



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 ORANGE**
- **Article number / formula:** 265S
- **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:**
SEPTODONT.
58 rue du Pont de Creteil
94100 Saint Maur des Fosses
France
Téléphone: +33(0)149767000
Fax: +33(0)148855401
msds@septodont.com
http://www.septodont.com
- **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 risk information:** For the wording of the listed risk phrases, refer to section 16.

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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
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CAS: 64-17-5 ethanol (<1%)

WEL (Great Britain)	Long-term value: 1920 mg/m ³ , 1000 ppm
MAK (Switzerland)	Short-term value: 1920 mg/m ³ , 1000 ppm Long-term value: 960 mg/m ³ , 500 ppm SSc;

· DNELs
CAS: 64-17-5 ethanol

Dermal	DNEL Worker long-term systemic	343 mg/kg bw/d
Inhalative	DNEL Worker long-term systemic	950 mg/m ³
	DNEL Worker acute/short-term local effects	19 mg/m ³

· PNECs
CAS: 64-17-5 ethanol

PNEC STP	0.72 mg/L
PNEC aqua (fresh water)	0.96 mg/L
PNEC aqua (marine water)	0.79 mg/L
PNEC sediment (fresh water)	3.6 mg/kg
PNEC sediment (marine water)	2.9 mg/kg
PNEC soil	0.63 mg/kg

· 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: Goggles recommended during refilling

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties
· General Information
· Appearance:

Form: Liquid

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· 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.
· 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)	38.61 %
· 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.

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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: 64-17-5 ethanol

Oral	LD50	7,060 mg/kg (rat)
Inhalative	LC50/4 h	20,000 mg/l (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.
- **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: 64-17-5 ethanol

EC50 72h	275 mg/l (Algae)
EC50 48h	12,340 mg/l (daphnia)

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EC50 96h 13,000 mg/l (fish)

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.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

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.

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· **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)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
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

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