

Safety Data Sheet

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



Revision date: 1/14/2022
 Supersedes date: 1/7/2022

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

1.1. Product identifier:

Product trade name: Kalama* Florosol S
Company product number: FLOROSOLS
REACH registration number: 01-0000015458-64-0004
Substance name: A mixture of: cis-tetrahydro-2-isobutyl-4-methylpyran-4-ol; trans-tetrahydro-2-isobutyl-4-methylpyran-4-ol
Substance identification number: EC 405-040-6; Index 603-101-00-3
Other means of identification: 32202; 2H-Pyran-4-ol, tetrahydro-4-methyl-2-(2-methylpropyl)-

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

Uses: Fragrance ingredient. Industrial applications. Professional applications. Consumer applications. See Annex for covered uses.
Uses advised against: Consumer products with potential for significant oral contact.

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
For further information about this SDS: Email: product.compliance@emeraldmaterials.com

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:

Eye Irritation, category 2, H319
 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):



Signal word:

Warning

Hazard statements:

H319 Causes serious eye irritation.

Precautionary statements:

P264 Wash skin thoroughly after handling.

P280 Wear eye protection/face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

SDS Name: Kalama* Florosol S

P337+P313 If eye irritation persists: Get medical advice/attention.

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>
0063500-71-0	Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	99-100	Eye Irrit. 2	H319
<u>CAS-No.</u>	<u>Chemical Name</u>	<u>REACH Registration No.</u>	<u>EC/List Number</u>	
0063500-71-0	Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	01-0000015458-64-0004	405-040-6	
<u>CAS-No.</u>	<u>Chemical Name</u>	<u>M-factor</u>	<u>SCLs</u>	<u>ATE</u>
0063500-71-0	Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	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: Immediately flush eyes with plenty of clean water for an extended time, not less than fifteen (15) minutes. Flush longer if there is any indication of residual chemical in the eye. Ensure adequate flushing of the eyes by separating the eyelids with fingers and roll eyes in a circular motion. If eye irritation persists: Get medical advice/attention.

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. Pre-existing skin problems may be aggravated by prolonged or repeated contact. 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: None known.

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. Personal Protective Equipment must be worn.

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 launder 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):**

Chemical Name	EU OELV	EU IOELV	ACGIH - TWA/Ceiling	ACGIH - STEL
Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	N/E	N/E	N/E	N/E
Chemical Name	UK WEL	Ireland OEL		
Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	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):**Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)**

Population	Route	Acute (local)	Acute (systemic)	Long Term (local)	Long Term (systemic)
Workers	Inhalation	N/E	N/E	N/E	44,1 mg/m ³
Workers	Dermal	N/E	N/E	N/E	41,7 mg/kg bw/day

Population	Route	Acute (local)	Acute (systemic)	Long Term (local)	Long Term (systemic)
General population	Inhalation	N/E	N/E	N/E	13 mg/m ³
General population	Dermal	N/E	N/E	N/E	25 mg/kg bw/day
General population	Oral	N/E	N/E	N/E	7,5 mg/kg bw/day
Human via the environment	Inhalation	N/E	N/E	N/E	13 mg/m ³
Human via the environment	Oral	N/E	N/E	N/E	7,5 mg/kg bw/day

Predicted No Effect Concentration (PNECs):**Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)**

Compartment	PNEC
Freshwater	0,094 mg/L
Freshwater sediment	0,412 mg/kg dw
Marine water	0,0094 mg/L
Marine water sediment	0,0412 mg/kg dw
Intermittent releases	0,94 mg/L
Soil	0,0902 mg/kg dw
STP	10 mg/L
Oral	No potential for bioaccumulation

N/E=Not established; N/A=Not applicable (not required); bw=body weight; dw=dry weight; ww=wet weight.

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: Safety glasses or goggles required.

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). Suggested material for protective gloves: PVC (polyvinyl chloride). 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. In case of insufficient ventilation, wear suitable respiratory equipment.

