - GES1 Formulation of fragrance compounds (compounding)
ES2: Formulation - GES2 Formulation of fragranced end-products (formulating)
ES3: Use by professional workers - GES4 Professional end use of washing and cleaning products
ES4: Use by professional workers - GES5 Professional end-use of polishes and wax blends
ES5: Consumer use - GES6 Consumer end-use of washing and cleaning products
ES6: Consumer use - GES7 Consumer end-use of air care products
ES7: Consumer use - GES8 Consumer end-use of biocides
ES8: Consumer use - GES9 Consumer end-use of polishes and wax blends
ES9: Consumer use - GES10 Consumer end-use of cosmetics

General remarks:

The first tier environmental risk assessments have been conducted using IFRA standard conditions as defined in the IFRA guidance for REACH Exposure Scenarios (version 2.1, December 2012). Higher tier assessments have been performed if safe use was not demonstrated using first tier assessments. In these cases Specific Environmental Release Categories (SpERCs) have been used or release fractions have been defined according to the A&B-tables in Appendix 1 of the 2003 Technical Guidance Document on Risk Assessment (EU TGD 2003), Part II.

Undecan-4-olide does not meet the criteria for any of the toxicological hazard classes and no adverse effects have been observed in studies conducted at the highest practicable and biologically-relevant concentration on toxicological endpoints. Exposure assessment would not normally be needed. However, exposure scenarios were developed in a worst-case to show that the risk is acceptable. Therefore long term systemic inhalation and dermal exposures were assessed for workers and long term systemic inhalation, oral and dermal exposures were assessed for consumers.

The industrial and professional worker exposure assessments have at first instance been performed using the ECETOC TRA Workers v3 model.

Consumer exposure assessments have been performed using ECETOC TRA 3 model (consumer module) in which:
- Fragrance concentration in fragranced end-product from the IFRA guidance (2012) is used at Tier 1.5 level consumer risk assessment;
- If necessary, further parameters are refined (Refined Tier 1.5) using the table of habits and practices for consumer products in western Europe from AISE (2009);
- If necessary, ECETOC TRA v3.1 with Specific Consumer Exposure Determinants (SCED)
- If Tier 2 refinement is necessary, ConsExpo v5.0 b01 according to the product sub category specific fact sheet or ECETOC TRA v3.1 with Specific Consumer Exposure Determinants (SCED) is used.

Reference: IFRA REACH Exposure scenarios for Fragrance Substances. Version 2.1/11 December 2012.

Exposure scenario (1): Formulation - GES1 Formulation of fragrance compounds (compounding)
1. Exposure scenario (1)

Short title of the exposure scenario:
Formulation - GES1 Formulation of fragrance compounds (compounding)

List of use descriptors:
Process category (PROC): PROC1, PROC3, PROC5, PROC8a, PROC8b, PROC9, PROC15
Environmental release category (ERC): ERC2 (SpERC IFRA 2.1a.v1, 2.1b.v1)

List of names of contributing worker scenarios and corresponding PROCs:
PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.
PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition.
PROC5 Mixing or blending in batch processes. Covers mixing or blending of solid or liquid materials in the context of manufacturing or formulating sectors, as well as upon end use.
PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities. Transfer includes loading, filling, dumping, bagging and weighing.

SDS Name: Kalama* Peach Lactone

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities. Transfer includes loading, filling, dumping, bagging.
PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing). Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage.
PROC15 Use as laboratory reagent. Use of substances at small scale laboratory (< 1 l or 1 kg present at workplace).

Name of contributing environmental scenario and corresponding ERCs:

ERC2 Formulation into mixture.

SpERC IFRA 2.1(a): Formulation of fragrance compounds at large/medium sites; SpERC IFRA 2.1(b): Formulation of fragrance compounds at small sites.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf). For further information on CEFIC (The European Chemical Industry Council) Specific Environmental Release Categories (SpERCs), see <http://www.cefic.org/Industry-support/Implementing-reach/Libraries/>.

2. Conditions of use affecting exposure

2.1 Control of workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately.

Product characteristics:

Concentration of substance:

- PROC1: Up to 100%.
- PROC3, PROC5, PROC8b, PROC15: >25%
- PROC8a, PROC9: 5-25%

Physical state: liquid.

Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Amounts used:

This information is not relevant for assessment of worker's exposure.

Frequency and duration of use/exposure:

Duration:

- PROC3, PROC5, PROC8a: 1-4 hours/day.
- PROC1, PROC8b, PROC9: 15 minutes-1 hour/day.
- PROC15: <15 minutes.

Human factors not influenced by risk management:

Exposed skin surface:

- PROC1, PROC3, PROC15: 240 cm² (one hand, face side only).
- PROC5, PROC9: 480 cm² (two hands, face side only).
- PROC8a, PROC8b: 960 cm² (two hands).

Other given operational conditions affecting workers exposure:

Location: Indoor use.

Domain: Industrial use.

Process temperature: ≤ 40 °C.

Technical conditions and measures to control dispersion from source towards the worker:

General ventilation:

- PROC1, PROC3, PROC8b, PROC9, PROC15: Good general ventilation (3-5 air changes per hour): 30%.
- PROC5, PROC8a: Enhanced general ventilation (5-10 air changes per hour): 70%.

Containment:

- PROC1: Closed system (minimal contact during routine operations).
- PROC3: Closed batch process with occasional controlled exposure.
- PROC8b, PROC9: Semi-closed process with occasional controlled exposure.
- PROC5, PROC8a, PROC15: No.

Local exhaust ventilation:

- PROC1, PROC3, PROC5, PROC8a, PROC8b, PROC15: Not required.
- PROC9: Yes (90% effectiveness).

Local exhaust ventilation (for dermal): Not required.

Occupational Health and Safety Management System: Advanced.

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

Respiratory protection: Not required.

Eye protection: Yes (chemical resistant face shield, goggles or safety glasses with side shields when there is potential for direct contact).

Dermal protection:

- PROC1, PROC15: No (Effectiveness Dermal: 0%).
- PROC3, PROC5, PROC8a, PROC8b, PROC9: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%).

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

Generally accepted standards of occupational hygiene are maintained.

Minimisation of manual phases/work tasks.

Minimisation of splashes and spills.

Avoidance of contact with contaminated tools and objects.

Regular cleaning of equipment and work area.

Training staff on good practice.

Management/supervision in place to check that RMMs in place are being used correctly and OCs followed.

2.2 Control of environmental exposure

General:

Environmental release may vary depending on the size of the compounding site according to IFRA guideline (2012). It is not more than 0.5% of

SDS Name: Kalama* Peach Lactone

the use volume for smaller compounding sites, whereas for large/medium sites it is not more than 0.2%.
All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Physical state: liquid.
Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Amounts used:

Maximum daily use at a site: 0,24 tons/day (large/medium site); 0,16 tons/day (small site).
Maximum annual use at a site: 60 tons/year (large/medium site); 40 tons/year (small site).
Percentage of tonnage used at regional scale: 10 %.

