

Product ZENOLIDE

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### ***1. Identification of the substance/mixture and of the company/undertaking***

#### **1.1 Product identifier**

Trade name : ZENOLIDE  
 Registration number : 01-2119524000-64-0000  
 SDS Number : R00000004378

#### **1.2 Relevant identified uses of the substance or mixture and uses advised against**

Use of the Substance/Mixture : Ingredient used in Flavour and/or Fragrance preparations

#### **1.3 Details of the supplier of the safety data sheet**

Company : IFF Benicarló, S.L.  
 Avda. Felipe Klein 2  
 12580 BENICARLÓ  
 Spain  
 Telephone : +34964470212  
 Telefax : +34964473411  
 E-mail address : sds@iff.com

Responsible/issuing person

#### **1.4 Emergency telephone number**

Refer to section 16 for country specific emergency contact number.

### ***2. Hazards identification***

#### **2.1 Classification of the substance or mixture**

##### **Classification (REGULATION (EC) No 1272/2008)**

Acute aquatic toxicity, Category 1 H400: Very toxic to aquatic life.  
 Chronic aquatic toxicity, Category 3 H412: Harmful to aquatic life with long lasting effects.

#### **2.2 Label elements**

##### **Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal word : Warning

Hazard statements : H410 Very toxic to aquatic life with long lasting

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effects.

Precautionary statements : **Prevention:**  
P273 Avoid release to the environment.  
**Response:**  
P391 Collect spillage.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

### 2.3 Other hazards

None reasonably foreseeable.

## 3. Composition/information on ingredients

### 3.1 Substances

Chemical name of the substance : 1,4-dioxacyclohexadecane-5,16-dione  
Chemical characterization : esters of aliphatic acids  
Molecular formula : C<sub>14</sub>H<sub>24</sub>O<sub>4</sub>  
Molecular weight : 256,20 g/mol  
CAS-No. : 54982-83-1  
EINECS-No. : 259-423-6  
REACH No. : 01-2119524000-64-0000

### Hazardous components

Chemical name	CAS-No. EC-No.	GHS Classification	Concentration [%]
1,4-dioxacyclohexadecane-5,16-dione	54982-83-1 259-423-6	Aquatic Acute1; H400 Aquatic Chronic3; H412	90 - 100

For the full text of the H-Statements mentioned in this Section, see Section 16.

### 3.2 Mixtures

Not applicable, product is a substance.

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### 4. First aid measures

#### 4.1 Description of first aid measures

- General advice : Take Hazard and Precautionary phrases (section 2) into account.
- If inhaled : Remove from exposure site to fresh air and keep at rest. If victim is unconscious, remove foreign bodies from the mouth. If victim has stopped breathing, give artificial respiration. Obtain medical advice.
- In case of skin contact : Remove contaminated clothes. Wash thoroughly with water (and soap). Contact physician if symptoms persist.
- In case of eye contact : Flush immediately with water for at least 15 minutes. Contact physician if symptoms persist.
- If swallowed : Rinse mouth with water and obtain medical advice.

#### 4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : No information available.
- Risks : No information available.

#### 4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : No information available.

### 5. Firefighting measures

#### 5.1 Extinguishing media

- Suitable extinguishing media : Carbondioxide, dry chemical, foam.
- Unsuitable extinguishing media : Do not use a direct waterjet on burning material.

#### 5.2 Special hazards arising from the substance or mixture

- Specific hazards during firefighting : Water may be ineffective.

#### 5.3 Advice for firefighters

- Further information : Standard procedure for chemical fires.

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### 6. Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Avoid inhalation and contact with skin and eyes. A self-contained breathing apparatus is recommended in case of a major spill.

#### 6.2 Environmental precautions

Environmental precautions : Keep away from drains, surface- and groundwater and soil.

#### 6.3 Methods and materials for containment and cleaning up

Methods for cleaning up : Clean up spillage promptly. Remove ignition sources. Provide adequate ventilation. Avoid excessive inhalation of vapours. Gross spillages should be contained by use of sand or inert powder and disposed of according to the local regulations.

#### 6.4 Reference to other sections

Prevent spreading over a wide area (e.g. by containment or oil barriers).

### 7. Handling and storage

#### 7.1 Precautions for safe handling

Advice on safe handling : Avoid excessive inhalation of concentrated vapors. Follow good manufacturing practices for housekeeping and personal hygiene. Wash any exposed skin immediately after any chemical contact, before breaks and meals, and at the end of each work period. Contaminated clothing and shoes should be thoroughly cleaned before re-use.

