

# SAFETY DATA SHEET

## According to Regulation (EC) No 1907/2006

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Trade name:	Vizol S INTENSIVE, eye drops		
Product code:	310001984	Date of compilation:	18.12.2024. Version: 1

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1. Product identifier		
Trade name:	Vizol S INTENSIVE, eye drops	
Chemical name:	Sodium hyaluronate 0,15% and dexpanthenol 2,0%	
Catalogue number:	Not applicable.	
UFI:	Not applicable.	
Form:	Liquid	
1.2. Relevant identified uses of the substance or mixture and uses advised against		
Uses:	Ophthalmic solution for dry eyes, eye drops	
Uses advised against:	-	
Reason why uses advised against:	-	
1.3. Details of the supplier of the safety data sheet		
Supplier:	JGL d.d.	
Address:	Svilno 20, 51 000 Rijeka, Hrvatska	
Telephone number:	+ 385 (0)51 660 700	
Telefax:	+ 385 (0)51 660 777	
e-mail of competent person:	<a href="mailto:sti@jgl.hr">sti@jgl.hr</a>	
National contact:	-	
1.4. Emergency telephone number		
National Protection and Rescue Directorate:	+385 112	
Medical information:	+385 1-23-48-342	
Other information:	-	
SECTION 2. Hazards identification		
2.1. Classification of the substance or mixture		
2.1.1. Classification according to Regulation (EC) No 1272/2008 (CLP)		
Hazard class and category code:	Hazard statement*:	
-	-	
2.1.2. Additional information		
According to the regulation, the product is not classified as hazardous.		
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2. Label elements		
Product identification:	Vizol S INTENSIVE, eye drops	
Identification number:	-	
Authorisation number:	-	
Hazard pictograms:	-	
Signal word:	-	
Hazard statement:	-	
Precautionary statement:	P501 Dispose of contents/container according to national legislative.	
Supplemental hazard information (EU):	-	
2.3. Other hazards		

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-				
<b>SECTION 3. Composition/information on ingredients</b>				
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
-	-	-	-	-
The product does not contain dangerous substances or ingredients, which would need to be declared on the safety data sheet.				

<b>SECTION 4. First aid measures</b>		
4.1.	Description of first aid measures	
	General notes:	When in doubt or if feeling unwell seek medical assistance. Never give anything by mouth to an unconscious person.
	Following inhalation:	No requirements under normal use conditions.
	Following skin contact:	No requirements under normal use conditions.
	Following eye contact:	No requirements under normal use conditions. This product is mentioned for use in the eyes and it is not expected to do any harm following acute exposure. In case discomfort or irritation develops, immediately discontinue product use and contact your eye care professional. If the patient is wearing contact lenses, remove them immediately. Rinse with water.
	Following ingestion:	Do not induce vomiting. Rinse mouth with water. Drink a glass or two of water. Consult a physician.
	Self-protection of the first aider	-
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	No specific symptoms are expected under normal use conditions.
	Following skin contact:	No specific symptoms are expected under normal use conditions.
	Following eye contact:	This product is mentioned for use in the eyes and it is not expected to do any harm following acute exposure.
	Following ingestion:	No specific symptoms are expected under normal use conditions.
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

<b>SECTION 5. Firefighting measures</b>		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
	Unsuitable extinguishing media:	-
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Do not breathe products of combustion.
5.3.	Advice for firefighters	
	Firefighters should wear appropriate protective clothing for firefighters (including helmets, protective boots and gloves) (EN 469) and self-contained breathing apparatus (SCBA) with a full face-piece (EN 137). Prevent any material from entering drains or waterways.	
5.4.	Additional information	
	-	