Frequency and duration of use:

Emission days: <=250 days/year.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use.
Industrial use.
Release fraction to air from process (initial release): 0.025; (final release): 0.025. Local release rate: 6 kg/day (large/medium site)(SpERC IFRA 2.1a.v1), 4 kg/day (small site)(SpERC IFRA 2.1b.v1).
Release fraction to wastewater from process: (initial release): 0,002; (final release): 0,002. Local release rate: 0,48 kg/day (large/medium site) (SpERC IFRA 2.1a.v1); (initial release): 0,005; (final release): 0,005. Local release rate: 0,8 kg/day (small site)(SpERC IFRA 2.1b.v1).
Release fraction to soil from process (final release): 0.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).
Process efficiency: Process optimized for highly efficient use of raw materials (very minimal environmental release).
Equipment cleaning: No release to wastewater from process as such, wastewater emissions limited to release generated from final equipment cleaning step using water.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=88,11%).
Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

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

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: ECETOC TRA Worker v3. Only highest figures are presented here.
Assessment method-Environment: ECETOC TRA version 3 in advanced mode and IFRA guidance on SpERCs.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Worker, long-term, systemic, Dermal	1,371 mg/kg bw/day	0,255	PROC5, PROC8b
Worker, long-term, systemic, Inhalation	9,675 mg/m3	0,509	PROC3
Worker, long-term, systemic, Combined routes	N/A	0,618	PROC5

Environment

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Freshwater	0,003 mg/L (a) / 0,005 mg/L (b)	0,182 (a) / 0,29 (b)	(a) large/medium site/ (b) small site
Freshwater sediment	0,26 mg/kg dw (a) / 0,415 mg/kg dw (b)	0,138 (a) / 0,22 (b)	(a) large/medium site/ (b) small site
Marine water	0,0003174 mg/L (a) 0,0005074 mg/L (b)	0,181 (a) / 0,29 (b)	(a) large/medium site/ (b) small site
Marine water sediment	0,026 mg/kg dw (a) / 0,041 mg/kg dw (b)	0,138 (a) / 0,22 (b)	(a) large/medium site/ (b) small site
Soil	0,049 mg/kg dw (a) / 0,081 mg/kg dw (b)	0,134 (a) / 0,222 (b)	(a) large/medium site/ (b) small site
STP	0,29 mg/L (a) / 0,048 mg/L (b)	<0,01 (a) / <0,01 (b)	(a) large/medium site/ (b) small site
Human via environment, Inhalation	0,001 mg/m3 (a) / 0,0007698 mg/m3 (b)	<0,01 (a) / <0,01 (b)	(a) large/medium site/ (b) small site
Human via environment, Oral	0,013 mg/kg bw/day (a) / 0,01 mg/kg bw/day (b)	<0,01 (a) / <0,01 (b)	(a) large/medium site/ (b) small site
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

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

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section

SDS Name: Kalama* Peach Lactone

2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Indoor use, PROC9: LEV used, no respirator required. Duration: PROC3, PROC5, PROC8a: 1-4 hours/day. PROC1, PROC8b, PROC9: 15 minutes-1 hour/day. PROC15: <15 minutes. Dermal protection: PROC1, PROC15: No (Effectiveness Dermal: 0%). PROC3, PROC5, PROC8a, PROC8b, PROC9: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%). Concentration of substance: PROC1: Up to 100%. PROC3, PROC5, PROC8b, PROC15: >25%. PROC8a, PROC9: 5-25%.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (2): Formulation - GES2 Formulation of fragranced end-products (formulating)

1. Exposure scenario (2)

Short title of the exposure scenario:

Formulation - GES2 Formulation of fragranced end-products (formulating)

List of use descriptors:

Process category (PROC): PROC1, PROC3, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15

Environmental release category (ERC): ERC2 (SpERC AISE 2.1.a.g; AISE 2.1.b,h; AISE 2.1.c,i; AISE 2.1.j + CE/AISE 2.3.a + CE 2.1.a; AISE 2.1.k + CE/AISE 2.3.b + CE 2.1.b; AISE 2.1.l + CE/AISE 2.3.c + CE 2.1.c; CE 2.2.a-c; CE 2.1.d-j).

List of names of contributing worker scenarios and corresponding PROCs:

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.

PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition.

PROC5 Mixing or blending in batch processes. Covers mixing or blending of solid or liquid materials in the context of manufacturing or formulating sectors, as well as upon end use.

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities. Transfer includes loading, filling, dumping, bagging and weighing.

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities. Transfer includes loading, filling, dumping, bagging.

PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing). Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage.

PROC14 Tableting, compression, extrusion, pelletisation, granulation. This covers processing of mixtures and/or substances into a defined shape for further use.

PROC15 Use as laboratory reagent. Use of substances at small scale laboratory (< 1 l or 1 kg present at workplace).

Name of contributing environmental scenario and corresponding ERCs:

ERC2 Formulation into mixture.

SpERC:

- GES2A: AISE Granular and low viscosity liquids (large site)(AISE 2.1.a,g).

- GES2B: AISE Granular and low viscosity liquids (medium site)(AISE 2.1.b,h).

- GES2C: AISE Granular and low viscosity liquids (small site)(AISE 2.1.c,i).

- GES2D: AISE High viscosity liquids+CE/AISE Solid products+CE Low viscosity liquids (large site)(AISE 2.1.j+CE/AISE 2.3.a+CE2.1.a).

- GES2E: AISE High viscosity liquids+CE/AISE Solid products+CE Low viscosity liquids (medium site)(AISE 2.1.k+CE/AISE 2.3.b+CE2.1.b).

- GES2F: AISE High viscosity liquids+CE/AISE Solid products+CE Low viscosity liquids (small site)(AISE 2.1.l+CE/AISE 2.3.c+CE2.1.c).

- GES2G: AISE + CE Fine fragrances (cleaning with solvent)(large/medium/small site)(CE 2.2a-c).

- GES2H: ERC2 default (large/medium/small site)(CE 2.1.d-j).

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf). For further information on CEFIC (The European Chemical Industry Council) Specific Environmental Release Categories (SpERCs), see <http://www.cefic.org/Industry-support/Implementing-reach/Libraries/>.

2. Conditions of use affecting exposure

2.1 Control of workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately.

Product characteristics:

Concentration of substance:

- PROC1, PROC3, PROC5, PROC8b, PROC15: 5-25%

- PROC8a, PROC9, PROC14: <1%

Physical state: liquid.

Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Amounts used:

This information is not relevant for assessment of worker's exposure.

Frequency and duration of use/exposure:

Duration:

- PROC14: >4-8 hours/day.

- PROC3, PROC5, PROC8a: 1-4 hours/day.

- PROC1, PROC8b, PROC9: 15 minutes-1 hour/day.

- PROC15: <15 minutes.

Human factors not influenced by risk management:

Exposed skin surface:

- PROC1, PROC3, PROC15: 240 cm² (one hand, face side only).

- PROC5, PROC9, PROC14: 480 cm² (two hands, face side only).

- PROC8a, PROC8b: 960 cm² (two hands).

SDS Name: Kalama* Peach Lactone

Other given operational conditions affecting workers exposure:

Location: Indoor use.
Domain: Industrial use.
Process temperature: <= 40 °C.

Technical conditions and measures to control dispersion from source towards the worker:

General ventilation: Good general ventilation (3-5 air changes per hour): 30%.
Containment:
- PROC1: Closed system (minimal contact during routine operations).
- PROC3: Closed batch process with occasional controlled exposure.
- PROC8b, PROC9: Semi-closed process with occasional controlled exposure.
- PROC5, PROC8a, PROC14, PROC15: No.
Local exhaust ventilation:
- PROC1, PROC3, PROC5, PROC8a, PROC9, PROC14, PROC15: Not required.
- PROC8b: Yes (95% effectiveness).
Local exhaust ventilation (for dermal): Not required.
Occupational Health and Safety Management System: Advanced.

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

Respiratory protection: Not required.
Eye protection: Yes (chemical resistant face shield, goggles or safety glasses with side shields when there is potential for direct contact).
Dermal protection:
- PROC1, PROC3, PROC8a, PROC9, PROC14, PROC15: No (Effectiveness Dermal: 0%).
- PROC5, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%).

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

Generally accepted standards of occupational hygiene are maintained.
Minimisation of manual phases/work tasks.
Minimisation of splashes and spills.
Avoidance of contact with contaminated tools and objects.
Regular cleaning of equipment and work area.
Training staff on good practice.
Management/supervision in place to check that RMMs in place are being used correctly and OCs followed.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Physical state: liquid.
Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Amounts used:

Maximum daily use at a site:
- GES2A: 0,15 tons/day.
- GES2B: 0,056 tons/day.
- GES2C: 0,046 tons/day.
- GES2D: 0,042 tons/day.
- GES2E, GES2F: 0,018 tons/day.
- GES2G: 0,064 tons/day.
- GES2H: 0,006 tons/day.
Maximum annual use at a site:
- GES2A: 37,5 tons/year.
- GES2B: 14 tons/year.
- GES2C: 11,5 tons/year.
- GES2D: 10,5 tons/year.
- GES2E: 4,5 tons/year.
- GES2F: 5,1 tons/year.
- GES2G: 16 tons/year.
- GES2H: 1,5 tons/year.