If appropriate, procedures used during the handling of this material should also be used when cleaning equipment or removing residual chemicals from tanks or other containers, especially when steam or hot water is used, as this may increase vapor concentrations in the workplace air. Where chemicals are openly handled, access should be restricted to properly trained employees.

Keep all heated processes at the lowest necessary temperature in order to minimize emissions of volatile chemicals into the air.

Advice on protection against fire and explosion : Keep away from ignition sources and naked flame.

#### 7.2 Conditions for safe storage, including any incompatibilities

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Requirements for storage areas and containers : Store in a cool, dry, ventilated area away from heat sources. Keep containers upright and tightly closed when not in use.

### 7.3 Specific end use(s)

Specific use(s) : No information available.

## 8. Exposure controls/personal protection

### 8.1 Control parameters

Contains no substances with occupational exposure limit values.

DNEL : End Use: Workers  
Exposure routes: Skin contact  
Potential health effects: Chronic effects  
Exposure time: 8 h  
Value: 25,8 mg/kg bw/day

DNEL : End Use: Workers  
Exposure routes: Inhalation  
Potential health effects: Chronic effects  
Exposure time: 8 h  
Value: 182 mg/m3

DNEL :

PNEC : Fresh water  
Value: 0,00088 mg/l

PNEC : Marine water  
Value: 0,000088 mg/l

PNEC : Fresh water sediment  
Value: 0,162 mg/kg

PNEC : Marine sediment  
Value: 0,0162 mg/kg

PNEC : Soil  
Value: 0,0318 mg/kg

PNEC : Sewage treatment plant

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Value: 1,8 mg/l

PNEC :

### 8.2 Exposure controls

#### Engineering measures

Where appropriate, use closed systems to transfer and process this material.

If appropriate, isolate mixing rooms and other areas where this material is used or openly handled. Maintain these areas under negative air pressure relative to the rest of the plant.

#### Personal protective equipment

Respiratory protection : Use local exhaust ventilation around open tanks and other open sources of potential exposures in order to avoid excessive inhalation, including places where this material is openly weighed or measured. In addition, use general dilution ventilation of the work area to eliminate or reduce possible worker exposures. No respiratory protection is required during normal operations in a workplace where engineering controls such as adequate ventilation, etc. are sufficient.

If engineering controls and safe work practices are not sufficient, an approved, properly fitted respirator with organic vapor cartridges or canisters and particulate filters should be used:

- a) while engineering controls and appropriate safe work practices and/or procedures are being implemented; or
- b) during short term maintenance procedures when engineering controls are not in normal operation or are not sufficient; or
- c) if normal operational workplace vapor concentration in the air is increased due to heat ;
- d) during emergencies; or
- e) if engineering controls and operational practices are not sufficient to reduce airborne concentrations below an established occupational exposure limit.

Hand protection : Avoid skin contact. Use chemically resistant gloves.

Eye protection : Use tight-fitting goggles, face shield or safety glasses with side shields if eye contact might occur.

Hygiene measures : To the extent deemed appropriate, implement pre-placement and

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regularly scheduled ascertainment of symptoms and spirometry testing of lung function for workers who are regularly exposed to this material.

To the extent deemed appropriate, use an experienced air sampling expert to identify and measure volatile chemicals that could be present in the workplace air to determine potential exposures and to ensure the continuing effectiveness of engineering controls and operational practices to minimize exposure.

### Environmental exposure controls

General advice : Keep away from drains, surface- and groundwater and soil.

## 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance : liquid at 20 °C (1.013 hPa)

Colour : colorless

Odour : conforms to standard

Odour Threshold : not determined

Flash point : 166 °C at 1.013 hPa

  

Lower explosion limit : not determined

Upper explosion limit : not determined

Flammability (solid, gas) : not determined

Oxidizing properties : not determined

Auto-ignition temperature : 395 °C at 1.013 hPa  
Method: Tested according to Annex V of Directive 67/548/EEC.

  

pH : not determined

Melting point : not determined

Boiling point : 337,30 °C at 1.013 hPa  
Note: Calculated

  

Vapour pressure : 0,00028 hPa at 25 °C  
Method: Tested according to Annex V of Directive 67/548/EEC.

  

Density : not determined

Water solubility : 0,075 g/l at 20 °C  
Method: Tested according to Annex V of Directive 67/548/EEC.

