



according to 1907/2006/EC, Article 31 & 2020/878/EC

Printing date 19.12.2023 Version number 1 Revision: 19.12.2023

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

· 1.1 Product identifier

· Trade name: EPICREM+

· Article number / formula: 363S

· 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 : Cosmetics for pharmaceutical use

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

SEPTODONT

58 rue du Pont de Créteil

94100 Saint Maur des Fosses

France

Téléphone: +33(0)149767000

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

Belgium - Brüssel: +32 070/245 245

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

Swiss Toxicological Information Centre (Zürich): +41 44 251 51 51 / www.toxi.ch.

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 C.L.P. regulation.

· Additional information:

This Regulation shall not apply to substances and mixtures in the following finished forms intended for the end user

- (a) medicinal products, as defined in Directive 2001/83/EC
- (b) medical devices, as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC;

· 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

The mixture shall not contain substances listed in accordance with Article 59(1) R.E.A.C.H as having endocrine disrupting properties, or be recognised as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation

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(EU) 2018/605 in a concentration equal to or greater than 0.1%.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Determination of endocrine-disrupting properties No further information available

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
- · **Description:** Preparation: composed of the substances listed below.
- · Dangerous components: Not classified as hazardous
- · SVHC Not applicable
- · Additional information: For the wording of the listed risk phrases, refer to section 16.

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: Do not induce vomiting; call for medical help immediately.
- · 4.2 Most important symptoms and effects, both acute and delayed:

No further relevant information is available.

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

No further relevant information is 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.
- · For non-emergency personnel No other relevant information available.
- · For emergency responders No other relevant information available.
- · 6.2 Environmental precautions:

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

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).

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· 6.4 Reference to other sections :

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: Protect from frost.
- · 7.3 Specific end use(s): No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

CAS: 56-81-5 glycerol (≤2.5%)

WEL (Great Britain) Long-term value: 10 mg/m³ MAK (Switzerland) Short-term value: 100 e mg/m³

Long-term value: 50 e mg/m³

SSc:

· Additional information:

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

- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

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

- · Respiratory protection: No special measures required.
- · Hand protection No special measures required.
- · Gloves material: Not applicable
- · Eye/face protection Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information

· Physical state

Liquid

· Form:

Thick cream

· Colour:

White

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Odour: Characteristic
 Odour threshold: Not determined.
 Melting point/freezing point: Not determined.

· Boiling point or initial boiling point and boiling

range Not determined.
• Flammability Not applicable.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Auto-ignition temperature: Not applicable.
Decomposition temperature: Not determined.

· pH at 20 °C 5.7-6.2

· Viscosity:

Kinematic viscosity Dynamic: Not determined. Not determined.

· Solubility

water: Fully miscible.
 Partition coefficient n-octanol/water (log value)
 Vapour pressure: Fully miscible.
 Not determined.

· Density and/or relative density

Density: Not determined.
 Relative density: Not determined.
 Vapour density: Not determined.

· 9.2 Other information:

Important information on protection of health and environment, and on safety.

· **Ignition temperature:** Product is not self igniting.

• **Explosive properties:** Product does not present an explosion hazard.

· Solvent content:

· COV (USA): 0.00 % · VOC (EC) 0.03 %

· Change in condition

• Evaporation rate : Not determined.

Information with regard to physical hazard classes

· Explosives Not classified as hazardous · Flammable gases Not classified as hazardous · Aerosols Not classified as hazardous · Oxidising gases Not classified as hazardous · Gases under pressure Not classified as hazardous · Flammable liquids Not classified as hazardous · Flammable solids Not classified as hazardous Not classified as hazardous · Self-reactive substances and mixtures · Pyrophoric liquids Not classified as hazardous

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Pyrophoric solids
 Self-heating substances and mixtures
 Not classified as hazardous

· Substances and mixtures, which emit flammable

gases in contact with water

Oxidising liquids

Oxidising solids

Organic peroxides

Corrosive to metals

Desensitised explosives

Not classified as hazardous
Not classified as hazardous
Not classified as hazardous
Not classified as hazardous

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 hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- · 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.
- · 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.
- · 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 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.

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- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- vPvB: Not applicable.
- 12.6 Endocrine disrupting properties For information on endocrine disrupting properties see section 11.
- · 12.7 Other adverse effects: 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.

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 or ID number

· DOT, ADR, ADN, IMDG, IATA none

· 14.2 UN proper shipping name

· ADR, ADN, IMDG, IATA none

· 14.3 Transport hazard class(es)

· ADR, ADN, IMDG, IATA

· Class none

· 14.4 Packing group

· ADR, IMDG, IATA none

· 14.5 Environmental hazards:

· Marine pollutant: Yes

• 14.6 Special precautions for user Not applicable.

· 14.7 Maritime transport in bulk according to IMO

instruments Not applicable.

· UN "Model Regulation": none

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Poisons Act
- Regulated explosives precursors

None of the ingredients is listed.

· Regulated poisons

None of the ingredients is listed.

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· Reportable explosives precursors

None of the ingredients is listed.

· Reportable poisons

None of the ingredients is listed.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

None of the ingredients is listed.

- · REGULATION (EU) 2019/1148
- Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

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.

Classification in accordance with Delegated Regulation (EU) 2022/692 of 16 February 2022 adapting to technical and scientific progress GB CLP for the 18th time and amending table 3 of Annex VI part 3 of Regulation (EC) 1272/2008.

Classification in accordance with Delegated Regulation (EU) 2023/1434 of 25 April 2023 adapting to technical and scientific progress for the 19th time GB CLP and amending Annex VI part 1, section 1.1.3 of Regulation (EC) 1272/2008.

Classification in accordance with Delegated Regulation (EU) 2023/1435 of 2 May 2023 adapting to technical and scientific progress for the 20th time GB CLP and amending Annex VI part 3 of Regulation (EC) 1272/2008.

This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

· Date of previous version: 19.12.2023

· Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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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) PBT: Persistent, Bioaccumulative and Toxic SVHC: Substances of Very High Concern vPvB: very Persistent and very Bioaccumulative

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