Percentage of tonnage used at regional scale: 10 %.

Frequency and duration of use:

Emission days: <=250 days/year.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use.
Industrial use.
Release fraction to air from process (initial release): 0,0; (final release): 0,0. Local release rate: 0 kg/day.
Release fraction to wastewater from process:
- GES2A: (initial release): 0,0001; (final release): 0,0001. Local release rate: 0,015 kg/day (AISE 2.1.a.v2)
- GES2B: (initial release): 0,001; (final release): 0,001. Local release rate: 0,056 kg/day (AISE 2.1.b.v2).
- GES2C: (initial release): 0,002; (final release): 0,002. Local release rate: 0,092 kg/day (AISE 2.1.c.v2)
- GES2D: (initial release): 0,001; (final release): 0,001. Local release rate: 0,042 kg/day (AISE 2.1.j.v2).
- GES2E: (initial release): 0,002; (final release): 0,002. Local release rate: 0,036 kg/day (AISE 2.1.k.v2)
- GES2F: (initial release): 0,004; (final release): 0,004. Local release rate: 0,072 kg/day (AISE 2.1.l.v2).
- GES2G: (initial release): 0,0; (final release): 0,0. Local release rate: 0 kg/day (CE 2.2a.v2)
- GES2H: (initial release): 0,02; (final release): 0,02. Local release rate: 0,12 kg/day (CE 2.1g.v2)
Release fraction to soil from process (final release): 0.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Process efficiency: Process optimized for highly efficient use of raw materials (very minimal environmental release).

Typical measures reducing emissions to waste water may include may include:

- Closed automated process and/or Closed transfer system and/or Closed batch systems and/or Semi-closed transfer system and/or Batch production of final product;
- Centralized process control;
- Re-use of process grey water for cleaning;
- Optimized and/or automated systems for the transport and handling of raw materials that minimize overall exposure levels and incidental spills;
- Reduced number of transfer and cleaning operations through manufacturing of different products from one premix (masterbatch) to which certain ingredients are added to yield the final products;
- Dedicated storage tanks for raw materials, premixes and final products;
- Recovery of materials through recycling residues of granular detergents in cleaning steps at packaging or transfer lines into the slurries.

Equipment cleaning:

- GES2A, GES2B, GES2C: Residues of granular detergents recovered in cleaning steps at packaging or transfer lines are recycled into the slurries.
- GES2D, GES2E: Equipment cleaning with minimized emissions to wastewater. Typically implemented measures for reducing emissions to waste water may include: Dry cleaning of equipment (e.g. use of absorbent materials and vacuum cleaning including incineration of resulting solid waste); Cleaning involving so-called pigs; Cleaning involving so-called ""cleaning in place"" (CIP System); Steam cleaning; Manual removal of residual products adhering to equipment (e.g. by manual scrubbing, vacuum cleaning, etc.); Use of two-liner systems (i.e. single use disposable reactor cover that is incinerated after use as solid waste).
- GES2F, GES2H: Equipment cleaned with water, washing disposed of with wastewater.
- GES2G: Equipment cleaned with organic solvent, washings are collected and disposed of as solvent waste.

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=88,11%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

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

All risk management measures utilised must also comply with all relevant local regulations.

General good practice: Trained staff, spill protection including waste reuse.

3. Exposure estimation and reference to its source

Assessment method-Health: ECETOC TRA Worker v3. Only highest figures are presented here.

Assessment method-Environment: ECETOC TRA version 3 in advanced mode and IFRA guidance on SpERCs. GES2A, GES2B, GES2C, GES2D, GES2E, GES2F: EU TDG 2003. Only highest figures are presented here.

Health

<u>Effect/Compartment</u>	<u>Exposure estimate/PEC</u>	<u>RCR</u>	<u>Notes</u>
Worker, long-term, systemic, Dermal	1,371 mg/kg bw/day	0,255	PROC8a
Worker, long-term, systemic, Inhalation	9,675 mg/m3	0,509	PROC5
Worker, long-term, systemic, Combined routes	N/A	0,662	PROC5

Environment

<u>Effect/Compartment</u>	<u>Exposure estimate/PEC</u>	<u>RCR</u>	<u>Notes</u>
Freshwater	0,001 mg/L	0,06	ERC2-GES2H (CE 2.1.d-j)
Freshwater sediment	0,086 mg/kg dw	0,046	ERC2-GES2H (CE 2.1.d-j)
Marine water	0,0001037 mg/L	0,059	ERC2-GES2H (CE 2.1.d-j)
Marine water sediment	0,008 mg/kg dw	0,045	ERC2-GES2H (CE 2.1.d-j)
Soil	0,012 mg/kg dw	0,034	ERC2-GES2H (CE 2.1.d-j)
STP	0,007 mg/L	<0,01	ERC2-GES2H (CE 2.1.d-j)
Human via environment, Inhalation	0,000008135 mg/m3	<0,01	ERC2-GES2H (CE 2.1.d-j)
Human via environment, Oral	0,0004765 mg/kg bw/day	<0,01	ERC2-GES2H (CE 2.1.d-j)
Human via environment, Combined routes	N/A	<0,01	ERC2-GES2H (CE 2.1.d-j)

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

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

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Indoor use, PROC8b: LEV used, no respirator required. Duration: PROC14: >4-8 hours/day. PROC3, PROC5, PROC8a: 1-4 hours/day. PROC1, PROC8b, PROC9: 15 minutes-1 hour/day. PROC15: <15 minutes. Dermal protection: PROC1, PROC3, PROC8a, PROC9, PROC14, PROC15: No (Effectiveness Dermal: 0%). PROC5, PROC8b: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%). Concentration of substance: PROC1, PROC3, PROC5, PROC8b, PROC15: 5-25%. PROC8a, PROC9, PROC14: <1%.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite

technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (3): Use by professional workers - GES4 Professional end use of washing and cleaning products

1. Exposure scenario (3)

Short title of the exposure scenario:

Use by professional workers - GES4 Professional end use of washing and cleaning products

List of use descriptors:

Sector of use category (SU): SU0

Product category (PC): PC35

Process category (PROC): PROC1, PROC2, PROC4, PROC8a, PROC8b, PROC10, PROC11, PROC13

Environmental release category (ERC): ERC8a

List of names of contributing worker scenarios and corresponding PROCs:

CS2: PROC1 (AISE P102, P105, P108, P111, P203, P204, P1101).

CS3: PROC2 (AISE P202).

CS4: PROC4 (AISE P112).

CS5: PROC4 (AISE P701, P704).

CS6: PROC8a (AISE P102, P105, P108, P111, P112, P203, P204, P309, P1101, P1102).

CS7: PROC8a (AISE P901, P902).

CS8: PROC8a (AISE P201).

CS9: PROC8a (AISE P301, P302, P303, P304, P305, P306, P312, P401, P402, P403, P409, P410, P808, P1104).

CS10: PROC8a (AISE P103, P308, P314, P315, P404, P405, P701, P702, P704, P1103).

CS11: PROC8a (AISE P703, P705, P706).

CS12: PROC8b (AISE P202).

CS13: PROC10 (AISE P310).

CS14: PROC10 (AISE P103, P201, P317, P411).

CS15: PROC10 (AISE P307).

CS16: PROC10 (AISE P113, P301, P302, P303, P304, P305, P403).

CS17: PROC10 (AISE P306, P312, P313, P314, P315, P316, P401, P402, P405, P409, P410, P808, P1103, P1104).

CS18: PROC10 (AISE P308, P311, P404).