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SECTION 6. Accidental release measures		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (Section 8).
	Accident prevention methods:	Ensure appropriate ventilation.
	Emergency procedures:	Prevent access to unauthorised personnel.
6.1.2.	For emergency responders:	
	Use personal protective equipment.	
6.2.	Environmental precautions:	
	Do not allow product to reach water/drains/sewage systems or permeable soil.	
6.3.	Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Prevent any material from entering drains or waterways.
6.3.2.	Cleaning up:	Absorb with inert material (sand, flintstone (diatomite soil), universal binder, sawdust) and collect in a suitable container. Dispose in accordance with local or national regulations. Wipe the spilled place again with ethanol or propanol (hyaluronic acid with water makes very slippery gel). Small quantities can be mopped up with dry cloth and wiped with ethanol or propanol.
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	See also Sections 8 and 13.	
SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protective measures	
	Measures to prevent fire:	Ensure appropriate ventilation.
	Measures to prevent aerosol and dust generation:	Adequate area ventilation where stored and manipulated. Packaging should be closed tight.
	Measures to protect the environment:	Packaging should be closed tight. Prevent any material from entering drains or waterways using water dams, covering drains with plastic folium.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Use good personal hygiene practices – wash hands at breaks and when done working with material. Do not eat, drink or smoke while working.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Store in original container at temperatures up to 25 °C.
	Packaging materials:	Store only in original container. Opened container after use close properly and keep in vertical position. Do not keep in unlabelled containers.
	Requirements for storage rooms and vessels:	-
	Advice for storage equipment:	-
	Further information on storage conditions:	-
7.3.	Specific end use(s)	

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Recommendations:	Shelf life: 24 months. In use shelf life: 6 months.
Industrial sector specific solutions:	-

### SECTION 8. Exposure controls/personal protection

#### 8.1. Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m <sup>3</sup>	
-	-	-/-	-/-	-

-				
Substance:	-			
EC No:	-	CAS No:	-	-

#### DNEL

##### Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	No data.	No data.	No data.	No data.
Inhalation	No data.	No data.	No data.	No data.
Dermal	No data.	No data.	No data.	No data.

Critical physical parameters: solubility, flammability, corrosivity:

##### Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	No data.	No data.	No data.	No data.
Inhalation	No data.	No data.	No data.	No data.
Dermal	No data.	No data.	No data.	No data.

#### PNEC

Environmental protection target	PNEC
Fresh water	No data.
Freshwater sediments	No data.
Marine water	No data.
Marine sediments	No data.
Food chain	No data.
Microorganisms in sewage treatment	No data.
Soil (agricultural)	No data.
Air	No data.

#### 8.2. Exposure controls

##### 8.2.1. Appropriate engineering controls

Substance/mixture related measures to prevent exposure during identified uses:	Adequate area ventilation where stored and manipulated. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.
Structural measures to prevent exposure:	According to section 7.

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	Organisational measures to prevent exposure:	According to section 7.
	Technical measures to prevent exposure:	Ensure appropriate ventilation.
8.2.2.	Personal protection equipment:	
8.2.2.1.	Eye and face protection:	No requirements under normal use conditions.
8.2.2.2.	Skin protection:	No requirements under normal use conditions.
	Hand protection:	No requirements under normal use conditions.
	Other skin protection:	No requirements under normal use conditions.
8.2.2.3.	Respiratory protection:	No requirements under normal use conditions.
8.2.2.4.	Thermal hazards:	-
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	According to section 6.
	Structural measures to prevent exposure:	According to section 6.
	Organisational measures to prevent exposure:	According to section 6.
	Technical measures to prevent exposure:	No data.

SECTION 9. Physical and chemical properties			
9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	visual
	Colour:	Bright, colourless	Ph.Eur 2.2.1., Ph.Eur 2.2.2. (Method 2)
	Odour/odour threshold:	No data.	-
	Melting point / freezing point;	No data.	-
	Boiling point or initial boiling point and boiling range:	No data.	-
	Flammability:	No data.	-
	Lower and upper explosion limit:	No data.	-
	Flash point:	No data.	-
	Auto-ignition temperature:	No data.	-
	Decomposition temperature:	No data.	-
	pH:	6,8 – 7,5	Ph. Eur. 2.2.3.
	Viscosity:	No data.	-
	Solubility:	No data.	-
	Partition coefficient n-octanol/water (log value):	No data.	-
	Vapour pressure:	No data.	-
	Density	1.004 – 1.009 g/cm <sup>3</sup>	Ph. Eur. 2.2.5.
	Relative vapour density:	No data.	-
	Particle characteristics:	No data.	-