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:	Colorless to light yellow
Odour:	Floral
Odour threshold:	Not Available
Melting point/Freezing point:	<-100°C (<-148°F)
Boiling point °C:	227 °C
Boiling point °F:	440 °F
Flammability:	Not flammable
Lower and upper explosion limit:	LEL: Not Available UEL: Not Available
Flash point:	106 °C (223 °F) DIN EN ISO 2719
Auto-ignition temperature:	328°C (622°F)
Decomposition temperature:	Not Available
pH:	Not Available
Kinematic viscosity:	247 mm ² /s (234 mPa.s) @ 20°C
Solubility in water:	23-24 g/L @ 23°C
Partition coefficient n-octanol/water (log value):	1.65 (23°C)
Vapour pressure:	0,01 hPa @ 20°C
Density and/or relative density:	0.943-0.953

SDS Name: Kalama* Florosol S

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 contact with strong 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>
Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	N/E	N/E	>2000 mg/kg	Rat/ adult	>2000 mg/kg	Rabbit/ 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>
Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	Mild irritant	Rabbit/ adult

Serious eye damage/irritation: Causes serious eye irritation - Category 2.

<u>Chemical Name</u>	<u>Eye irritation</u>	<u>Species</u>
Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	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>
Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	Non-sensitizer (OECD 406)	Guinea Pig/ adult

Carcinogenicity: Not classified (no relevant information found).

Germ cell mutagenicity: Not classified (based on available data, the classification criteria are not met). TETRAHYDRO-2-ISOBUTYL-4-METHYLPYRAN-4-OL, MIXED ISOMERS (cis and trans): 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). TETRAHYDRO-2-ISOBUTYL-4-METHYLPYRAN-4-OL, MIXED ISOMERS (cis and trans): Reproductive toxicity, oral, rats: NOAEL (no-observed adverse-effect-level) 1113 mg/kg bw/day (OECD 443). Reproductive toxicity, dermal, rats: NOAEL (no-observed adverse-effect-level) 1000 mg/kg bw/day (OECD 421). Developmental toxicity, oral, rats: NOAEL of 1113 mg/kg bw/day (OECD 443). Developmental toxicity dermal, rats: NOAEL (no-observed-adverse-effect level), maternal toxicity=1000 mg/kg bw/day; NOAEL, developmental toxicity=1000 mg/kg bw/day (OECD 414).

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). TETRAHYDRO-2-ISOBUTYL-4-METHYLPYRAN-4-OL, MIXED ISOMERS (cis and trans): Repeated dose toxicity study: NOAEL (No-Observed-Adverse-Effect-Level), oral, rat - 125 mg/kg bw/day; NOAEL, dermal, rat - 1000 mg/kg bw/day.

Aspiration hazard: Not classified (based on available data, the classification criteria are not met).

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: Causes serious eye irritation.

Skin: Repeated or prolonged skin contact may cause 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>
Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	Fish	LC50 354 mg/L (96 hours) (OECD 203)	N/E	N/E
Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	Invertebrates	EC50 320 mg/L (48 hours) (OECD 202)	N/E	N/E
Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	Algae	EC50 >100 mg/L (72 hours) (OECD 201)	EC50 >1000 mg/L(72 hours) (OECD 201)	EC10 232 mg/L(72 hours) (OECD 201)
Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	Micro-organisms	EC50 >1000 mg/L (3 hours) (OECD 209)		

12.2. Persistence and degradability:

<u>Chemical Name</u>	<u>Biodegradation</u>
Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	Not readily biodegradable (OECD 301B); Inherently biodegradable (OECD 301D)

12.3. Bioaccumulative potential:

<u>Chemical Name</u>	<u>Bioconcentration Factor (BCF)</u>	<u>Log Kow</u>
Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	N/E	1.65 (23°C)

12.4. Mobility in soil:

<u>Chemical Name</u>	<u>Mobility in soil (Koc/Kow)</u>
Tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	41.48 (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

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

SDS Name: Kalama* Florosol S

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):

H319 Causes serious eye irritation.

Reason for revision: Changes in Section(s): 1, 8, 11, 12, Annex

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

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

Emerald Kalama Chemical, LLC

1499 SE Tech Center Place, Suite 300

Vancouver, WA 98683

United States

Annex

Exposure Scenarios

Substance information:

Name of substance: 2H-Pyran-4-ol, tetrahydro-4-methyl-2-(2-methylpropyl)-.