  

Partition coefficient: n- : log Pow: 3,650

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octanol/water  
Solubility in other solvents : not determined  
Viscosity, dynamic : not determined  
Viscosity, kinematic : not determined  
Relative vapour density : not determined  
Evaporation rate : not determined

### 9.2 Other information

Refractive index : not determined  
Relative density : 1,0540 - 1,0620 at 20 °C  
Method: ISO 279

## 10. Stability and reactivity

### 10.1 Reactivity

No hazards to be specially mentioned.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Note: Presents no significant reactivity hazard, by itself or in contact with water. Avoid contact with strong acids, alkali or oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : Direct sources of heat.

### 10.5 Incompatible materials

Materials to avoid : Avoid contact with strong acids, alkali or oxidizing agents.

### 10.6 Hazardous decomposition products

Hazardous decomposition products : Carbon monoxide and unidentified organic compounds may be formed during combustion.

## 11. Toxicological information

### 11.1 Information on toxicological effects

Acute toxicity

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Acute oral toxicity : LD50: 4.500 mg/kg  
Species: Rat  
Method: OECD Test Guideline 401  
Test substance: (undiluted)

Acute dermal toxicity : LD50: >= 5.000 mg/kg  
Species: Rabbit  
Method: OECD Test Guideline 402

### Skin corrosion/irritation

Skin irritation : No information available.  
Skin irritation : Species: Rabbit  
Result: No skin irritation  
Classification: No skin irritation  
Method: OECD Test Guideline 404  
Exposure time: 4 h

### Serious eye damage/eye irritation

No information available.  
Eye irritation : Species: Rabbit  
Result: No eye irritation  
Classification: No eye irritation  
Method: OECD Test Guideline 405  
Exposure time: 24 h

### Respiratory or skin sensitisation

No information available.  
Sensitisation : Buehler Test  
Species: Guinea pig  
Result: causes no sensitization  
Method: OECD Test Guideline 406  
Test substance: 100%

### Germ cell mutagenicity

No information available.  
Genotoxicity in vitro : Ames test  
Result: negative  
Method: Mutagenicity (Escherichia coli - reverse mutation assay)

### Carcinogenicity

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No information available.

### Reproductive toxicity

No information available.

Teratogenicity : Species: Rat  
Application Route: Oral  
Number of exposures: 1x /day  
Method: OECD 414

### Target Organ Systemic Toxicant - Single exposure

No information available.

### Target Organ Systemic Toxicant - Repeated exposure

No information available.

: Species: Rat, male and female  
Application Route: Oral  
Exposure time: 28-day ()  
Number of exposures: 1x /day  
NOEL: 619,5 mg/kg  
Method: OECD Test Guideline 407

### Aspiration hazard

No information available.

## 12. Ecological information

### 12.1 Toxicity

Toxicity to fish : LC50: 0,88 mg/l  
Exposure time: 96 h  
  
Species: Oncorhynchus mykiss (rainbow trout)  
flow-through test Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50: > 14 mg/l  
Exposure time: 48 h  
Species: Daphnia magna (Water flea)  
static test Method: OECD Test Guideline 202

Toxicity to algae : EC50: 17 mg/l  
Exposure time: 72 h  
Species: Pseudokirchneriella subcapitata (microalgae)  
static test Method: OECD Test Guideline 201

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: NOEC: 0,61 mg/l  
Exposure time: 72 h  
Species: Pseudokirchneriella subcapitata (microalgae)  
static test Method: OECD Test Guideline 201

### 12.2 Persistence and degradability

No information available.

Biodegradability : aerobic  
Result: Readily biodegradable.  
100 %  
Method: CO2 Evolution Test  
Remarks:  
IFF

### 12.3 Bioaccumulative potential

No information available.

Bioaccumulation : Remarks:  
Does not bioaccumulate.

### 12.4 Mobility in soil

### 12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Other adverse effects

No information available.

## 13. Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of according to local regulations. Avoid disposing into drainage systems and into the environment.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

## 14. Transport information

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### ADR

UN number : 3082  
Description of the goods : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(ETHYLENE DODECANEDIOATE)  
Labels : 9  
Packing group : III  
Environmentally hazardous : yes

### IATA

UN number : 3082  
Description of the goods : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(ETHYLENE DODECANEDIOATE)  
Labels : 9  
Packing group : III  
Environmentally hazardous : yes

### IMDG

UN number : 3082  
Description of the goods : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(ETHYLENE DODECANEDIOATE)  
Labels : 9  
Packing group : III  
Marine pollutant : yes (ETHYLENE DODECANEDIOATE)

**Special precautions for user** : No special precautions required.

## 15. Regulatory information

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

Water contaminating class : WGK 2water endangering  
(Germany)

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has been carried out for this substance.

## 16. Other information

Full text of H-Statements referred to under sections 2 and 3.

