

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/17/2021

Reviewed on 12/17/2021

* 1 Identification

- **Product identifier**

- **Trade name: Asclera, all concentrations**

- **Application of the substance / the mixture**

Asclera® (polidocanol) is a sclerosing agent indicated to treat uncomplicated spider veins (varicose veins ≤ 1 mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3 mm in diameter) in the lower extremity.

- **Details of the supplier of the safety data sheet**

- **Manufacturer/Supplier:**

- **Manufacturer:**

Chemische Fabrik Kreussler & Co. GmbH
Postfach 120454
D-65082 Wiesbaden

- **Supplier:**

Methapharm Inc.
Coral Springs FL 33065
Tel: 1-833-766-8346

- **Information department:**

Department T-PS
+49 (0) 611 9271-0
msds-tc@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.

- **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 protective gloves / eye protection.

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.

- **Classification system:**

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



Health = 2

Fire = 0

Reactivity = 0

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



Health = *2

Fire = 0

Reactivity = 0

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- **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:**

64-17-5	ethanol	Flam. Liq. 2, H225; Eye Irrit. 2A, H319	1-5%
9002-92-0	Ethoxylated lauryl alcohol	Eye Dam. 1, H318; Acute Tox. 4, H302	1-5%

- **Additional information:** For the wording of the listed hazard 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**

Wear protective equipment. Keep unprotected persons away.

- **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).

- **Reference to other sections**

No dangerous substances are released.

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

- **Protective Action Criteria for Chemicals**

- **PAC-1:**

64-17-5	ethanol	1,800 ppm
9002-92-0	Ethoxylated lauryl alcohol	2.9 mg/m ³
7778-77-0	potassium dihydrogenorthophosphate	9.6 mg/m ³

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· PAC-2:		
64-17-5	ethanol	3300* ppm
9002-92-0	Ethoxylated lauryl alcohol	31 mg/m ³
7778-77-0	potassium dihydrogenorthophosphate	110 mg/m ³
· PAC-3:		
64-17-5	ethanol	15000* ppm
9002-92-0	Ethoxylated lauryl alcohol	200 mg/m ³
7778-77-0	potassium dihydrogenorthophosphate	630 mg/m ³

* 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.
- **Storage class:** 12
- **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:**
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
At this time, the remaining constituent has no known exposure limits.

64-17-5 ethanol (1-5%)	
PEL	Long-term value: 1900 mg/m ³ , 1000 ppm
REL	Long-term value: 1900 mg/m ³ , 1000 ppm
TLV	Short-term value: 1000 ppm
	A3

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Breathing equipment:** Not required.
- **Protection of hands:**
PVC or PE 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.

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- **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:** 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
· Odor 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.
· 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):	1 g/cm ³ (8.35 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 at 20 °C (68 °F):	10 mPas
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	4.2 %
VOC (US)	4.2 %
	42.3 g/l / 0.35 lb/gal
· Other information	No further relevant information available.

10 Stability and reactivity

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

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- **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:**

ATE (Acute Toxicity Estimate)

Oral	LD-50	116,291-327,999 mg/kg (mouse)
Dermal	LD-50	>47,332 mg/kg (rabbit)
Inhalative	LC-50/4 h	2,769-2,958 mg/l (rat)

64-17-5 ethanol

Oral	LD-50	10,470 mg/kg (rat) (OECD 401)
	NOAEL	>3,000 mg/kg (rat) (OECD 451)
Dermal	LD-50	>2,000 mg/kg (rabbit) (OECD 402)
Inhalative	LC-50/4 h	117-125 mg/l (rat) (OECD 403)

9002-92-0 Ethoxylated lauryl alcohol

Oral	LD-50	1,150 mg/kg (mouse)
		1,000 mg/kg (rat)

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

64-17-5 ethanol

LC-50 48 h	12,340 mg/L (Daphnia magna)
EC-50 48h	12,900 mg/l (Selenastrum capricomutum) (OECD 203)
EC-50 72h	275 mg/l (Chlorella Vulgaris) (OECD 201)
LC-50 96h	13,000 mg/l (Oncorhynchus mykiss) (OECD 203)

- **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.

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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.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

* 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 components have the value ACTIVE.

- **Hazardous Air Pollutants**

None of the ingredients is 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.

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· Chemicals known to cause reproductive toxicity for males:		
None of the ingredients is listed.		
· Chemicals known to cause developmental toxicity:		
64-17-5	ethanol	
· New Jersey Right-to-Know List:		
64-17-5	ethanol	
7558-79-4	disodium hydrogenorthophosphate	
· Pennsylvania Right-to-Know List:		
64-17-5	ethanol	
7558-79-4	disodium hydrogenorthophosphate	
· Carcinogenicity categories		
· EPA (Environmental Protection Agency)		
None of the ingredients is listed.		
· TLV (Threshold Limit Value)		
64-17-5	ethanol	A3
· MAK (German Maximum Workplace Concentration)		
64-17-5	ethanol	5
· NIOSH-Ca (National Institute for Occupational Safety and Health)		
None of the ingredients is listed.		
· Canadian Substances Listings:		
· Canadian Domestic Substances List (DSL):		
All ingredients are listed.		
· Canadian Non-Domestic Substances List (NDSL)		
None of the ingredients is listed.		
· Canadian Ingredient disclosure list (limit 0.1%)		
All ingredients are listed.		
· Canadian Ingredient disclosure list (limit 1%)		
9002-92-0	Ethoxylated lauryl alkohol	

· **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 protective gloves / eye protection.

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	1-5

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· **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.

· **Contact:**

· **Date of preparation / last revision** 12/17/2021 / 4

· **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

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)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flam. Liq. 2: Flammable liquids – Category 2

Acute Tox. 4: Acute toxicity – Category 4

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

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

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