EC# 405-040-6 / CAS# 63500-71-0

REACH Registration number: 01-0000015458-64-0004.

List of exposure scenarios:

ES1: Industrial compounding

ES2: Industrial formulation

ES3: Use at industrial sites - Industrial use of washing and cleaning products

ES4: Use by professional workers - Professional use in polishes, wax blends, washing and cleaning products

ES5: Consumer use - Consumer end uses

General remarks:

The first tier environmental exposure assessments have at first instance been performed using EUSES v2.1.2 which is part of Chemical Safety Assessment and Reporting tool version 3.6 (CHESAR v3.6).

This substance is classified as having the potential to induce eye irritation (H319). However, the available data do not provide quantitative dose-response information. In these circumstances, Qualitative Chemical Safety Assessment (CSA) is appropriate when there is no basis for setting a DNEL or DMEL, with the aim of reducing or avoiding contact, through the implementation of risk management measures (RMMs) and operational conditions (OCs) that are proportional to the level of concern for the health hazard posed by the substance. Exposures should be controlled to a level that results in an acceptable level of risk (i.e. implementation of the RMMs will ensure that the likelihood of an exposure occurring is negligible, and therefore the risk is considered to be controlled to a level of no concern).

If the user complies with the following generic statements, risks due to eye irritation can be considered to be adequately controlled: Avoid direct eye contact with product, also via contamination on hands. Use suitable eye protection. Clean up contamination/spills as soon as they occur. Wash off any eye contamination immediately. Provide basic employee training to prevent / minimise exposures and to report any eye effects that may develop.

The worker dermal and inhalation exposure assessments for industrial and professional uses have been performed using ECETOC TRA Worker v3 model integrated in the Chemical Safety Assessment and Reporting tool (CHESAR v3.6).

Consumer exposure assessments have been performed using ECETOC TRA v3.1 (R15) model (consumer module) or the AISE REACT Consumer Tool.

Exposure scenario (1): Industrial compounding

1. Exposure scenario (1)

Short title of the exposure scenario:

Industrial compounding

List of use descriptors:

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

Environmental release category (ERC): ERC2

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.

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.

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. Implementation of the Risk Management Measures (RMMs) will ensure that the likelihood of an exposure occurring is negligible, and therefore the risk is considered to be controlled to a level of no concern.

Product characteristics:

Concentration of substance in mixture/article: <=100%.

Physical form of the used product: Liquid, including paste/slurry/suspension.

Vapour pressure: 3,707 Pa at 40 °C

Frequency and duration of use/exposure:

Duration of activity: <=8 hours/day.

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, PROC9, PROC15: Basic general ventilation (1-3 air changes per hour): 0%.

- PROC5, PROC8b: Good general ventilation (3-5 air changes per hour): 30%.

- PROC8a: Enhanced general ventilation (5-10 air changes per hour): 70%.

Local exhaust ventilation: 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: No (Effectiveness Dermal: 0%).

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:

SDS Name: Kalama* Florosol S

Vapour pressure: 0,01 hPa at 20 °C

Amounts used:

Maximum daily use at a site: 1 ton/day.
Maximum annual use at a site: 100 tons/year.
Percentage of tonnage used at regional scale: 20 %.

Frequency and duration of use:

Emission days: <=100 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: 25 kg/day.
Release fraction to wastewater from process (initial release): 0,0007; (final release): 0,0007. Local release rate: 0,7 kg/day.
Release fraction to soil from process (final release): 0,0001.

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 (Effectiveness Water: 0,526%).
Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

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

External treatment and disposal of waste should comply with applicable local and/or national regulations.