CS19: PROC10 (AISE P703, P705, P706).

CS20: PROC10 (AISE P902).

CS21: PROC11 (AISE P113, P302, P304, P306, P313, P315, P402, P411, P702, P1104).

CS22: PROC11 (AISE P308, P311).

CS23: PROC11 (AISE P703, P706).

CS24: PROC11 (AISE P902).

CS25: PROC11 (AISE P901).

CS26: PROC13 (AISE P606, P607).

CS27: PROC13 (AISE P309, P1102).

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions.

PROC4 Chemical production where opportunity for exposure arises.

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities. Transfer includes loading, filling, dumping, bagging and weighing.

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities. Transfer includes loading, filling, dumping, bagging.

PROC10 Roller application or brushing. This includes application of paints, coatings, removers, adhesives or cleaning agents to surfaces with potential exposure arising from splashes.

PROC11 Non industrial spraying. Air dispersive techniques i.e. dispersion into air (= atomization) by e.g. pressurized air, hydraulic pressure or centrifugation, applicable for liquids and powders.

PROC13 Treatment of articles by dipping and pouring.

Name of contributing environmental scenario and corresponding ERCs:

CS1: ERC8a.

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor).

Further explanations:

PC35 Washing and cleaning products.

Professional Use of Laundry products:

- AISE P102 Laundry detergent: Semi-automatic process (PROC1, PROC8a).

- AISE P103 Laundry detergent: Manual process (PROC8a, PROC10).

- AISE P105 Conditioner (softener/starch): Semi-automatic process (PROC1, PROC8a).

- AISE P108 Laundry aid (gasing): Semi-automatic process (PROC1, PROC8a).

- AISE P111 Laundry aid (non-gasing): Semi-automatic process (PROC1, PROC8a).

- AISE P112 Laundry aid (non-gasing): Manual process (PROC4, PROC8a).

- AISE P113 Prespotter/Stain remover: Manual process (PROC10, PROC11).

Professional Use of Dishwash products:

- AISE P201 Dishwash product: Manual process (PROC8a, PROC10).

- AISE P202 Dishwash and rinse aid product: Automatic process (PROC2, PROC8b).

- AISE P203 Dishwash product: Semi-automatic process (PROC1, PROC8a).

- AISE P204 Rinse aid: Automatic process (PROC1, PROC8a).

Professional Use of Vehicle cleaning Products:

- AISE P701 Car wash product: Semi-Automatic process (PROC4, PROC8a).

- AISE P702 Car wash product: Spray and rinse process (PROC8a, PROC11).

- AISE P703 Car wash product: Spray and wipe manual process (PROC8a, PROC10, PROC11).

- AISE P704 Dewaxing product: Semi-Automatic process (PROC4, PROC8a).

SDS Name: Kalama* Peach Lactone

- AISE P705 Boat cleaner: Manual process (PROC8a, PROC10).
- AISE P706 Boat cleaner: Spray and wipe manual process (PROC8a, PROC10, PROC11).
- Professional Use of Medical Devices:
 - AISE P1101 Medical devices: Semi-automatic process (PROC1, PROC8a).
 - AISE P1102 Medical devices: Dipping process (PROC8a, PROC13).
 - AISE P1103 Medical devices: Manual process (PROC8a, PROC10).
 - AISE P1104 Medical devices: Spray process (PROC8a, PROC10, PROC11).
- Professional Use of Facade/surface Cleaning Products:
 - AISE P901 Facade/surface cleaner: High pressure process (PROC8a, PROC11).
 - AISE P902 Facade/surface cleaner: Medium pressure process (PROC8a, PROC10, PROC11).
- Professional Use of Floor care products:
 - AISE P401 Floor cleaner: Semi-Automatic process (PROC8a, PROC10).
 - AISE P402 Floor cleaner: Spray and wipe manual process (PROC8a, PROC10, PROC11).
 - AISE P403 Floor cleaner: Manual process (PROC8a, PROC10).
 - AISE P404 Floor stripper: Manual process (PROC8a, PROC10).
 - AISE P405 Floor stripper: Semi-Automatic process (PROC8a, PROC10).
 - AISE P409 Carpet cleaner: Manual process (PROC8a, PROC10).
 - AISE P410 Carpet cleaner: Semi-Automatic process (PROC8a, PROC10).
 - AISE P411 Carpet pre-spotters: Spray and brush manual process (PROC10, PROC11).
- Professional Use of General surface cleaning products:
 - AISE P301 General purpose cleaner: Manual process (PROC8a, PROC10).
 - AISE P302 General purpose cleaner: Spray and wipe manual process (PROC8a, PROC10, PROC11).
 - AISE P303 Kitchen cleaner: Manual process (PROC8a, PROC10).
 - AISE P304 Kitchen cleaner: Spray and wipe manual process (PROC8a, PROC10, PROC11).
 - AISE P305 Sanitary cleaner: Manual process (PROC8a, PROC10).
 - AISE P306 Sanitary cleaner: Spray and wipe manual process (PROC8a, PROC10, PROC11).
 - AISE P307 Descaling agent: Manual process (PROC10).
 - AISE P308 Descaling agent: Spray and rinse manual process (PROC8a, PROC10, PROC11).
 - AISE P309 Periodic cleaning by dipping (PROC8a, PROC13).
 - AISE P310 Oven/Grill Cleaner: Manual process (PROC10).
 - AISE P311 Oven/Grill Cleaner: Spray and wipe manual process (PROC10, PROC11).
 - AISE P312 Glass cleaner: Manual process (PROC8a, PROC10).
 - AISE P313 Glass cleaner: Spray and wipe manual process (PROC10, PROC11).
 - AISE P314 Surface disinfectant: Manual process (PROC8a, PROC10).
 - AISE P315 Surface disinfectant: Spray and rinse manual process (PROC8a, PROC10, PROC11).
 - AISE P316 Metal cleaning agent: Manual process (PROC10).
 - AISE P317 Wet wipe: Manual process (PROC10).
- Professional Use of Maintenance Products:
 - AISE P606 Drain unblocker: Manual process (PROC13).
 - AISE P607 Drain cleaner: Manual process (PROC13).
- Professional Use of Pharmacos products:
 - AISE P808 Animal housing care: Manual process (PROC8a, PROC10).

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately.

Product characteristics:

Concentration of substance: <1%.

Physical state: liquid.

Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Amounts used:

This information is not relevant for assessment of worker's exposure.

Frequency and duration of use/exposure:

Duration:

- PROC1, PROC2, PROC4 (CS5), PROC10 (CS20), PROC11 (CS25): >4-8 hours/day.

- PROC10 (CS14, CS15, CS16, CS17, CS18, CS19): 1-4 hours/day.

- PROC8a (CS9, CS10, CS11), PROC10 (CS13), PROC11 (CS21, CS22, CS23, CS24), PROC13 (CS27): 15 minutes-1 hour/day.

- PROC4 (CS4), PROC8a (CS6, CS7, CS8), PROC8b, PROC13 (CS26): <15 minutes.

Human factors not influenced by risk management:

Exposed skin surface:

- PROC1: 240 cm² (one hand, face side only).

- PROC2, PROC4, PROC13: 480 cm² (two hands, face side only).

- PROC8a, PROC8b, PROC10: 960 cm² (two hands).

- PROC11: 1500 cm² (two hands and upper wrists).

Other given operational conditions affecting workers exposure:

Location:

- PROC1, PROC2, PROC4 (CS4), PROC8a (CS6, CS8), PROC8b, PROC10 (CS13, CS14, CS15, CS18), PROC11 (CS22), PROC13: Indoor use.

- PROC4 (CS5), PROC8a (CS7, CS9, CS10), PROC10 (CS16, CS17), PROC11 (CS20, CS21, CS24, CS25): Indoor/outdoor use.

SDS Name: Kalama* Peach Lactone

- PROC8a (CS11), PROC10 (CS19), PROC11 (CS23): Outdoor use.
Domain: Professional use.
Process temperature: <= 40 °C.