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H400 Very toxic to aquatic life.  
H412 Harmful to aquatic life with long lasting effects.

### Further information

In December 2003, the National Institute for Occupational Safety and Health ("NIOSH") published an Alert on preventing lung disease in workers who use or make flavorings [NIOSH Publication Number 2004-110]. In August 2004, the United States Flavor and Extract Manufacturers Association (FEMA) issued a report entitled "Respiratory Safety in the Flavor Manufacturing Workplace".

Both of these reports provide recommendations for reducing employee exposure and for medical surveillance in the workplace. The recommendations in these reports are generally applicable to the use of any chemical in the workplace and you are strongly urged to review both of these reports.

The report published by FEMA also contains a list of "high priority" chemicals. If any of these chemicals are present in this product at a concentration  $\geq 1.0\%$  due to an intentional addition by IFF, the chemical(s) will be identified in this safety data sheet.

According to Regulation (EC) No. 1907/2006 the information in this safety data sheet is based on the properties of the material known to IFF at the time the data sheet was issued. The safety data sheet is intended to provide information for a health and safety assessment of the material and the circumstances, under which it is packaged, stored or applied in the workplace. For such a safety assessment International Flavors & Fragrances holds no responsibility. This document is not intended for quality assurance purposes.

### Emergency telephone number

Austria	+43 1 406 43 43
Belgium	+32 70 245 245
Bulgaria	+359 2 9154 409 (N. I. Pirogov). poison_centre@mail.orbitel.bg
Croatia	(+385 1) 2348342
Czech Republic	+420 224 919 293 / +420 224 915 402
Denmark	+45 82 12 12 12
Estonia	16662 (National), International (+372) 626 93 90
Finland	+358 9 471977
France	+ 33 (0)1 45 42 59 59
Germany	+31 13 4642 211
Greece	+31 13 4642 211
Hungary	(+36-80) 201-199
Iceland	+354 543 2222
Ireland	+353 1 8092566 / +353 1 8379964
Italy	+39 06 68593726
Latvia	+371 67042473

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Lithuania	+370 5 236 20 52 or +370 687 53378
Luxembourg	+352 8002 5500
Malta	+356 21224071
Netherlands	+31 30 2748888 (Only for the purpose of informing medical personnel in cases of acute intoxications).
Norway	+47 22 59 13 00
Poland	+31 13 4642 211
Portugal	808 250 143
Poland	+31 13 4642 211
Portugal	808 250 143
Romania	+31 13 4642 211
Slovakia	+31 13 4642 211
Slovenia	+31 13 4642 211
Spain	+34 91 562 04 20 (only for the purpose of informing medical personnel in cases of acute intoxications).
Sweden	+46 112
United Kingdom	+44 111 (England, Wales & Scotland)

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# ANNEX

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### INDEX

1. **GES1 Formulation of fragrance compounds (mixing of fragrance substances into fragrance compounds)**
2. **GES2 Formulation of fragranced end-products (mixing of fragrance compounds into fragranced end-products)**

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### **1. Short title of Exposure Scenario: GES1 Formulation of fragrance compounds (mixing of fragrance substances into fragrance compounds)**

- |                                |   |
|--------------------------------|---|
| Main User Groups               | : <b>SU 3: Industrial uses:</b> Uses of substances as such or in preparations at industrial sites   |
| Process category               | : <b>PROC 8b (IFRA F-1):</b> Material transfers from/to vessel/container at dedicated facility (IFRA F-1)<br><b>PROC 1 (IFRA F-2):</b> Storage (IFRA F-2)<br><b>PROC 3 (IFRA F-3):</b> Mixing operations (closed systems) in batch process including filling of equipment and sample collection (IFRA F-3)<br><b>PROC 5 (IFRA-F4):</b> Mixing operations (open systems) in batch process including filling of equipment and sample collection (IFRA F-4)<br><b>PROC 15 (IFRA F-5):</b> QC laboratory (IFRA F-5)<br><b>PROC 9 (IFRA F-6):</b> Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (IFRA F-6)<br><b>PROC 8a (IFRA F-7):</b> Equipment cleaning and maintenance (IFRA F-7) |
| Environmental release category | : <b>spERC 2 IFRA 2.1a.v1:</b> Formulation of fragrance compounds at large medium sites<br><b>spERC IFRA 2.1b.v1:</b> Formulation of fragrance compounds at small sites   |