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: CHESAR v3.6 Worker TRA v3. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

<u>Effect/Compartment</u>	<u>Exposure estimate/PEC</u>	<u>RCR</u>	<u>Notes</u>
Worker, long-term, systemic, Dermal	13,71 mg/kg bw/day	0,329	PROC5, PROC8a, PROC8b
Worker, long-term, systemic, Inhalation	35,88 mg/m3	0,814	PROC9, PROC15
Worker, long-term, systemic, Combined routes	N/A	0,978	PROC9

Environment

<u>Effect/Compartment</u>	<u>Exposure estimate/PEC</u>	<u>RCR</u>	<u>Notes</u>
Freshwater	0,04 mg/L	0,421	
Freshwater sediment	0,306 mg/kg dw	0,744	
Marine water	0,00395 mg/L	0,439	
Marine water sediment	0,031 mg/kg dw	0,747	
Soil	0,021 mg/kg dw	0,233	
STP	0,348 mg/L	0,035	
Human via environment, Inhalation	0,00191 mg/m3	<0,01	
Human via environment, Oral	0,023 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 of activity: <=8 hours/day. Concentration of substance in mixture/article: <=100%.

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): Industrial formulation

1. Exposure scenario (2)

Short title of the exposure scenario:

Industrial formulation

List of use descriptors:

Process category (PROC): PROC1, PROC3, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15
Environmental release category (ERC): ERC2

List of names of contributing worker scenarios and corresponding PROCs:

SDS Name: Kalama* Florosol S

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.

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. Implementation of the Risk Management Measures (RMMs) will ensure that the likelihood of an exposure occurring is negligible, and therefore the risk is considered to be controlled to a level of no concern.

Product characteristics:

Concentration of substance in mixture/article: <=100%.

Physical form of the used product: Liquid, including paste/slurry/suspension.

Vapour pressure: 3,707 Pa at 40 °C

Frequency and duration of use/exposure:

Duration of activity: <=8 hours/day.

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).

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, PROC9, PROC14, PROC15: Basic general ventilation (1-3 air changes per hour): 0%.

- PROC5, PROC8b: Good general ventilation (3-5 air changes per hour): 30%.

- PROC8a: Enhanced general ventilation (5-10 air changes per hour): 70%.

Local exhaust ventilation: 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: No (Effectiveness Dermal: 0%).

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:

Vapour pressure: 0,01 hPa at 20 °C

Amounts used:

Maximum daily use at a site: 1 ton/day.

Maximum annual use at a site: 100 tons/year.

Percentage of tonnage used at regional scale: 20 %.

Frequency and duration of use:

Emission days: <=100 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: 25 kg/day.

Release fraction to wastewater from process (initial release): 0,0007; (final release): 0,0007. Local release rate: 0,7 kg/day.

Release fraction to soil from process (final release): 0,0001.

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 (Effectiveness Water: 0,526%).

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

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

External treatment and disposal of waste should comply with applicable local and/or national regulations.

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: CHESAR v3.6 Worker TRA v3. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

<u>Effect/Compartment</u>	<u>Exposure estimate/PEC</u>	<u>RCR</u>	<u>Notes</u>
Worker, long-term, systemic, Dermal	13,71 mg/kg bw/day	0,329	PROC5, PROC8a, PROC8b
Worker, long-term, systemic, Inhalation	35,88 mg/m3	0,814	PROC9, PROC14, PROC15
Worker, long-term, systemic, Combined routes	N/A	0,978	PROC9

Environment

<u>Effect/Compartment</u>	<u>Exposure estimate/PEC</u>	<u>RCR</u>	<u>Notes</u>
Freshwater	0,04 mg/L	0,421	
Freshwater sediment	0,306 mg/kg dw	0,744	
Marine water	0,00395 mg/L	0,439	
Marine water sediment	0,031 mg/kg dw	0,747	
Soil	0,021 mg/kg dw	0,233	
STP	0,348 mg/L	0,035	
Human via environment, Inhalation	0,00191 mg/m3	<0,01	
Human via environment, Oral	0,023 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 of activity: <=8 hours/day. Concentration of substance in mixture/article: <=100%.

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 at industrial sites - Industrial use of washing and cleaning products**1. Exposure scenario (3)****Short title of the exposure scenario:**

Use at industrial sites - Industrial use of washing and cleaning products

List of use descriptors:

Product category (PC): PC35

Process category (PROC): PROC1, PROC2, PROC4, PROC7, PROC8b, PROC10, PROC13

Environmental release category (ERC): ERC4

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.

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.

PROC7 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.

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.

PROC13 Treatment of articles by dipping and pouring.

Name of contributing environmental scenario and corresponding ERCs:

ERC4 Use of non-reactive processing aid at industrial site (no inclusion into or onto article).