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9.2.	Other information					
	Osmolality: 260 – 320 mOsmol/kg (Ph. Eur.2.2.35.)					
SECTION 10.: Stability and reactivity						
10.1.	Reactivity:	Not reactive under normal use conditions.				
10.2.	Chemical stability:	Product is stable under normal conditions of use.				
10.3.	Possibility of hazardous reactions:	No hazardous reactions are expected under normal use conditions.				
10.4.	Conditions to avoid:	Keep stored as prescribed. Avoid high temperatures.				
10.5.	Incompatible materials:	No data.				
10.6.	Hazardous decomposition products:	Under normal use conditions no hazardous decomposition products are expected.				
SECTION 11. Toxicological information						
11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008					
	Acute toxicity: -					
Route of exposure:		Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure time	Results
Oral:		No data.	No data.	No data.	No data.	No data.
Oral		No data.	No data.	No data.	No data.	No data.
Intravenous:		No data.	No data.	No data.	No data.	No data.
Specific target organ toxicity – single exposure (STOT SE):						
		Specific effects		Target organ	Note	
Oral:		No data.		No data.	No data.	
Dermal:		No data.		No data.	No data.	
Inhalation:		No data.		No data.	No data.	
Aspiration hazard:						
No information.						
Irritation and corrosion:						
		Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation		No data.	No data.	No data.	No data.	No data.
Serious eye damage/irritation		No data.	No data.	No data.	No data.	No data.
Sensitization						
Skin sensitization:		The product is not classified as sensitising.				
Respiratory sensitization:		The product is not classified as sensitising.				
Symptoms related to the physical, chemical and toxicological characteristics						
Oral exposure:		No data.				
Dermal exposure:		No data.				
Inhalation exposure:		No data.				
Eye exposure:		No data.				
Repeated dose toxicity (subacute, subchronic, chronic)						

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	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No data.	No data.	No data.	No data.	No data.	No data.
Subacute dermal	No data.	No data.	No data.	No data.	No data.	No data.
Subacute inhalation	No data.	No data.	No data.	No data.	No data.	No data.
Subchronic oral	No data.	No data.	No data.	No data.	No data.	No data.
Subchronic dermal	No data.	No data.	No data.	No data.	No data.	No data.
Subchronic inhalation	No data.	No data.	No data.	No data.	No data.	No data.
Chronic oral	No data.	No data.	No data.	No data.	No data.	No data.
Chronic dermal	No data.	No data.	No data.	No data.	No data.	No data.
Chronic inhalation	No data.	No data.	No data.	No data.	No data.	No data.

### Specific target organ toxicity – repeated exposure (STOT RE):

	Specific effects	Target organ	Note
Subacute oral	No data.	No data.	No data.
Subacute dermal	No data.	No data.	No data.
Subacute inhalation	No data.	No data.	No data.
Subchronic oral	No data.	No data.	No data.
Subchronic dermal	No data.	No data.	No data.
Subchronic inhalation	No data.	No data.	No data.
Chronic oral	No data.	No data.	No data.
Chronic dermal	No data.	No data.	No data.
Chronic inhalation	No data.	No data.	No data.

### CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)

Carcinogenicity:	No data.
Mutagenicity <i>in-vitro</i> :	No data.
Genotoxicity:	No data.
Mutagenicity <i>in-vivo</i> :	No data.
Germ cell mutagenicity:	No data.
Reproductive toxicity:	No data.

Summary of evaluation of the CMR properties: The product is not classified as carcinogenic, mutagenic or toxic for reproduction.

11.2.	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	This product does not contain any known or suspected endocrine disrupting.
11.2.2.	Other information:
	No data.

## SECTION 12. Ecological information

12.1.	Toxicity
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Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish:	LC <sub>50</sub>	96 hours	No data.	No data.	No data.	No data.
Crustacea:	EC <sub>50</sub>	48 hours	No data.	No data.	No data.	No data.
Algae/aquatic plants:	IC <sub>50</sub>	72 hours	No data.	No data.	No data.	No data.
Other organisms:	-	-	-	-	-	-
Chronic (long-term) toxicity	Doza	Exposure time	Species	Method	Evaluation	Note
Fish:	LC <sub>50</sub>	96 hours	No data.	No data.	No data.	No data.
Crustacea:	EC <sub>50</sub>	48 hours	No data.	No data.	No data.	No data.
Algae/aquatic plants:	IC <sub>50</sub>	72 hours	No data.	No data.	No data.	No data.
Other organisms:	-	-	-	-	-	-

12.2.	Persistence and degradability					
	Abiotic degradation					
	Degradation half-lives		Method	Evaluation		Note
Marine water	No data.		No data.	No data.		No data.
Fresh water	No data.		No data.	No data.		No data.
Air	No data.		No data.	No data.		No data.
Soil	No data.		No data.	No data.		No data.