Technical conditions and measures to control dispersion from source towards the worker:

General ventilation:

- PROC8a (CS11), PROC10 (CS19), PROC11 (CS23): Outdoors (outdoor use).
- PROC1, PROC2, PROC4, PROC8a (CS7-CS10), PROC8b, PROC10 (CS13-CS18, CS20), PROC11 (CS24, CS25), PROC13: Basic general ventilation (1-3 air changes per hour): 0%.
- PROC11 (CS21, CS22): Good general ventilation (3-5 air changes per hour): 30%.

Containment:

- PROC1: Closed system (minimal contact during routine operations).
- PROC2: Closed continuous process with occasional controlled exposure.
- PROC4, PROC8b: Semi-closed process with occasional controlled exposure.
- PROC8a, PROC10, PROC11, PROC13: No.

Local exhaust ventilation: Not required.

Local exhaust ventilation (for dermal): Not required.

Occupational Health and Safety Management System: Basic.

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

Respiratory protection: Unless otherwise stated, Not required.

- PROC8a (CS7), PROC10 (CS20), PROC11 (CS24, CS25): Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%).

Dermal protection:

- PROC1, PROC2, PROC4 (CS5), PROC8a (CS8, CS9): No (Effectiveness Dermal: 0%).
- PROC4 (CS4), PROC8a (CS6, CS7, CS10, CS11), PROC8b, PROC10, PROC11 (CS24), PROC13: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%).
- PROC11 (CS21-CS23, CS25): Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%).

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

Generally accepted standards of occupational hygiene are maintained.

Minimisation of manual phases/work tasks.

Minimisation of splashes and spills.

Avoidance of contact with contaminated tools and objects.

Regular cleaning of equipment and work area.

Training staff on good practice.

Management/supervision in place to check that RMMs in place are being used correctly and OCs followed.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Physical state: liquid.

Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Amounts used:

Daily wide dispersive use: 0,000165 tons/day.

Percentage of tonnage used at regional scale: 10 %.

Frequency and duration of use:

Emission days: <=365 days/year.

Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use.

Professional use.

Release fraction to air from process (initial release): 1,00; (final release): 1,00.

Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,165 kg/day.

Release fraction to soil from process (final release): 0.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=88,11%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

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

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: ECETOC TRA Worker v3. Only highest figures are presented here.

Assessment method-Environment: ECETOC TRA version 3 in advanced mode and IFRA guidance on SpERCs.

Health

<u>Effect/Compartment</u>	<u>Exposure estimate/PEC</u>	<u>RCR</u>	<u>Notes</u>
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Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Worker, long-term, systemic, Dermal	2,143 mg/kg bw/day	0,398	PROC11 (CS24)
Worker, long-term, systemic, Inhalation	11,52 mg/m3	0,606	PROC10 (CS14, CS15, CS16, CS17, CS18)
Worker, long-term, systemic, Combined routes	N/A	0,765	PROC11 (CS21, CS22, CS23)

Environment

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Freshwater	0,001 mg/L	0,075	
Freshwater sediment	0,108 mg/kg dw	0,057	
Marine water	0,0001304 mg/L	0,074	
Marine water sediment	0,011 mg/kg dw	0,057	
Soil	0,017 mg/kg dw	0,046	
STP	0,01 mg/L	<0,01	
Human via environment, Inhalation	0,000008148 mg/m3	<0,01	
Human via environment, Oral	0,0006959 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

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

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Indoor/outdoor use, without LEV. Respiratory protection: PROC8a (CS7), PROC10 (CS20), PROC11 (CS24, CS25): Yes (Respirator with APF of 10) (Effectiveness Inhalation: 90%). Duration: PROC1, PROC2, PROC4 (CS5), PROC10 (CS20), PROC11 (CS25): >4-8 hours/day. PROC10 (CS14, CS15, CS16, CS17, CS18, CS19): 1-4 hours/day. PROC8a (CS9, CS10, CS11), PROC10 (CS13), PROC11 (CS21, CS22, CS23, CS24), PROC13 (CS27): 15 minutes-1 hour/day. PROC4 (CS4), PROC8a (CS6, CS7, CS8), PROC8b, PROC13 (CS26): <15 minutes. Dermal protection: PROC1, PROC2, PROC4 (CS5), PROC8a (CS8, CS9): No (Effectiveness Dermal: 0%). PROC4 (CS4), PROC8a (CS6, CS7, CS10, CS11), PROC8b, PROC10, PROC11 (CS24), PROC13: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%). PROC11 (CS21-CS23, CS25): Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%). Concentration of substance: <1%.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (4): Use by professional workers - GES5 Professional end use of polishes and wax blends**1. Exposure scenario (4)****Short title of the exposure scenario:**

Use by professional workers - GES5 Professional end use of polishes and wax blends

List of use descriptors:

Sector of use category (SU): SU0

Product category (PC): PC31

Process category (PROC): PROC2, PROC8b, PROC10, PROC11

Environmental release category (ERC): ERC8a

List of names of contributing worker scenarios and corresponding PROCs:

CS2: PROC2 (AISE P605).

CS3: PROC8b (AISE P605).

CS4: PROC10 (AISE P601, P602 (wipe), P603, P604 (wipe), P609 (wipe)).

CS5: PROC10 (AISE P406, P407, P408 (wipe), P608).

CS6: PROC11 (AISE P602 (spray), P604 (spray), P609 (spray)).

CS7: PROC11 (AISE P408 (spray)).

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions.

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities. Transfer includes loading, filling, dumping, bagging. PROC10 Roller application or brushing. This includes application of paints, coatings, removers, adhesives or cleaning agents to surfaces with potential exposure arising from splashes.

PROC11 Non industrial spraying. Air dispersive techniques i.e. dispersion into air (= atomization) by e.g. pressurized air, hydraulic pressure or centrifugation, applicable for liquids and powders.

Name of contributing environmental scenario and corresponding ERCs:

CS1: ERC8a.

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor).

Further explanations:

PC31 Polishes and wax blends.

Professional Use of Maintenance Products:

- AISE P601 Furniture care product: Manual process (PROC10).

- AISE P602 Furniture care product: Spray and wipe manual process (PROC10, PROC11).

- AISE P603 Leather care product: Manual process (PROC10).

- AISE P604 Leather care product: Spray and wipe manual process (PROC10, PROC11).

- AISE P605 Leather care product: Semi-automatic process (PROC2, PROC8b).

SDS Name: Kalama* Peach Lactone

- AISE P608 Stainless steel care: Manual process (PROC10).
 - AISE P609 Stainless steel care: Spray and wipe manual process (PROC10, PROC11).
- Professional Use of Floor care products:
- AISE P406 Polish/impregnating agent: Manual process (PROC10).
 - AISE P407 Polish/impregnating agent: Semi-Automatic process (PROC10).
 - AISE P408 Polish/impregnating agent: Spray and wipe manual process (PROC10, PROC11).

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately.

Product characteristics:

Concentration of substance: <1%.

Physical state: liquid.

Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Amounts used:

This information is not relevant for assessment of worker's exposure.

Frequency and duration of use/exposure:

Duration:

- PROC2: >4-8 hours/day.
- PROC10: 1-4 hours/day.
- PROC8b, PROC11 (CS7): 15 minutes-1 hour/day.
- PROC11 (CS6): <15 minutes.

Human factors not influenced by risk management:

Exposed skin surface:

- PROC2: 480 cm² (two hands, face side only).
- PROC8b, PROC10: 960 cm² (two hands).
- PROC11: 1500 cm² (two hands and upper wrists).

Other given operational conditions affecting workers exposure:

Location: Indoor use.

Domain: Professional use.

Process temperature: ≤ 40 °C.

Technical conditions and measures to control dispersion from source towards the worker:

General ventilation: Unless otherwise stated, Basic general ventilation (1-3 air changes per hour): 0%.

- PROC11 (CS7): Good general ventilation (3-5 air changes per hour): 30%.