### **2.1 Contributing scenario controlling environmental exposure for: spERC 2 IFRA 2.1a.v1, spERC IFRA 2.1b.v1**

#### **Amount used**

- |                        |                                      |
|------------------------|--------------------------------------|
| Daily amount per site  | : <= 40 kg/day(Large/medium site)    |
| Annual amount per site | : <= 10000 kg/day(Large/medium site) |
| Daily amount per site  | : <= 26 kg/day(Small site)           |
| Annual amount per site | : <= 6600 kg/day(Small site)         |

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**Environment factors not influenced by risk management**

Flow rate : 18.000 m3/d

**Other given operational conditions affecting environmental exposure**

Emission or Release Factor: Air : 2,5 %  
 Emission or Release Factor: Water : 0,2 %  
 Emission or Release Factor: Soil : 0 %  
 Remarks : Large/medium site

Emission or Release Factor: Air : 2,5 %  
 Emission or Release Factor: Water : 0,5 %  
 Emission or Release Factor: Soil : 0 %  
 Remarks : Small site

**Conditions and measures related to municipal sewage treatment plant**

Type of Sewage Treatment Plant : Municipal sewage treatment plant  
 Flow rate of sewage treatment plant : 2.000 m3/d  
 effluent  
 Effectiveness (of a measure) : 89 %

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

Waste treatment : Dispose of waste product or used containers according to local regulations.

**2.2 Contributing scenario controlling worker exposure for: PROC 8b (IFRA F-1), PROC 1 (IFRA F-2), PROC 3 (IFRA F-3), PROC 5 (IFRA-F4), PROC 15 (IFRA F-5), PROC 9 (IFRA F-6), PROC 8a (IFRA F-7), PROC 8b (IFRA F-1)**

**Product characteristics**

Physical Form (at time of use) : Liquid substance

**Organisational measures to prevent /limit releases, dispersion and exposure**

No adverse effects are observed in any of the human health endpoints including repeated dose and reproductive toxicity studies up to the limit dose level. Therefore it can be concluded that no hazards are identified and no DNELs need to be derived for these endpoints. Human health exposure assessment for this scenario is not relevant.

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

#### Environment

Contributing Scenario	Exposure Assessment Method	Specific conditions	Compartment	Value type	Level of Exposure	Risk characterisation ratio (PEC/PNEC):
spERC 2 IFRA 2.1a.v1	EUSES		Fresh water		0,506µg/L	0,576
spERC 2 IFRA 2.1a.v1	EUSES		Fresh water sediment		93µg/kg dw	0,574
spERC 2 IFRA 2.1a.v1	EUSES		Marine water		0,0502µg/L	0,571
spERC 2 IFRA 2.1a.v1	EUSES		Marine sediment		9,22µg/kg dw	0,569
spERC 2 IFRA 2.1a.v1	EUSES		Sewage treatment plant		4,45µg/L	< 0,01
spERC 2 IFRA 2.1a.v1	EUSES		Soil		17µg/kg dw	0,527
spERC IFRA 2.1b.v1	EUSES		Fresh water		0,795µg/L	0,903
spERC IFRA 2.1b.v1	EUSES		Fresh water sediment		146µg/kg dw	0,901
spERC IFRA 2.1b.v1	EUSES		Marine water		0,079µg/L	0,898
spERC IFRA 2.1b.v1	EUSES		Marine sediment		15µg/kg dw	0,896
spERC IFRA 2.1b.v1	EUSES		Sewage treatment plant		7,34µg/L	< 0,01
spERC	EUSES		Soil		28µg/kg dw	0,867

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IFRA 2.1b.v1						
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### Workers

Contributing Scenario	Exposure Assessment Method	Specific conditions	Value type	Level of Exposure	Risk characterisation ratio (PEC/PNEC):
	Not relevant.				

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

As a downstream user your main obligations under REACH are to:

1. Check if your use is covered by the exposure scenario(s). If this is not the case, you can communicate with your supplier with the aim of having your use covered by an exposure scenario or you may develop your own chemical safety report;

2.a. (Workers) Follow the instructions in this safety data sheet and the conditions of use indicated in the exposure scenario(s) in section 2.2. However, if you have another combination of operational conditions (OCs) and/or risk management measures (RMMs) which allow you to achieve the same level of safety (RCRs <1) you can use scaling to demonstrate that you are in compliance. If scaling is not possible or still results in RCRs >1 then you should implement the OCs and RMMs recommended in this exposure scenario or contact your Supplier in case you need further support;

2.b. (Environment) Follow the instructions in this safety data sheet and check if your daily and annual amounts used are below the default maximum values indicated in section 2.1. In case you are above the indicated values you can use scaling to demonstrate that you are in compliance, e.g. by replacing the default figure for the river and/or sewage treatment plant flow rates with the actual rates. Background information on PEC Regional freshwater is 5.368E-5 mg/L. If scaling is not possible or still results in RCRs >1, then you should contact your Supplier for further support;

3. Contact your Supplier if you have new information on the hazard of the substance or mixture or if you believe that the risk management measures are not appropriate;

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4. Provide your own downstream users with information on hazards, safe conditions of use and appropriate risk management advice for your mixtures if you are a formulator.

