

Safety Data Sheet

acc. to OSHA HCS


Printing date 04/29/2015

Reviewed on 04/29/2015

* 1 Identification

- **Product identifier**
- **Trade name: Asclera, all concentrations**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture**
Different concentrations of Aethoxysklerol are required, depending on the size of the varices or the severity of haemorrhoidal disease to be treated.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
- **Manufacturer:**
Chemische Fabrik Kreussler & Co. GmbH
Postfach 120454
D-65082 Wiesbaden
- **Supplier:**
Merz North America, Inc.
Northchase 1 Building
6501 Six Forks Road
Raleigh, NC 27615
Telephone: 888-972-4588
- **Information department:**
Department QA
Herr Dr. Lotter
+49 (0) 611 9271-203
Matthias.Lotter@kreussler.com
- **Emergency telephone number:**
Hazmat Service Emergency number: 800-373-7542
International Shipments: +1-484-951-2432

* 2 Hazard(s) identification

- **Classification of the substance or mixture**
Eye Irrit. 2A H319 Causes serious eye irritation.
 - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
 - **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
 - **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
 - **Label elements**
 - **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
 - **Hazard pictograms**
- 

GHS07
- **Signal word** Warning
 - **Hazard statements**
Causes serious eye irritation.
 - **Precautionary statements**
Wear eye protection / face protection.
Wash thoroughly after handling.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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If eye irritation persists: Get medical advice/attention.

- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	1	Health = 1
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **Other hazards**

The product does not contain any organic halogen compounds (AOX), nitrates, heavy metal compounds or formaldehydes.

- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

* 3 Composition/information on ingredients

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

- **Dangerous components:**

3055-99-0	Ethoxylated lauryl alcohol	Xn R22; Xi R41; N R50	1.0-5.0%
64-17-5	ethanol	F R11	1.0-5.0%

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

* 4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **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 least 15 minutes under running water. Seek medical attention.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Dilute with plenty of water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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- **Reference to other sections** No dangerous substances are released.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **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.
- **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.
- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

64-17-5 ethanol (1.0-5.0%)

PEL	Long-term value: 1900 mg/m ³ , 1000 ppm
REL	Long-term value: 1900 mg/m ³ , 1000 ppm
TLV	Short-term value: 1880 mg/m ³ , 1000 ppm

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

PVC or PE gloves

- **Eye protection:** Goggles recommended during refilling or if risk of splashing

* 9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:	Fluid
Color:	Colorless
Odor:	Characteristic
Odour threshold:	Not determined.

- **pH-value at 20 °C (68 °F):** 7

- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

- **Flash point:** Not applicable.

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· Flammability (solid, gaseous):	Not determined.
· Ignition temperature:	
· 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):	1 g/cm ³ (8.345 lbs/gal)
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Fully miscible.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic at 20 °C (68 °F):	10 mPas
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	4.2 %
· Other information	No further relevant information available.

10 Stability and reactivity

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

* 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:**
Acute oral toxicity: >2000mg/kg (Rats)
calculated from data of constituent parts.

3055-99-0 Ethoxylated lauryl alcohol

Oral	LD-50	1170-3300 mg/kg (mouse)
		4150 mg/kg (rat)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.

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- **Additional toxicological information:**
- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)	
64-17-5 ethanol	1

· 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

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
 - Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
 - The product may not be released into the environment without control.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

* 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Dispose of in accordance with local, state, and federal Regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

* 14 Transport information

- | | |
|---------------------------------------|-----------------|
| · UN-Number | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |

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· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

· **UN "Model Regulation":** -

* 15 Regulatory information

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

· **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

64-17-5 | ethanol

· **Carcinogenity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

64-17-5 | ethanol

A3

· **MAK (German Maximum Workplace Concentration)**

64-17-5 | ethanol

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· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **Canadien Substances Listings:**

· **Canadien Domestic Substances List (DSL):**

All ingredients are listed.

· **Canadien Ingredient disclosure list (limit 0.1%)**

All ingredients are listed.

· **Canadien Ingredient disclosure list (limit 1%)**

3055-99-0 | Ethoxylated lauryl alcohol

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07

- **Signal word** Warning

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- **Hazard statements**

Causes serious eye irritation.

- **Precautionary statements**

Wear eye protection / face protection.

Wash thoroughly after handling.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

- **National regulations:**

- **Technical instructions (air):**

Class	Share in %
NK	1,0-5,0

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

* 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.

The information of Items 4 through 8 and 10 through 12 partially refers not to the use and the proper application of the product (see Directions for Use/Product Information) but to the release of larger quantities in the case of accidents and irregularities.

The information exclusively describes the safety requirements of the product(s) and is based on the present state of our experience.

Non-ionic tensides can have varying characteristics and classifications despite same CAS-No.

- **Department issuing SDS:**

Department QA

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- **Contact:** Mr. Dr. Lotter

- **Date of preparation / last revision** 04/29/2015 / 2

- **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

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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

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