Containment:

- PROC2: Closed continuous process with occasional controlled exposure.
- PROC8b: Semi-closed process with occasional controlled exposure.
- PROC10, PROC11: No.

Local exhaust ventilation: Not required.

Local exhaust ventilation (for dermal): Not required.

Occupational Health and Safety Management System: Basic.

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

Respiratory protection: Not required.

Dermal protection:

- PROC2: No (Effectiveness Dermal: 0%).
- PROC8b, PROC10: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%).
- PROC11: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%).

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

Generally accepted standards of occupational hygiene are maintained.

Minimisation of manual phases/work tasks.

Minimisation of splashes and spills.

Avoidance of contact with contaminated tools and objects.

Regular cleaning of equipment and work area.

Training staff on good practice.

Management/supervision in place to check that RMMs in place are being used correctly and OCs followed.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Physical state: liquid.

Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Amounts used:

Daily wide dispersive use: 0,00011 tons/day.

Percentage of tonnage used at regional scale: 10 %.

Frequency and duration of use:

Emission days: ≤365 days/year.

Wide dispersive use.

Environmental factors not influenced by risk management:

SDS Name: Kalama* Peach Lactone

Flow rate of receiving surface water: >=18,000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use.

Professional use.

Release fraction to air from process (initial release): 1,00; (final release): 1,00.

Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,11 kg/day.

Release fraction to soil from process (final release): 0.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=88,11%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

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

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: ECETOC TRA Worker v3. Only highest figures are presented here.

Assessment method-Environment: ECETOC TRA version 3 in advanced mode and IFRA guidance on SpERCs.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Worker, long-term, systemic, Dermal	1,071 mg/kg bw/day	0,199	PROC11 (CS6, CS7)
Worker, long-term, systemic, Inhalation	11,52 mg/m3	0,606	PROC10 (CS4, CS5)
Worker, long-term, systemic, Combined routes	N/A	0,765	PROC11 (CS7)

Environment

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Freshwater	0,0009907 mg/L	0,057	
Freshwater sediment	0,081 mg/kg dw	0,043	
Marine water	0,00009772 mg/L	0,056	
Marine water sediment	0,008 mg/kg dw	0,042	
Soil	0,011 mg/kg dw	0,031	
STP	0,007 mg/L	<0,01	
Human via environment, Inhalation	0,000008139 mg/m3	<0,01	
Human via environment, Oral	0,000539 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

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

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Indoor use, without LEV, no respirator required. Duration: PROC2: >4-8 hours/day. PROC10: 1-4 hours/day. PROC8b, PROC11 (CS7): 15 minutes-1 hour/day. PROC11 (CS6): <15 minutes. Dermal protection: PROC2: No (Effectiveness Dermal: 0%). PROC8b, PROC10: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%). PROC11: Yes (chemically resistant gloves conforming to EN374 with basic employee training) (Effectiveness Dermal: 90%). Concentration of substance: <1%.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (5): Consumer use - GES6 Consumer end-use of washing and cleaning products

1. Exposure scenario (5)

Short title of the exposure scenario:

Consumer use - GES6 Consumer end-use of washing and cleaning products

List of use descriptors:

Product category (PC): PC35

Environmental release category (ERC): ERC8a, ERC8d

Name of contributing environmental scenario and corresponding ERCs:

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor).

ERC8d Widespread use of non-reactive processing aid (no inclusion into or onto article, outdoor).

Further explanations:

PC35 Washing and cleaning products:

- CS1: Laundry and dish washing products:

- AISE C1 Laundry regular (powder, liquid);

SDS Name: Kalama* Peach Lactone

- AISE C2 Laundry compact (powder, liquid/gel, tablet);
 - AISE C3 Fabric conditioners (liquid regular, liquid concentrate);
 - AISE C4 Laundry additives (powder bleach, liquid bleach, tablet);
 - AISE C5 Hand dishwashing (liquid regular, liquid concentrate);
 - AISE C6 Machine dishwashing (powder, liquid, tablet);
 - AISE C12 Laundry aids (ironing aids-starch spray, ironing aids-other).
- CS2: Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners):
- AISE C7 Surface cleaners (liquid, powder, gel neat);
 - AISE C8 Toilet cleaners (powder, liquid, gel, tablet);
 - AISE C11 Carpet cleaners (liquid);
 - AISE C15 Wipes (bathroom, kitchen, floor);
 - AISE C21 High pressure washers/cleaners (liquid);
 - AISE C22 Automotive care (liquid).
- CS3: Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners):
- AISE C7 Surface cleaners (spray neat);
 - AISE C10 Oven cleaners (trigger spray);
 - AISE C11 Carpet cleaners (spray);
 - AISE C22 Automotive care (spray).

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

Product characteristics:

Concentration of substance in mixture:

- PC35 (CS1): Up to 0,001 g/g.
- PC35 (CS2): Up to 0,003 g/g.
- PC35 (CS3): Up to 0,002 g/g.

Physical state: liquid.

Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Oral contact foreseen: No.

Spray: PC35 (CS1, CS2): No. PC35 (CS3): Yes.

Amounts used:

Applied amounts for each use event:

- PC35 (CS1): 50 g.
- PC35 (CS2): 250 g.
- PC35 (CS3): 35 g.

Frequency and duration of use/exposure:

Duration covers exposure up to:

- PC35 (CS1): 1 hour/event.
- PC35 (CS2): 0.33 hour/event.
- PC35 (CS3): 4 hours/event.

Frequency - covers use frequency: up to 1 time/day.

Human factors not influenced by risk management:

Body parts potentially exposed: Hands.

Dermal transfer factor=1.

Other given operational conditions affecting consumers exposure:

Location: Indoor use.

Conditions and measures related to information and behavioral advice to consumers:

Assessment tool used: ECETOC TRA 3 model (consumer module) in which: Fragrance concentration in fragranced end-product from the IFRA guidance (2012) is used at Tier 1.5 level consumer risk assessment; further parameters are refined if necessary (Refined Tier 1.5) using the table of habits and practices for consumer products in western Europe from AISE (2009).

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Physical state: liquid.

Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Amounts used:

Daily wide dispersive use: 0,000055 tons/day.

Percentage of tonnage used at regional scale: 10 %.

Frequency and duration of use:

Emission days: <=365 days/year.

Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m³/day (default).

Other given operational conditions affecting environmental exposure:

Indoor/Outdoor use.

Consumer use.

Release fraction to air from process (initial release): 1,00; (final release): 1,00.

SDS Name: Kalama* Peach Lactone

Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,055 kg/day.
Release fraction to soil from process (final release): 0,2.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=88,11%).
Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

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

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: ECETOC TRA 3 model (consumer module) and IFRA guidance. Only highest figures are presented here.

Assessment method-Environment: ECETOC TRA version 3 in advanced mode and IFRA guidance on SpERCs.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Consumer, long-term, systemic, Dermal	0,429 mg/kg bw/day	0,159	PC35 (CS2)
Consumer, long-term, systemic, Inhalation	1,287 mg/m3	0,275	PC35 (CS3)
Consumer, long-term, systemic, Oral	0 mg/kg bw/day	<0,01	PC35
Consumer, long-term, systemic, Combined routes	N/A	0,407	PC35 (CS3)

Environment

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Freshwater	0,0006642 mg/L	0,038	
Freshwater sediment	0,054 mg/kg dw	0,029	
Marine water	0,00006507 mg/L	0,037	
Marine water sediment	0,005 mg/kg dw	0,028	
Soil	0,006 mg/kg dw	0,016	
STP	0,003 mg/L	<0,01	
Human via environment, Inhalation	0,00000813 mg/m3	<0,01	
Human via environment, Oral	0,0003821 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

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

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (6): Consumer use - GES7 Consumer end-use of air care products

1. Exposure scenario (6)

Short title of the exposure scenario:

Consumer use - GES7 Consumer end-use of air care products

List of use descriptors:

Product category (PC): PC3
Environmental release category (ERC): ERC8a

Name of contributing environmental scenario and corresponding ERCs:

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor).