Further explanations:

PC35 Washing and cleaning 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 workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately. Implementation of the Risk Management Measures (RMMs) will ensure that the likelihood of an exposure occurring is negligible, and therefore the risk is considered to be controlled to a level of no concern.

Product characteristics:

Concentration of substance in mixture/article: <=100%.

Physical form of the used product: Liquid, including paste/slurry/suspension.

Vapour pressure: 3,707 Pa at 40 °C

Frequency and duration of use/exposure:

Duration of activity: <=8 hours/day.

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).

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

- PROC7: 1500 cm² (two hands and upper wrists).

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, PROC2, PROC4: Basic general ventilation (1-3 air changes per hour): 0%.

- PROC7, PROC8b: Good general ventilation (3-5 air changes per hour): 30%.

- PROC10, PROC13: Enhanced general ventilation (5-10 air changes per hour): 70%.

Local exhaust ventilation: Unless otherwise stated, Not required.

- PROC7: Yes (95% effectiveness).

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, PROC2, PROC4, PROC8b, PROC13: No (Effectiveness Dermal: 0%).

- PROC7, PROC10: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%).

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:

Vapour pressure: 0,01 hPa at 20 °C

Amounts used:

Maximum daily use at a site: 0,009 ton/day.

Maximum annual use at a site: 20 tons/year.

Percentage of tonnage used at regional scale: 10 %.

Frequency and duration of use:

Emission days: <=220 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:

Industrial use.

Release fraction to air from process (initial release):1,00; (final release): 1,00. Local release rate: 9 kg/day.

Release fraction to wastewater from process (initial release): 0,10; (final release): 0,10. Local release rate: 0,9 kg/day.

Release fraction to soil from process (final release): 0,05.

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 (Effectiveness Water: 0,526%).

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

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

External treatment and disposal of waste should comply with applicable local and/or national regulations.

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: CHESAR v3.6 Worker TRA v3. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Worker, long-term, systemic, Dermal	13,71 mg/kg bw/day	0,329	PROC8b, PROC13
Worker, long-term, systemic, Inhalation	35,88 mg/m3	0,814	PROC4
Consumer, long-term, systemic, Combined routes	N/A	0,978	PROC4

Environment

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Freshwater	0,049 mg/L	0,527	
Freshwater sediment	0,383 mg/kg dw	0,931	
Marine water	0,00495 mg/L	0,55	
Marine water sediment	0,038 mg/kg dw	0,935	
Soil	0,055 mg/kg dw	0,613	
STP	0,448 mg/L	0,045	
Human via environment, Inhalation	0,015 mg/m3	<0,01	
Human via environment, Oral	0,186 mg/kg dw/day	0,025	
Human via environment, Combined routes	N/A	0,026	

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, no respirator required. Duration of activity: <=8 hours/day. Local exhaust ventilation: PROC1, PROC2, PROC4, PROC8b, PROC10, PROC13: Not required. PROC7: Yes (95% effectiveness). Dermal protection: PROC7, PROC10: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%). Concentration of substance in mixture/article: <=100%.

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 - Professional use in polishes, wax blends, washing and cleaning products**1. Exposure scenario (4)****Short title of the exposure scenario:**

Use by professional workers - Professional use in polishes, wax blends, washing and cleaning products

List of use descriptors:

Product category (PC): PC31, PC35

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

Environmental release category (ERC): ERC8a, ERC8d

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.

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:

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).

SDS Name: Kalama* Florosol S

Further explanations:

PC31 Polishes and wax blends.
PC35 Washing and cleaning 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 workers exposure

General:

Generally accepted standards of occupational hygiene are maintained. Smoking, eating and drinking are prohibited at the workplace. Spills are cleaned immediately. Implementation of the Risk Management Measures (RMMs) will ensure that the likelihood of an exposure occurring is negligible, and therefore the risk is considered to be controlled to a level of no concern.

Product characteristics:

Concentration of substance in mixture/article:
- PROC1, PROC2: <=100%.
- PROC4, PROC8a, PROC8b, PROC10, PROC11, PROC13: <=5,0%.
Physical form of the used product: Liquid, including paste/slurry/suspension.
Vapour pressure: 3,707 Pa at 40 °C

Frequency and duration of use/exposure:

Duration of activity: <=8 hours/day.

