



Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 21.11.2019

Version number 3

Revision: 21.11.2019

SECTION 1: Identification of the substance/mixture and of the company/undertaking**· 1.1 Product identifier****· Trade name: CALYPSO FRAMBOISE****· Article number / formula: 263S****· 1.2 Relevant identified uses of the substance or mixture and uses advised against***No further relevant information available.***· Application of the substance / the preparation : dental product****· 1.3 Details of the supplier of the safety data sheet****· Manufacturer/Supplier:**

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· 1.4 Emergency telephone number:

France (INRS 24h/24) - Tel : +33 (0)1 45 42 59 59

Ireland - Tel : 00 353 1 8092568 - 00 353 1 8379964 (24h/24) EU Tel: 112

Belgique / Luxembourg : (+352) 8002-5500

*UK : Call NHS 999 in a medical emergency. If you urgently need medical help or advice but it's not a life-threatening situation, call 111 (24/7). The NHS 111 number is currently only available in certain areas. If you're outside of these areas, you should call NHS Direct on 0845 4647***SECTION 2: Hazards identification****· 2.1 Classification of the substance or mixture****· Classification according to Regulation (EC) No 1272/2008 :***The product is not classified, according to the CLP regulation.***· 2.2 Label elements****· Labelling according to Regulation (EC) No 1272/2008** Not classified as hazardous**· Hazard pictograms** Not classified as hazardous**· Signal word** Not classified as hazardous**· Hazard statements** Not classified as hazardous**· 2.3 Other hazards****· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****· 3.2 Chemical characterisation: Mixtures****· Description:** Mixture: consisting of the following components.**· Dangerous components:** Not classified as hazardous**· SVHC** No**· Additional information:** For the wording of the listed risk phrases, refer to section 16.

GB

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SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Provide fresh air; consult a doctor in case of medical complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult a doctor.
- **4.2 Most important symptoms and effects, both acute and delayed :**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed :**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture :** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures :** Not required.
- **6.2 Environmental precautions:**
Dilute with plenty of water.
Do not allow the product to enter sewers/ surface water or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections :**
No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protective equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling :** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s) :** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.

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· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

CAS: 56-81-5 glycerol (50-100%)

| | |
|---------------------|---|
| WEL (Great Britain) | Long-term value: 10 mg/m ³ |
| MAK (Switzerland) | Short-term value: 100 e mg/m ³ |
| | Long-term value: 50 e mg/m ³ |
| | SSc; |

CAS: 57-55-6 Propylene glycol (25-50%)

| | |
|---------------------|---|
| WEL (Great Britain) | Long-term value: 474* 10** mg/m ³ , 150* ppm |
| | *total vapour and particulates **particulates |

· Additional information:

The most current valid lists have been used as a basis for the production of this document.

· 8.2 Exposure controls

· Personal protective equipment:

· General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

· Respiratory protection: Not required.

· Protection of hands: Not required.

· Gloves material : -

· Eye protection: Not required.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

| | |
|---------------------------|------------------------------------|
| Form: | Liquid |
| Colour: | According to product specification |
| · Odour: | Characteristic |
| · Odour threshold: | Not determined. |

· pH-value: Not determined.

· Change in condition

| | |
|---|---------------|
| Melting point/freezing point: | Undetermined. |
| Initial boiling point and boiling range: | Undetermined. |

· Flash point: Not applicable.

· Flammability (solid, gas): Not applicable.

· Ignition temperature: Not applicable.

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not self igniting.

· Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

| | |
|---------------|-----------------|
| Lower: | Not determined. |
| Upper: | Not determined. |

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- **Vapour pressure at 20 °C:** 0.1 hPa
- **Density:** Not determined.
- **Relative density :** Not determined.
- **Vapour density :** Not determined.
- **Evaporation rate :** Not determined.
- **Solubility in / Miscibility with water:** Fully miscible.
- **Segregation coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic:** Not determined.
 - Kinematic:** Not determined.
- **Solvent content:**
 - VOC (EC)** 35.17 %
- **9.2 Other information :** No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions :** No dangerous reactions known.
- **10.4 Conditions to avoid :** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

CAS: 56-81-5 glycerol

| | | |
|--------|------|------------------------|
| Oral | LD50 | >12,600 mg/kg (rat) |
| Dermal | LD50 | >18,700 mg/kg (rabbit) |

CAS: 57-55-6 Propylene glycol

| | | |
|--------|------|-----------------------|
| Oral | LD50 | 2,000 mg/kg (rat) |
| Dermal | LD50 | 20,800 mg/kg (rabbit) |

CAS: 121-33-5 vanillin

| | | |
|------|------|-------------------|
| Oral | LD50 | 1,580 mg/kg (rat) |
|------|------|-------------------|

CAS: 18472-51-0 D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1)

| | | |
|--------|------|-----------------------|
| Oral | LD50 | >2,000 mg/kg (rat) |
| Dermal | LD50 | >2,000 mg/kg (rabbit) |

- **Primary irritant effect:**
- **On the skin:** Based on available data, the classification criteria are not met.

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- **On the eyes:** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitization** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

CAS: 56-81-5 glycerol

LC50 96h 54,000 mg/l (Oncorhynchus mykiss)

EC50 48h 10,000 mg/l (daphnia)

CAS: 57-55-6 Propylene glycol

LC50 48h >900 mg/l (fish)

LC50 96h 40,613 mg/l (Oncorhynchus mykiss)

NOEC >20,000 mg/l (Algae)

EC50 96h 19,000 mg/l (Algae)

CAS: 18472-51-0 D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1)

LC50 96h 2.08 mg/l (fish)

EC50 72h 0.081 mg/l (Algae)

EC50 48h 0.087 mg/l (Crustaceans)

· **12.2 Persistence and degradability :** No further relevant information available.

· **12.3 Bioaccumulative potential :** No further relevant information available.

· **12.4 Mobility in soil :** No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Other adverse effects :** No further relevant information available.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**

· **Recommendation :** Smaller quantities can be disposed of with household waste.

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|---|
| · 14.1 UN-Number · ADR, ADN, IMDG, IATA | Not classified as hazardous for transport |
| · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA | Not classified as hazardous for transport |
| · 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class | Not classified as hazardous for transport |
| · 14.4 Packing group · ADR, IMDG, IATA | Not classified as hazardous for transport |
| · 14.5 Environmental hazards: · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Not classified as hazardous for transport |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods
 IATA: International Air Transport Association
 GHS: Globally Harmonised System of Classification and Labelling of Chemicals
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 VOC: Volatile Organic Compounds (USA, EU)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 SVHC: Substances of Very High Concern
 vPvB: very Persistent and very Bioaccumulative