

Written on: 27.04.2016
Revised on: 09.11.2021
Valid from: 09.11.2021
Revision: 04

Substitutes version: 17.08.2021

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name / Trade name: HYLO GEL, HYLO-FORTE, HYCOSAN EXTRA, HYLO CONFORT PLUS, Hylomax-COMOD

Index-No.: -

EG-No.: -

CAS-No.: -

REACH-No.: -

Other names:

1.2 Relevant identified uses of the product and uses advised against

Relevant identified uses: Rewetting Eye Drops (Ophthalmic)

Use that is not recommended: -

1.3 Details of the Supplier of the Product Safety Data Sheet

Manufacturer / Provider

URSAPHARM Arzneimittel GmbH

Street/Postbox

Industriestraße 35

Nat.-Sign/Postal Code/City

66129 Saarbrücken

Contact for information

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1.4 Emergency Phone

+49 6805 9292 0

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification in accordance to Regulation (EG) Nr. 1272/2008

No hazardous product as specified in Directive 67/548/EEC.

HYLO-GEL is not a dangerous good according to IATA Dangerous Goods Regulation (DGR) 56th Edition 2015.

2.2 Label elements

Label elements according to Regulation (EG) Nr. 1272/2008

Pictogram: not applicable

Signal word: not applicable

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Hazard determining components concerning labelling

contains: not applicable

Hazard information:

not applicable

Safety information:

not applicable

Further labelling elements

not applicable

2.3 Other hazards

not applicable

3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Ingredient	%	EG-No.:	CAS-No.:	Index-No.:	REACH-Reg.No.	Classification according to Regulation (EG) Nr. 1272/2008:
Sodium hyaluronate	0.2		9067-32-7			
Citric acid anhydrous	*		77-92-9			
Sodium citrate dihydrate	*		6132-04-3			
Sorbitol	*		50-70-4			
Water	*		7732-18-5			

* Proprietary information

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice

HYLO-GEL is a certified medical device for lubrication of the eye surface in eyes that are dry, burning or have foreign body sensation due to environmental conditions as well as after ophthalmosurgical interventions. No first aid measures are usually required, if a person comes into contact with this product.

If inhaled

If breathed in, move person into fresh air. Consult a physician.

In case of skin contact

Rinse exposed area with mild soap and water.

In case of eye contact

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If irritation occurs seek advice of a Health Care Professional.
If swallowed
Rinse mouth with water and drink a substantial amount of water.

4.2 Most important symptoms and effects, both acute and delayed

no data available

4.3 Indication of any immediate medical attention and special treatment needed

no data available

5. FIREFIGHTING MEASURE

5.1 Extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Container may produce toxic fumes under decomposition by fire.

5.3 Advice for firefighters

Self-contained breathing apparatus and protective equipment should be worn.

5.4 Further information

no data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Notify safety personnel of leaks or spills. Provide adequate ventilation.

6.2 Environmental precautions

Waste material should be handled in accordance with Federal, State and Local Environmental Regulations via a licensed waste disposal container.

6.3 Methods and materials for containment and cleaning up

Cover spills with inert, non-combustible absorbent material and remove to disposal container.

6.4 Reference to other sections

None.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

See packing or/and package leaflet.

General hygiene measures

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7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Store at room temperature <25°C.

Requirements for storage rooms and container

Store at room temperature <25°C.

Storage class:

7.3 Specific end-use

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Limits of exposure in occupational use

None.

8.2 Exposure controls

Technical precautions

Not required.

Individual / personal precautions

Eye / Face protection

Not required.

Skin protection

Not required.

Body protection

Not required.

Respiratory protection

Not required.

Control of environmental exposure

Not required.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

A clear, colorless, isotonic, buffered sterile solution.

- Physical condition:

- Colour:

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Odour :	no data available
Odour Threshold :	no data available
pH :	6.8 - 7.9
Melting point/freezing point :	no data available
Initial boiling point and boiling range :	no data available
Flash point :	no data available
Evaporation rate :	no data available
Flammability (solid, gas) :	no data available
Upper/lower flammability or explosive limits:	no data available
Vapour pressure :	no data available
Vapour density :	no data available
Relative density 25 °/25 °C:	1.015
Water solubility :	Soluble
Partition coefficient: n-octanol/water :	no data available
Auto-ignition temperature :	no data available
Decomposition temperature :	no data available
Viscosity :	no data available
Explosive properties :	no data available
Oxidizing properties :	no data available

9.2 Other safety information

no data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

no data available

10.2 Chemical stability

Stable under recommended storage conditions

10.3 Possibility of hazardous reactions

In recommended use none. In case of fire potentially toxic fumes because of the container.

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

Strong oxidizing and reducing agents

10.6 Hazardous decomposition products

no data available

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Technical documentation with Clinical evaluation and Risk analysis: determined safe for use.

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12. Ecological information

12.1 Toxicity

no data available

12.2 Persistence and degradability

not applicable

12.3 Bioaccumulative potential

Concentration in organisms is not to be expected.

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

no data available

12.6 Other adverse effects

none

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Disposal must be done in compliance with the respective national regulations.

Contaminated packaging

Outer packaging must be disposed of in compliance with country-specific regulations or must be passed to a packaging return system if applicable.

14 TRANSPORT INFORMATION

No hazardous product as specified in Directive 67/548/EEC.

HYLO-GEL is not a dangerous good according to IATA Dangerous Goods Regulation (DGR) 56th Edition 2015.

14.1 UN-number

not applicable

14.2 UN proper shipping name

ADR/RID

not applicable

IMDG-Code / ICAO-TI / IATA-DGR

not applicable

14.3 Transport hazard class

not applicable, no dangerous goods

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14.4 Packaging group

not applicable

14.5 Environmental hazards

Label for environmentally hazardous substances

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: yes / no

Marine Pollutant: yes / no

14.6 Special precautions for user

not applicable

14.7 Transport in bulk according to Annex II of MARPOL 72/78 and the IBC Code

Pollution category (X, Y or Z) : not applicable

Type of ship (1, 2 or 3) : not applicable

15. Regulatory information

Labeling according to EC Directive 1272/2008 is not required.

15.1 Safety health and environmental regulations / legislations specific for the product

EU-Regulation e.g.

Regulation (EG) No. 1005/2009 (Substances that deplete the ozone layer): not applicable

Regulation (EG) No. 850/2004 (Persistent organic pollutants): not applicable

Regulation (EG) No. 689/2008 (Export and import of dangerous chemicals): not applicable

Regulation (EG) No. 648/2004 (Detergents): not applicable

Restrictions acc. to title VIII of regulation (EG) No. 1907/2006: not applicable

National Regulations e.g. not applicable

Water hazard class

Solvents regulation (31. BImSchV)

Hazardous Incident Ordinance (12. BImSchV)

Technical instruction air (TA-Luft)

Further relevant regulations

not applicable

15.2 Chemical safety assessment

not applicable

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16. Other information

Changes since the last version

No change of information; new format of PSDS.

Other Information

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.