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: 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: Good general ventilation (3-5 air changes per hour): 30%.
Local exhaust ventilation: Unless otherwise stated, Not required.
- PROC11: Yes (80% effectiveness).
Occupational Health and Safety Management System: Basic.

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, PROC2, PROC4, PROC8a, PROC8b, PROC10, PROC13: No (Effectiveness Dermal: 0%).
- PROC11: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%).

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:

Vapour pressure: 0,01 hPa at 20 °C

Amounts used:

Daily wide dispersive use: 0,00022 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.
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: 0,22 kg/day.
Release fraction to soil from process (final release):
- ERC8a: 0,00.
- ERC8d: 0,20.

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 (Effectiveness Water: 0,526%).

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

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

External treatment and disposal of waste should comply with applicable local and/or national regulations.

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: CHESAR v3.6 Worker TRA v3. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

<u>Effect/Compartment</u>	<u>Exposure estimate/PEC</u>	<u>RCR</u>	<u>Notes</u>
Worker, long-term, systemic, Dermal	5,486 mg/kg bw/day	0,132	PROC10
Worker, long-term, systemic, Inhalation	35,88 mg/m3	0,814	PROC2, PROC8a, PROC10
Worker, long-term, systemic, Combined routes	N/A	0,945	PROC10

Environment

<u>Effect/Compartment</u>	<u>Exposure estimate/PEC</u>	<u>RCR</u>	<u>Notes</u>
Freshwater	0,016 mg/L	0,167	PROC8a, PROC8d
Freshwater sediment	0,121 mg/kg dw	0,295	PROC8a, PROC8d
Marine water	0,00157 mg/L	0,174	PROC8a, PROC8d
Marine water sediment	0,012 mg/kg dw	0,296	PROC8a, PROC8d
Soil	0,00729 mg/kg dw	0,081	PROC8a, PROC8d
STP	0,109 mg/L	0,011	PROC8a, PROC8d
Human via environment, Inhalation	0,00000333 mg/m3	<0,01	PROC8a, PROC8d
Human via environment, Oral	0,000814 mg/kg bw/day	<0,01	PROC8a, PROC8d
Human via environment, Combined routes	N/A	<0,01	PROC8a, PROC8d

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, no respirator required. Duration of activity: <=8 hours/day. Local exhaust ventilation: PROC11: Yes (80% effectiveness). Dermal protection: PROC11: Yes (chemically resistant gloves conforming to EN374) (Effectiveness Dermal: 80%). Concentration of substance in mixture/article: PROC1, PROC2: <=100%. PROC4, PROC8a, PROC8b, PROC10, PROC11, PROC13: <=5,0%.

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 - Consumer end uses**1. Exposure scenario (5)****Short title of the exposure scenario:**

Consumer use - Consumer end uses

List of use descriptors:

Product category (PC): PC3, PC8, PC28, PC31, PC35, PC39

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:

PC3 Air care products.

- CS1: Air fresheners aerosol - aqueous, concentrated (mini-aerosol, timed release aerosol)(AISE C17).

- CS2: Air fresheners non aerosol - perfume in/on solid substrate.

- CS3: Air fresheners non aerosol - diffusers (heated+electrical).

PC31 Polishes and wax blends.

- CS4: Furniture floor and leather care (spray, liquid) - spray (furniture, shoes)(AISE C20).

PC35 Washing and cleaning products.

- CS5: Laundry regular (liquid)(AISE C1).

- CS6: Fabric conditioners (liquid concentrate)(AISE C3)

- CS7: Laundry additives (liquid bleach)(AISE C4).

- CS8: Hand dishwashing (liquid concentrate)(AISE C5).

SDS Name: Kalama* Florosol S

- CS9: Machine dishwashing (liquid)(AISE C6).
- CS10: Surface cleaners (liquid)(AISE C7).
- CS12: Surface cleaners (spray)(AISE C7).
- CS13: Surface cleaners (powder)(AISE C7).
- CS13: Laundry aids (ironing aids-spray)(AISE C12).
- CS14: Wipes (bathroom) (AISE C15).

