

## 1 Identification

- **1.1 Product identifier**
- **Trade name:** Cleoderm™
- **Application of the substance / the mixture** Additive for cosmetic or pharmaceutical preparations
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Fagron Inc  
2400 Pilot Knob Road  
St. Paul, MN 55120  
www.fagron.us  
QA@fagron.us
- **Information department:**  
Tel.: 800-423-6967  
Fax: 800-339-1596
- **1.4 Emergency telephone number:**  
Emergency Telephone:  
US: 1-800-535-5053  
International: 1-352-323-3500

Distributor: Bella Corp Trading Pty Ltd  
6/34 Dominions Rd, Ashmore QLD 4214  
Australia | T: 07 5597 4169  
E: bellacorp@bellacorp.com.au  
  
IN CASE OF EMERGENCY: Chemtrec  
Outside USA and Canada:  
+1 703-527-3887  
NSW Poisons Information  
Centre: 131 126 (24 hours)

## 2 Hazard(s) identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Eye Irrit. 2A H319 Causes serious eye irritation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labeled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard statements**  
H319 Causes serious eye irritation.
- **Precautionary statements**  
P264 Wash 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.  
P337+P313 If eye irritation persists: Get medical advice/attention.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## 3 Composition/information on ingredients

- **3.2 Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

(Contd. on page 2)

USA

# Safety Data Sheet

acc. to OSHA HCS

Page 2/8

Trade name: Cleoderm™

(Contd. of page 1)

· **Dangerous components:**

CAS: 629-50-5 EINECS: 211-093-4	tridecane Flam. Liq. 4, H227	≤2.5%
CAS: 1120-21-4 EINECS: 214-300-6	undecane Flam. Liq. 4, H227	≤2.5%
	Ethylenglycolmonophenylether ⚠ Acute Tox. 4, H302; Eye Irrit. 2A, H319	≤2.5%
CAS: 70445-33-9 ELINCS: 408-080-2	3-(2-ethylhexyloxy)propane-1,2-diol ⚠ Eye Dam. 1, H318	≤2.5%
CAS: 153-18-4 EINECS: 205-814-1	Rutoside-Trihydrate Rutosidum trihydricum ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	≤2.5%

## 4 First-aid measures

· **4.1 Description of first aid measures**

· **After inhalation:** Supply fresh air; consult doctor in case of complaints.

· **After skin contact:** Generally the product does not irritate the skin.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** Rinse out mouth and then drink plenty of water.

· **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.

## 5 Fire-fighting measures

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.

· **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.

## 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 to enter sewers/ surface 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**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

(Contd. on page 3)

USA

# Safety Data Sheet

acc. to OSHA HCS

Page 3/8

Trade name: Cleoderm™

(Contd. of page 2)

## · Protective Action Criteria for Chemicals

### · PAC-1:

504-63-2	Propanediol	7.8 mg/m <sup>3</sup>
629-50-5	tridecane	0.0073 ppm
1120-21-4	undecane	2.3 ppm
	Ethylenglycolmonophenylether	1.5 ppm
107-88-0	1,3-Butanediol	120 mg/m <sup>3</sup>
6381-92-6	Edetate Disodium Dihydrate Sodium Edetate Dinatrii Edetas	30 mg/m <sup>3</sup>

### · PAC-2:

504-63-2	Propanediol	86 mg/m <sup>3</sup>
629-50-5	tridecane	0.08 ppm
1120-21-4	undecane	26 ppm
	Ethylenglycolmonophenylether	16 ppm
107-88-0	1,3-Butanediol	1,300 mg/m <sup>3</sup>
6381-92-6	Edetate Disodium Dihydrate Sodium Edetate Dinatrii Edetas	330 mg/m <sup>3</sup>

### · PAC-3:

504-63-2	Propanediol	520 mg/m <sup>3</sup>
629-50-5	tridecane	2.3 ppm
1120-21-4	undecane	150 ppm
	Ethylenglycolmonophenylether	97 ppm
107-88-0	1,3-Butanediol	4,500 mg/m <sup>3</sup>
6381-92-6	Edetate Disodium Dihydrate Sodium Edetate Dinatrii Edetas	2,000 mg/m <sup>3</sup>

## 7 Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** 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:** Store in cool, dry conditions in well sealed receptacles.
- **7.3 Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

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

(Contd. on page 4)

USA

Trade name: Cleoderm™

(Contd. of page 3)

- **8.1 Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing.  
Avoid contact with the eyes.  
Avoid contact with the eyes and skin.
- **Breathing equipment:** Fresh air mask
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**



Tightly sealed goggles

## 9 Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:

Liquid

Color:

Whitish

- **Odor:**

Herbal, Floral

- **Odor threshold:**

Not determined.

(Contd. on page 5)

USA

# Safety Data Sheet

acc. to OSHA HCS

Page 5/8

Trade name: Cleoderm™

(Contd. of page 4)

· pH-value at 20 °C (68 °F):	5-6
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	100 °C (212 °F)
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not applicable.
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density at 20 °C (68 °F):	0.99-0.998 g/cm <sup>3</sup> (8.26155-8.32831 lbs/gal)
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Fully miscible.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	5.4 %
Water:	81.8 %
VOC content:	5.40 %
Solids content:	9.4 %
· 9.2 Other information	No further relevant information available.

## 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.

USA

(Contd. on page 6)

Trade name: Cleoderm™

(Contd. of page 5)

## 11 Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **on the skin:** Based on available data, the classification criteria are not met.
- **on the eye:**  
Causes serious eye irritation.
- **Sensitization:** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **Carcinogenic categories**

### · IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

### · NTP (National Toxicology Program)

None of the ingredients is listed.

### · OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

## 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.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 2 (Self-assessment): hazardous for water  
Do not allow product to reach ground water, water course or sewage system.  
Danger to drinking water if even small quantities leak into the ground.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

## 13 Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

USA

(Contd. on page 7)

# Safety Data Sheet

acc. to OSHA HCS

Page 7/8

Trade name: Cleoderm™

(Contd. of page 6)

## 14 Transport information

· 14.1 UN-Number	-
· DOT, ADR, IMDG, IATA	Void
· 14.2 UN proper shipping name	-
· DOT, ADR, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· DOT, ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

## 15 Regulatory information

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

### · Hazardous Air Pollutants

None of the ingredients is listed.

- National regulations:

Class	Share in %
NK	5.4

- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

## 16 Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

### · Relevant phrases

H227 Combustible liquid.  
H302 Harmful if swallowed.  
H315 Causes skin irritation.  
H318 Causes serious eye damage.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.

(Contd. on page 8)

USA

# Safety Data Sheet

acc. to OSHA HCS

Page 8/8

Trade name: Cleoderm™

(Contd. of page 7)

- **Department issuing SDS:**

Fagron US  
Quality Assurance

- **Contact:** QA@fagron.us

- **Date of preparation / last revision** 10/22/2019 / -

- **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

DOT: US Department of Transportation

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flam. Liq. 4: Flammable liquids – Category 4

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

- **\* Data compared to the previous version altered.**

USA