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### **1. Short title of Exposure Scenario: GES2 Formulation of fragranced end-products (mixing of fragrance compounds into fragranced end-products)**

- |                                |  |
|--------------------------------|--|
| Main User Groups               | : <b>SU 3:</b> Industrial uses: Uses of substances as such or in preparations at industrial sites  |
| Process category               | : <b>PROC 8b (AISE M-6):</b> Material transfers from/to vessel/container at dedicated facility (AISE M-6)<br><b>PROC 1 (AISE M-1):</b> Storage (AISE M-1)<br><b>PROC 3 (AISE M-3):</b> Mixing operations (closed systems) in batch process including filling of equipment and sample collection (AISE M-3)<br><b>PROC 5 (AISE M-5):</b> Mixing operations (open systems) in batch process including filling of equipment and sample collection (AISE M-5)<br><b>PROC 15 (AISE M-9):</b> QC Laboratory (AISE M-9)<br><b>PROC 9 (AISE M-7):</b> Transfer of substance or mixture into small containers (dedicated filling line, including weighing) (AISE M-7)<br><b>PROC 14 (AISE M-8):</b> Production of mixtures or articles by tableting, compression, extrusion or pelletisation (AISE M-8)<br><b>PROC 8a:</b> Equipment cleaning and maintenance |
| Environmental release category | : <b>AISE 2.1.a,g:</b> spERC AISE Granular & Low Viscosity Liquids - large scale<br><b>CE 2.2.a-c:</b> spERC AISE & CE Fine Fragrances (cleaning with solvent) - all scales<br><b>AISE 2.1.b,h:</b> spERC AISE Granular & Low Viscosity Liquids - medium scale<br><b>CE 2.1.d-j:</b> GES2H default - all scales<br><b>AISE 2.1.c,i:</b> spERC AISE Granular & Low Viscosity Liquids - small scale<br><b>AISE 2.1.j CE/AISE 2.3a CE 2.1.a:</b> spERC AISE High Viscosity Liquids + CE/AISE Solid Products + CE Low Viscosity Liquids - large scale<br><b>AISE 2.1.k CE/AISE 2.3.b CE 2.1.b:</b> spERC AISE High Viscosity Liquids + CE/AISE Solid Products + CE Low Viscosity Liquids - medium scale<br><b>AISE 2.1.l CE/AISE 2.3.c CE 2.1.c:</b> spERC AISE High Viscosity Liquids + CE/AISE Solid Products + CE Low Viscosity Liquids - small scale |

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**2.1 Contributing scenario controlling environmental exposure for: AISE 2.1.a,g, AISE 2.1.b,h, AISE 2.1.c,i, AISE 2.1.j CE/AISE 2.3a 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**

**Amount used**

Daily amount per site	: 240 kg (AISE 2.1.a,g)
	: 90 kg (AISE 2.1.b,h)
	: 37 kg (AISE 2.1.c,i)
	: 70 kg (AISE 2.1.j CE/AISE 2.3.a CE 2.1.a)
	: 26 kg (AISE 2.1.k CE/AISE 2.3.b CE 2.1.b)
	: 22 kg (AISE 2.1.l CE/AISE 2.3.c CE 2.1.c)
	: 100 kg (CE 2.2.a-c)
	: 4,8 kg (CE 2.1.d-j)
Annual amount per site	: 60800 kg (AISE 2.1.a,g)
	: 23200 kg (AISE 2.1.b,h)
	: 9200 kg (AISE 2.1.c,i)
	: 17600 kg (AISE 2.1.j CE/AISE 2.3.a CE 2.1.a)
	: 6400 kg (AISE 2.1.k CE/AISE 2.3.b CE 2.1.b)
	: 5600 kg (AISE 2.1.l CE/AISE 2.3.c CE 2.1.c)
	: 25600 kg (CE 2.2.a-c)
	: 1200 kg (CE 2.1.d-j)