PC8 Biocidal products.

- CS15: Insecticides (liquid electric, spray neat).
- CS16: Repellents.

PC28 Perfumes, fragrances (CS17).

PC39 Cosmetics, personal care products (CS18).

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 consumer exposure

General:

CS14-CS18 (PC8, PC28, PC39): Risk assessment only required for the environment under REACH as human health is covered by alternative legislation.

Product characteristics:

Concentration of substance in mixture/article:

- CS4, CS11: $\leq 0,1\%$.
- CS1: $\leq 0,25\%$.
- CS13: $\leq 0,5\%$.
- CS5, CS7-CS9: $\leq 1\%$.
- CS6, CS10, CS12, CS14: $\leq 2\%$.
- CS3: $\leq 10\%$.
- CS2: $\leq 100\%$.

Physical form of the used product: Liquid.

Exposure via inhalation route: CS1-CS4, CS11, CS13: Yes. CS5-CS10, CS12, CS14: Not relevant.

Exposure via dermal route: CS1-CS3, CS9: Dermal exposure assumed to be negligible. CS4-CS8, CS10-CS14: Yes.

Oral contact foreseen: CS1-CS7, CS10-CS14: No. CS8, CS9: Yes.

Spray: CS1, CS4, CS11, CS13: Yes. CS2, CS3, CS5-CS10, CS12, CS14: No.

Amounts used:

Applied amounts for each use event:

- CS1: $\leq 8,4$ g.
- CS2: $\leq 0,00174$ g.
- CS3: $\leq 0,00072$ g.
- CS4: total mass sprayed per use - ≤ 60000 mg (inhalation); concentration in wash solution - ≤ 1000 mg/cm³ (dermal).
- CS5: concentration in wash solution - ≤ 1000 mg/cm³ (dermal).
- CS6: ≤ 90 g; concentration in wash solution - ≤ 10 mg/m³ (dermal).
- CS7: ≤ 100 g; concentration in wash solution - ≤ 1000 mg/cm³ (dermal).
- CS8, CS9: concentration in wash solution - ≤ 1 mg/cm³ (dermal).
- CS10: concentration in wash solution - ≤ 22 mg/cm³ (dermal).
- CS11: total mass sprayed per use - ≤ 30000 mg (inhalation); concentration in wash solution - ≤ 1000 mg/cm³ (dermal).
- CS12: concentration in wash solution - ≤ 8 mg/cm³ (dermal).
- CS13: ≤ 20 g; total mass sprayed per use - ≤ 20000 mg (inhalation).
- CS14: concentration in wash solution - ≤ 1000 mg/cm³ (dermal).

Time weight average concentration predicted using the BAMA indoor air single spray model (TWA BAMA):

- CS1: 6,619 mg/m³.
- CS2: 20,795 mg/m³.
- CS3: 0,137 mg/m³.

Frequency and duration of use/exposure:

Duration covers exposure up to:

- CS5-CS7, CS11, CS14: 0,167 hours/event.
- CS1, CS2: 0,25 hours/event.
- CS10, CS12: 0,33 hours/event.
- CS8: 0,75 hours/event.
- CS4, CS13: 1 hour/event.
- CS3: 4 hours/event.

Frequency: covers use frequency: frequent use per year.

- CS4, CS14: up to 0,43 times/day.
- CS13: up to 0,71 times/day.
- CS1- CS3, CS9-CS12: up to 1 time/day.
- CS7: up to 1,1 times/day.
- CS6: up to 1,4 times/day.
- CS5: up to 2 times/day.
- CS8: up to 3 times/day.

Human factors not influenced by risk management:

Body parts potentially exposed:

- CS4, CS10-CS12, CS14: Hands.
- CS5-CS7: Whole body.

SDS Name: Kalama* Florosol S

- CS8: Hands and forearms.
- Inhalation factor = 1.
Dermal transfer factor=1.
Oral transfer factor = 1.