Further explanations:

PC3 Air care products:
- CS1: AISE C17 Air fresheners aerosol (aqueous, non-aqueous, concentrated (mini-aerosol, timed release aerosol)).
- CS2: AISE C18 Air fresheners non aerosol (perfume in/on solid substrate (gel), diffusers (heated), candles).

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

Product characteristics:

Concentration of substance in mixture:

SDS Name: Kalama* Peach Lactone

- PC3 (CS1): Up to 0,002 g/g.
 - PC3 (CS2): Up to 0,05 g/g.
- Physical state: liquid.
Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C
Exposure via dermal route:
- PC3 (CS1): Dermal exposure assumed to be negligible.
 - PC3 (CS2): Yes (Fingertips).
- Oral contact foreseen: No.
Spray: PC3 (CS2): No. PC3 (CS1): Yes.

Amounts used:

- Applied amounts for each use event:
- PC3 (CS1): 8,4 g.
 - PC3 (CS2): 50 g.

Frequency and duration of use/exposure:

- Duration covers exposure up to:
- PC3 (CS1): 0.25 hour/event.
 - PC3 (CS2): 8 hours/event.
- Frequency: covers use frequency:
- PC3 (CS1): up to 1,14 times/day; frequent use per year.
 - PC3 (CS2): up to 1 time/day.

Human factors not influenced by risk management:

- Body parts potentially exposed:
- PC3 (CS1): dermal exposure negligible compared to inhalation.
 - PC3 (CS2): fingertips.
- Inhalation factor = 1.
Dermal transfer factor=1.

Other given operational conditions affecting consumers exposure:

Location: Indoor use.

Conditions and measures related to information and behavioral advice to consumers:

Assessment tool used: ECETOC TRA 3 model (consumer module) in which: Fragrance concentration in fragranced end-product from the IFRA guidance (2012) is used at Tier 1.5 level consumer risk assessment; further parameters are refined if necessary (Refined Tier 1.5) using the table of habits and practices for consumer products in western Europe from AISE (2009); ECETOC TRA v3.1 with Specific Consumer Exposure Determinants (SCED) for PC3 (CS2)-SCED AISE C17.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Physical state: liquid.
Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Amounts used:

Daily wide dispersive use: 0,000055 tons/day.
Percentage of tonnage used at regional scale: 10 %.

Frequency and duration of use:

Emission days: <=365 days/year.
Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use.
Consumer use.
Release fraction to air from process (initial release): 1,00; (final release): 1,00.
Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,055 kg/day.
Release fraction to soil from process (final release): 0,0.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=88,11%).
Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

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

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: PC3 (CS1): ECETOC TRA 3.1 model (consumer module) (SCED AISE C17). PC3 (CS2): ECETOC TRA 3 model (consumer module) and IFRA guidance. Only highest figures are presented here.
Assessment method-Environment: ECETOC TRA version 3 in advanced mode and IFRA guidance on SpERCs.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
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Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Consumer, long-term, systemic, Dermal	0,03 mg/kg bw/day	0,011	PC3 (CS2)
Consumer, long-term, systemic, Inhalation	1,041 mg/m ³	0,222	PC3 (CS1)
Consumer, long-term, systemic, Oral	0 mg/kg bw/day	<0,01	PC3
Consumer, long-term, systemic, Combined routes	N/A	0,222	PC3 (CS1)

Environment

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Freshwater	0,0006642 mg/L	0,038	
Freshwater sediment	0,054 mg/kg dw	0,029	
Marine water	0,00006507 mg/L	0,037	
Marine water sediment	0,005 mg/kg dw	0,028	
Soil	0,006 mg/kg dw	0,016	
STP	0,003 mg/L	<0,01	
Human via environment, Inhalation	0,00000813 mg/m ³	<0,01	
Human via environment, Oral	0,0003821 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

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

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (7): Consumer use - GES8 Consumer end-use of biocides**1. Exposure scenario (7)****Short title of the exposure scenario:**

Consumer use - GES8 Consumer end-use of biocides

List of use descriptors:

Product category (PC): PC8

Environmental release category (ERC): ERC8a, ERC8d

Name of contributing environmental scenario and corresponding ERCs:

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor).

ERC8d Widespread use of non-reactive processing aid (no inclusion into or onto article, outdoor).

Further explanations:

PC8 Biocidal products:

- CS1: AISE C19 Insecticides (spray neat, liquid electric).

- CS2: AISE C19 Repellents.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure**2.1 Control of consumer exposure****Product characteristics:**

Concentration of substance in mixture/product:

- PC8 (CS1 Insecticides (spray neat), CS2 Repellents): Up to 1%.

- PC8 (CS1 Insecticides (liquid electric)): Up to 0,01 g/g.

Physical state: liquid.

Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Exposure via inhalation route:

- PC8 (CS1): Yes

- PC8 (CS2): Negligible release to air expected.

Oral contact foreseen:

- PC8 (CS1 Insecticides (liquid electric)): No.

- PC8 (CS1 Insecticides (spray neat), CS2 Repellents): Yes.

Spray: PC8 (CS1 Insecticides (liquid electric), CS2 Repellents): No. PC8 (CS1 Insecticides (spray neat)): Yes.

Amounts used:

Applied amounts for each use event:

- PC8 (CS1 Insecticides (spray neat)): Inhalation mass generation rate 1.1 g/sec for spray duration 19.8 sec; Dermal contact rate 269 mg/min for 19.8 sec.

- PC8 (CS1 Insecticides (liquid electric)): 0,5 g.

- PC8 (CS2 Repellents): 6 g.

Frequency and duration of use/exposure:

Duration covers exposure up to:

SDS Name: Kalama* Peach Lactone

- PC8 (CS1 Insecticides (spray neat)): 19,8 seconds/event (dermal, oral); 240 minutes/event (inhalation).
 - PC8 (CS1 Insecticides (liquid electric)): 8 hours/event.
 - PC8 (CS2 Repellents): 180 minutes/event.
- Frequency - covers use frequency:
- PC8 (CS1 Insecticides (spray neat)): 0.25 times/day; daily use during 3-month period.
 - PC8 (CS1 Insecticides (liquid electric)): up to 1 time/day; frequent use per year.
 - PC8 (CS2 Repellents): up to 54 times/year.

Human factors not influenced by risk management:

- Body parts potentially exposed:
- PC8 (CS1 Insecticides (liquid electric)): fingertips.
 - PC8 (CS2 Repellents): Skin contact area up to 17500 cm².
- Inhalation factor = 1.
Dermal transfer factor=1.

Other given operational conditions affecting consumers exposure:

Location: Indoor/outdoor use.
Inhalation exposure model: PC8 (CS1 Insecticides (spray neat)) - Covers use in room size of 58 m³.

Conditions and measures related to information and behavioral advice to consumers:

Assessment tool used: ECETOC TRA 3 model (consumer module) in which: Fragrance concentration in fragranced end-product from the IFRA guidance (2012) is used at Tier 1.5 level consumer risk assessment; further parameters are refined if necessary (Refined Tier 1.5) using the table of habits and practices for consumer products in western Europe from AISE (2009); ECETOC TRA v3.1 with Specific Consumer Exposure Determinants (SCED) for PC8 (CS1 Insecticides (liquid electric))-SCED AISE C19b; External tool ConsExpo v5.0 b01 according to the product sub category specific fact sheet for PC8 (CS1 Insecticides (spray neat); CS2 Repellents).

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Physical state: liquid.
Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Amounts used:

Daily wide dispersive use: 0,000055 tons/day.
Percentage of tonnage used at regional scale: 10 %.

Frequency and duration of use:

Emission days: <=365 days/year.
Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m³/day (default).