	Biodegradation					
% Degradation	Time (days)		Method	Evaluation		Note
No data.	No data.		No data.	No data.		No data.

12.3.	Bioaccumulative potential					
	Octanol-water partition coefficient (log K <sub>ow</sub> )					
Value	Concentration	pH	°C	Method	Evaluation	Note
No data.	No data.	No data.	No data.	No data.	No data.	No data.

	Bioconcentration factor (BCF)					
Value	Species		Method	Evaluation		Note
No data.	No data.		No data.	No data.		No data.

	Chronic ecotoxicity					
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC <sub>50</sub>	No data.	No data.	No data.	No data.	No data.
Chronic toxicity on crustacea (Daphnia)	EC <sub>50</sub>	No data.	No data.	No data.	No data.	No data.

12.4.	Mobility in soil					
	Known or predicted distribution in environmental compartments:					



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	No data.				
	Surface tension:				
	Value	°C	Concentration	Method	Note
	No data.	No data.	No data.	No data.	No data.
	Adsorption/desorption				
Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-Water	No data.	No data.	No data.	No data.	No data.
Water-Air	No data.	No data.	No data.	No data.	No data.
Soil-Air	No data.	No data.	No data.	No data.	No data.
12.5.	Results of PBT and vPvB assessment				
	This product does not contain any substances that are assessed to be PBT or vPvB.				
12.6.	Endocrine disrupting properties				
	This product does not contain any known or suspected endocrine disrupting.				
12.7.	Other adverse effects				
	No data.				

<b>SECTION 13. Disposal considerations</b>	
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Waste should be handled in accordance with local or national regulations.
13.1.2.	Waste codes/waste designations according to Low:
	-
13.1.3.	Waste treatment – relevant information:
	Do not pour into drains or waterways.
13.1.4.	Sewage disposal – relevant information:
	-
13.1.5.	Other disposal recommendations:
	-
13.1.6.	Relevant Community provisions:
	National waste disposal regulations.

<b>SECTION 14. Transport information</b>	
	Transporting/shipment by road (ADR)

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UN number or ID number:	-
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	-
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by inland waterways (ADN)	
UN number or ID number:	-
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number or ID number:	-
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Maritime transport in bulk according to IMO instruments:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number or ID number:	-
UN proper shipping name:	-
Transport hazard class(es):	-
Environmental hazards:	-
Special precautions for user:	-
Further information:	
Not dangerous according to transport regulations.	

SECTION 15. Regulatory information	
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorisations and/or restrictions on use

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	Authorisations:	-
	Restrictions:	-
	Other EU regulations:	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	Chemical act NN18/13, NN115/18, NN37/20, Dangerous goods transportation act NN79/07, waste control regulations, Croatian legislative for employee's protection
15.2.	Chemical safety assessment	
	No Chemical Safety Assessment has been carried out for this mixture.	

SECTION 16. Other information		
16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways ADR - Agreement concerning the International Carriage of Dangerous Goods by Road ATE - Acute Toxicity Estimate CAS - Chemical Abstracts Service number CMR - Carcinogen, Mutagen, or Reproductive Toxicant DNEL - Derived No Effect Level EC-Number - EINECS and ELINCS Number IMDG - International Maritime Code for Dangerous Goods IATA - International Air Transport Association ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods GHS - Globally Harmonized System of Classification and Labelling of Chemicals LC50 - Lethal concentration, 50 percent LD50 - Lethal Dose, 50 percent PNEC(s) - Predicted No Effect Concentration(s) RID - Regulations concerning the International Carriage of Dangerous Goods by Rail STOT - Specific Target Organ Toxicity (STOT) RE - Repeated Exposure (STOT) SE - Single Exposure
16.3.	Key literature references and source of data:	Supplier's SDS for raw materials Product specification (internal document, SpecDP001021/11)
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
	Classification	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H:	-
16.6.	Training advice:	-
16.7.	Further information:	-

ANNEX: Exposure scenario resulting to Chemical safety assessment
-