**Environment factors not influenced by risk management**

Flow rate : 18.000 m3/d

**Other given operational conditions affecting environmental exposure**

Continuous exposure

Number of emission days per year : 250

Emission or Release Factor: Air : 0 %

Emission or Release Factor: Soil : 0 %

Emission or Release Factor: Water : 0,01 %

Remarks : AISE 2.1.a,g, AISE 2.1.b,h, AISE 2.1.j CE/AISE 2.3.a CE 2.1.a

Emission or Release Factor: Water : 0,2 %

Remarks : AISE 2.1.c,i, AISE 2.1.k CE/AISE 2.3.b CE 2.1.b

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Emission or Release Factor: Water : 0,4 %  
 Remarks : AISE 2.1.1 CE/AISE 2.3.c CE 2.1.c

Emission or Release Factor: Water : 0 %  
 Remarks : CE 2.2.a-c

Emission or Release Factor: Water : 2 %  
 Remarks : CE 2.1.d-j

**Conditions and measures related to municipal sewage treatment plant**

Type of Sewage Treatment Plant : Municipal sewage treatment plant  
 Flow rate of sewage treatment plant effluent : 2.000 m3/d  
 Effectiveness (of a measure) : 89 %  
 Sludge Treatment : Can be landfilled, when in compliance with local regulations.  
 Remarks : 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 2.1.1 CE/AISE 2.3.c CE 2.1.c, CE 2.1.d-j  
 Effectiveness (of a measure) : 100 %  
 Remarks : CE 2.2.a-c

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

Waste treatment : Dispose of waste product or used containers according to local regulations.

**2.2 Contributing scenario controlling worker exposure for: PROC 8b (AISE M-6), PROC 15 (AISE M-9), PROC 1 (AISE M-1), PROC 3 (AISE M-3), PROC 5 (AISE M-5), PROC 8a, PROC 9 (AISE M-7), PROC 14 (AISE M-8)**

**Organisational measures to prevent /limit releases, dispersion and exposure**

No adverse effects are observed in any of the human health endpoints including repeated dose and reproductive toxicity studies up to the limit dose level. Therefore it can be concluded that no hazards are identified and no DNELs need to be derived for these endpoints. Human health exposure assessment for this scenario is not relevant.

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

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### Environment

Contributing Scenario	Exposure Assessment Method	Specific conditions	Compartment	Value type	Level of Exposure	Risk characterisation ratio (PEC/PNEC):
AISE 2.1.a.g	EUSES		Fresh water		0,196µg/L	0,223
AISE 2.1.a.g	EUSES		Fresh water sediment		36µg/kg dw	0,222
AISE 2.1.a.g	EUSES		Marine water		0,0192µg/L	0,218
AISE 2.1.a.g	EUSES		Marine sediment		3,52µg/kg dw	0,217
AISE 2.1.a.g	EUSES		Sewage treatment plant		1,33µg/L	< 0,01
AISE 2.1.a.g	EUSES		Soil		5,03µg/kg dw	0,158
AISE 2.1.b,h	EUSES		Fresh water		0,562µg/L	0,639
AISE 2.1.b,h	EUSES		Fresh water sediment		103µg/kg dw	0,637
AISE 2.1.b,h	EUSES		Marine water		0,0557µg/L	0,634
AISE 2.1.b,h	EUSES		Marine sediment		10µg/kg dw	0,632
AISE 2.1.b,h	EUSES		Sewage treatment plant		5µg/L	< 0,01
AISE 2.1.b,h	EUSES		Soil		19µg/kg dw	0,591
AISE 2.1.c,i	EUSES		Fresh water		0,471µg/L	0,535
AISE 2.1.c,i	EUSES		Fresh water sediment		86µg/kg dw	0,534
AISE 2.1.c,i	EUSES		Marine water		0,0467µg/L	0,53
AISE 2.1.c,i	EUSES		Marine sediment		8,57µg/kg dw	0,529
AISE 2.1.c,i	EUSES		Sewage treatment plant		4,09µg/L	< 0,01
AISE 2.1.c,i	EUSES		Soil		15µg/kg dw	0,483
AISE 2.1.j CE/AISE 2.3a CE 2.1.a	EUSES		Fresh water		0,453µg/L	0,515
AISE 2.1.j CE/AISE 2.3a CE 2.1.a	EUSES		Fresh water sediment		83µg/kg dw	0,514