Other given operational conditions affecting environmental exposure:

Indoor/Outdoor use.
Consumer use.
Release fraction to air from process (initial release): 1,00; (final release): 1,00.
Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,055 kg/day.
Release fraction to soil from process (final release): 0,2.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=88,11%).
Size of municipal sewage system/treatment plant: >=2000 m³/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

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

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: PC8 (CS1 Insecticides (spray neat), CS2 Repellents): External tool ConsExpo v5.0 b01 ; PC8 (CS1 Insecticides (liquid electric)): ECETOC TRA 3.1 model (consumer module) (SCED AISE C19b). Only highest figures are presented here.
Assessment method-Environment: ECETOC TRA version 3 in advanced mode and IFRA guidance on SpERCs.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Consumer, long-term, systemic, Dermal	0,15 mg/kg bw/day	0,06	PC8 (CS2)
Consumer, long-term, systemic, Inhalation	0,00048 mg/m ³	<0,01	PC8 (CS1)
Consumer, long-term, systemic, Oral	0,006 mg/kg bw/day	<0,01	PC8 (CS2)
Consumer, long-term, systemic, Combined routes	N/A	0,063	PC8 (CS2)

Environment

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Freshwater	0,0006642 mg/L	0,038	
Freshwater sediment	0,054 mg/kg dw	0,029	

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Marine water	0,00006507 mg/L	0,037	
Marine water sediment	0,005 mg/kg dw	0,028	
Soil	0,006 mg/kg dw	0,016	
STP	0,003 mg/L	<0,01	
Human via environment, Inhalation	0,00000813 mg/m3	<0,01	
Human via environment, Oral	0,0003821 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

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

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (8): Consumer use - GES9 Consumer end-use of polishes and wax blends

1. Exposure scenario (8)

Short title of the exposure scenario:

Consumer use - GES9 Consumer end-use of polishes and wax blends

List of use descriptors:

Product category (PC): PC31

Environmental release category (ERC): ERC8a

Name of contributing environmental scenario and corresponding ERCs:

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor).

Further explanations:

PC31 Polishes and wax blends.

- CS1: AISE C20 Furniture floor and leather care: waxes and creams (floor, furniture, shoes).

- CS2: AISE C20 Furniture floor and leather care: spray (furniture, shoes).

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

Product characteristics:

Concentration of substance in mixture: Up to 0,001 g/g.

Physical state: liquid.

Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Oral contact foreseen: No.

Spray: PC31 (CS1): No. PC31 (CS2): Yes.

Amounts used:

Applied amounts for each use event:

- PC31 (CS1): 550 g.

- PC31 (CS2): 135 g.

Frequency and duration of use/exposure:

Duration covers exposure up to: 4 hours/event.

Frequency - covers use frequency: up to 1 time/day.

Human factors not influenced by risk management:

Body parts potentially exposed: Hands.

Dermal transfer factor=1.

Other given operational conditions affecting consumers exposure:

Location: Indoor use.

Conditions and measures related to information and behavioral advice to consumers:

Assessment tool used: ECETOC TRA 3 model (consumer module) in which: Fragrance concentration in fragranced end-product from the IFRA guidance (2012) is used at Tier 1.5 level consumer risk assessment; further parameters are refined if necessary (Refined Tier 1.5) using the table of habits and practices for consumer products in western Europe from AISE (2009).

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Physical state: liquid.

Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Amounts used:

Daily wide dispersive use: 0,000055 tons/day.

Percentage of tonnage used at regional scale: 10 %.

SDS Name: Kalama* Peach Lactone

Frequency and duration of use:

Emission days: <=365 days/year.
Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use.
Consumer use.
Release fraction to air from process (initial release): 1,00; (final release): 1,00.
Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,055 kg/day.
Release fraction to soil from process (final release): 0.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=88,11%).
Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

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

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Health: ECETOC TRA 3 model (consumer module) and IFRA guidance. Only highest figures are presented here.
Assessment method-Environment: ECETOC TRA version 3 in advanced mode and IFRA guidance on SpERCs.

Health

<u>Effect/Compartment</u>	<u>Exposure estimate/PEC</u>	<u>RCR</u>	<u>Notes</u>
Consumer, long-term, systemic, Dermal	0,143 mg/kg bw/day	0,053	PC31 (CS1, CS2)
Consumer, long-term, systemic, Inhalation	1,985 mg/m3	0,424	PC31 (CS2)
Consumer, long-term, systemic, Oral	0 mg/kg bw/day	<0,01	PC31 (CS1, CS2)
Consumer, long-term, systemic, Combined routes	N/A	0,477	PC31 (CS2)

Environment

<u>Effect/Compartment</u>	<u>Exposure estimate/PEC</u>	<u>RCR</u>	<u>Notes</u>
Freshwater	0,0006642 mg/L	0,038	
Freshwater sediment	0,054 mg/kg dw	0,029	
Marine water	0,00006507 mg/L	0,037	
Marine water sediment	0,005 mg/kg dw	0,028	
Soil	0,006 mg/kg dw	0,016	
STP	0,003 mg/L	<0,01	
Human via environment, Inhalation	0,00000813 mg/m3	<0,01	
Human via environment, Oral	0,0003821 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

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

Health

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

Exposure scenario (9): Consumer use - GES10 Consumer end-use of cosmetics

1. Exposure scenario (9)

Short title of the exposure scenario:

Consumer use - GES10 Consumer end-use of cosmetics

List of use descriptors:

Product category (PC): PC28, PC39
Environmental release category (ERC): ERC8a

Name of contributing environmental scenario and corresponding ERCs:

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor).

Further explanations:

PC28 Perfumes, fragrances.

SDS Name: Kalama* Peach Lactone

PC39 Cosmetics, personal care products.

For further information on standardized use descriptors see the European Chemical Agency (ECHA) Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

2. Conditions of use affecting exposure

2.1 Control of consumer exposure

General:

For cosmetic and personal care products, risk assessment only required for the environment under REACH as human health is covered by alternative legislation.

2.2 Control of environmental exposure

General:

All risk management measures utilised must also comply with all relevant local regulations.

Product characteristics:

Physical state: liquid.

Vapour pressure: 0,27 Pa at 25 °C; 0,71 Pa at 40 °C

Amounts used:

Daily wide dispersive use: 0,000055 tons/day.

Percentage of tonnage used at regional scale: 10 %.

Frequency and duration of use:

Emission days: <=365 days/year.

Wide dispersive use.

Environmental factors not influenced by risk management:

Flow rate of receiving surface water: >=18,000 m3/day (default).

Other given operational conditions affecting environmental exposure:

Indoor use.

Consumer use.

Release fraction to air from process (initial release): 1,00; (final release): 1,00.

Release fraction to wastewater from process (initial release): 1,00; (final release): 1,00. Local release rate: 0,055 kg/day.

Release fraction to soil from process (final release): 0.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:

Dry sludge application to agricultural soil: Yes (default).

Conditions and measures related to municipal sewage treatment plant:

Municipal Sewage Treatment Plant (STP): Yes (Efficiency=88,11%).

Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

Conditions and measures related to external treatment of waste for disposal:

Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Conditions and measures related to external recovery of waste:

External recovery and recycling of waste should comply with applicable local and/or national regulations.

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

All risk management measures utilised must also comply with all relevant local regulations.

3. Exposure estimation and reference to its source

Assessment method-Environment: ECETOC TRA version 3 in advanced mode and IFRA guidance on SpERCs.

Environment

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Freshwater	0,0006642 mg/L	0,038	
Freshwater sediment	0,054 mg/kg dw	0,029	
Marine water	0,00006507 mg/L	0,037	
Marine water sediment	0,005 mg/kg dw	0,028	
Soil	0,006 mg/kg dw	0,016	
STP	0,003 mg/L	<0.01	
Human via environment, Inhalation	0,00000813 mg/m3	<0,01	
Human via environment, Oral	0,0003821 mg/kg bw/day	<0,01	
Human via environment, Combined routes	N/A	<0,01	

RCR=Risk characterization ratio (PEC/PNEC or Exposure estimate/DNEL); PEC=Predicted environmental concentration.

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

Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination. If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.