Other given operational conditions affecting consumers exposure:

Location: Indoor use.
Body weight: 60 kg.
Inhalation exposure model - covers use in room size of:
- CS1, CS2: 2,5 m3.
- CS11: 15 m3.
- CS13: 20 m3.
- CS3, CS4: 58 m3.
Inhalation rate:
- CS1-CS3: 0,54 m3/hour.
- CS4, CS11, CS13: 1,08 m3/hour.
Skin contact area:
- CS4, CS10-CS12, CS14: up to 857,5 cm2.
- CS8: up to 2082,5 cm2.
- CS6: up to 16398 cm2.
- CS5, CS7: up to 17225 cm2.
Thickness of product layer in contact with skin: CS4-CS8, CS10-CS12, CS14: 0,01 cm.
Fraction of product layer in contact with skin: CS4-CS8, CS10-CS12, CS14: 1. CS13: 0,01.
Fraction remaining in final liquor before spinning: CS6, CS7: 0,025.
Fraction of liquor remaining in final liquor after final spinning: CS6, CS7: 0,6.
Total fabric weight: CS6, CS7: 3500 g.
Fabric density: CS6, CS7: 10 mg/cm2.
Amount of water left on dishes after rinsing: CS8, CS9: 0,000055 mL/cm2.
Area of dishes in daily contact with food: CS8, CS9: 5400 cm2.

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

Assessment tool used: ECETOC TRA v3.1 (R15) 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.
- CS1-CS3: Tier 2 AISE REACT 1.0 Consumer Tool used for inhalation exposure.
- CS4, CS11, CS13: Tier 2 AISE REACT 1.0 Consumer Tool used for inhalation and dermal exposures.
- CS5-CS7, CS10, CS12, CS14: Tier 2 AISE REACT 1.0 Consumer Tool used for dermal exposure.
- CS8: Tier 2 AISE REACT 1.0 Consumer Tool used for dermal and oral exposures.
- CS9: Tier 2 AISE REACT 1.0 Consumer Tool used for oral exposure.

Conditions and measures related to personal protection and hygiene:

General ventilation: ventilation rate:
- CS1, CS2: 2 air changes/ hour.
- CS3: 0.5 air changes/ hour.

2.2 Control of environmental exposure

General:

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

Product characteristics:

Vapour pressure: 0,01 hPa at 20 °C

Amounts used:

Daily wide dispersive use: 0,00022 tons/day.

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: 0,22 kg/day.
Release fraction to soil from process (final release):
- ERC8a: 0,00.
- ERC8d: 0,20.

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 (Effectiveness Water: 0,526%).
Size of municipal sewage system/treatment plant: >=2000 m3/day (standard town).

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

External treatment and disposal of waste should comply with applicable local and/or national regulations.

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

SDS Name: Kalama* Florosol S

Assessment method-Health: ECETOC TRA v3.1 (R15) 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. Tier 2 AISE REACT 1.0 Consumer Tool. Only highest figures are presented here.

Assessment method-Environment: EUSES 2.1.2.

Health

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Consumer, long-term, systemic, Dermal	2,86 mg/kg bw/day	0,114	PC35 (CS14)
Consumer, long-term, systemic, Inhalation	0,047 mg/m3	<0,01	PC3 (CS2)
Consumer, long-term, systemic, Oral	0,0000495 mg/kg bw/day	<0,01	PC35 (CS8, CS9)
Consumer, long-term, systemic, Combined routes	N/A	0,114	PC35 (CS14)

Environment

Effect/Compartment	Exposure estimate/PEC	RCR	Notes
Freshwater	0,016 mg/L	0,167	PROC8a, PROC8d
Freshwater sediment	0,121 mg/kg dw	0,295	PROC8a, PROC8d
Marine water	0,00157 mg/L	0,174	PROC8a, PROC8d
Marine water sediment	0,012 mg/kg dw	0,296	PROC8a, PROC8d
Soil	0,00729 mg/kg dw	0,081	PROC8a, PROC8d
STP	0,109 mg/L	0,011	PROC8a, PROC8d
Human via environment, Inhalation	0,00000333 mg/m3	<0,01	PROC8a, PROC8d
Human via environment, Oral	0,000814 mg/kg bw/day	<0,01	PROC8a, PROC8d
Human via environment, Combined routes	N/A	<0,01	PROC8a, PROC8d

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.