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AISE 2.1.j CE/AISE 2.3.a CE 2.1.a	EUSES		Marine water	0,0449µg/L	0,51
AISE 2.1.j CE/AISE 2.3.a CE 2.1.a	EUSES		Marine sediment	8,24µg/kg dw	0,509
AISE 2.1.j CE/AISE 2.3.a CE 2.1.a	EUSES		Sewage treatment plant	3,91µg/L	< 0,01
AISE 2.1.j CE/AISE 2.3.a CE 2.1.a	EUSES		Soil	15µg/kg dw	0,462
AISE 2.1.k CE/AISE 2.3.b CE 2.1.b	EUSES		Fresh water	0,347µg/L	0,394
AISE 2.1.k CE/AISE 2.3.b CE 2.1.b	EUSES		Fresh water sediment	64µg/kg dw	0,393
AISE 2.1.k CE/AISE 2.3.b CE 2.1.b	EUSES		Marine water	0,0342µg/L	0,389
AISE 2.1.k CE/AISE 2.3.b CE 2.1.b	EUSES		Marine sediment	6,29µg/kg dw	0,388
AISE 2.1.k CE/AISE 2.3.b CE 2.1.b	EUSES		Sewage treatment plant	2,85µg/L	< 0,01
AISE 2.1.k CE/AISE 2.3.b CE 2.1.b	EUSES		Soil	11µg/kg dw	0,337
AISE 2.1.l CE/AISE 2.3.c CE 2.1.c	EUSES		Fresh water	0,56µg/L	0,636
AISE 2.1.l	EUSES		Fresh water	103µg/kg dw	0,634

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CE/AISE 2.3.c CE 2.1.c			sediment			
AISE 2.1.1 CE/AISE 2.3.c CE 2.1.c	EUSES		Marine water		0,0555µg/L	0,631
AISE 2.1.1 CE/AISE 2.3.c CE 2.1.c	EUSES		Marine sediment		10µg/kg dw	0,629
AISE 2.1.1 CE/AISE 2.3.c CE 2.1.c	EUSES		Sewage treatment plant		4,98µg/L	< 0,01
AISE 2.1.1 CE/AISE 2.3.c CE 2.1.c	EUSES		Soil		19µg/kg dw	0,588
CE 2.2.a-c	EUSES		Fresh water		0,0629µg/L	0,071
CE 2.2.a-c	EUSES		Fresh water sediment		12µg/kg dw	0,071
CE 2.2.a-c	EUSES		Marine water		0,00585µg/L	0,067
CE 2.2.a-c	EUSES		Marine sediment		1,07µg/kg dw	0,066
CE 2.2.a-c	EUSES		Sewage treatment plant		0µg/L	< 0,01
CE 2.2.a-c	EUSES		Soil		0,0224µg/kg dw	< 0,01
CE 2.1.d-j	EUSES		Fresh water		0,595µg/L	0,676
CE 2.1.d-j	EUSES		Fresh water sediment		109µg/kg dw	0,674
CE 2.1.d-j	EUSES		Marine water		0,0591µg/L	0,671
CE 2.1.d-j	EUSES		Marine sediment		11µg/kg dw	0,669
CE 2.1.d-j	EUSES		Sewage treatment plant		5,34µg/L	< 0,01
CE 2.1.d-j	EUSES		Soil		20µg/kg dw	0,63

### Workers

Contributing Scenario	Exposure Assessment Method	Specific conditions	Value type	Level of Exposure	Risk characterization ratio

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# ANNEX

## INTERNATIONAL FLAVORS & FRAGRANCES

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					(PEC/PN EC):
	Not relevant.				

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

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As a downstream user your main obligations under REACH are to:

1. Check if your use is covered by the exposure scenario(s). If this is not the case, you can communicate with your supplier with the aim of having your use covered by an exposure scenario or you may develop your own chemical safety report;

2.a. (Workers) Follow the instructions in this safety data sheet and the conditions of use indicated in the exposure scenario(s) in section 2.2. However, if you have another combination of operational conditions (OCs) and/or risk management measures (RMMs) which allow you to achieve the same level of safety (RCRs <1) you can use scaling to demonstrate that you are in compliance. If scaling is not possible or still results in RCRs >1 then you should implement the OCs and RMMs recommended in this exposure scenario or contact your Supplier in case you need further support;

2.b. (Environment) Follow the instructions in this safety data sheet and check if your daily and annual amounts used are below the default maximum values indicated in section 2.1. In case you are above the indicated values you can use scaling to demonstrate that you are in compliance, e.g. by replacing the default figure for the river and/or sewage treatment plant flow rates with the actual rates. Background information on PEC Regional freshwater is 5.368E-5 mg/L. If scaling is not possible or still results in RCRs >1, then you should contact your Supplier for further support;

3. Contact your Supplier if you have new information on the hazard of the substance or mixture or if you believe that the risk management measures are not appropriate;

4. Provide your own downstream users with information on hazards, safe conditions of use and appropriate risk management advice for your mixtures if you are a formulator.

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