SAFETY DATA SHEET
According to Regulation (EC) No 1907/2006

Trade name:	Aqua Maris Classic, 100% Natural Seawater Nasal Spray for Dry and Irritated Nose, Saline Nasal Mouisturizer for Everyday Use, Adults and Kids, 30 ml				
Product code:	-	Date of compilation:	07.02.2023.	Version:	1

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	Aqua Maris Classic, 100% Natural Seawater Nasal Spray for Dry and Irritated Nose, Saline Nasal Mouisturizer for Everyday Use, Adults and Kids, 30 ml
	Chemical name:	Not applicable.
	Catalogue number:	Not applicable.
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Medical device
	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, 51000 Rijeka, Croatia
	Telephone number:	+385 (0)51 660 700
	Telefax:	+385 (0)51 660 777
	e-mail of competent person:	stl@jgl.hr
	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	
	-	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2.	Label elements	
	Product identification:	Aqua Maris Classic, nasal spray, 30 ml
	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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SECTION 3. Composition/information on ingredients

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.				

SECTION 4. First aid measures

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 specific treatment is necessary since this material is not likely to be hazardous by inhalation.
	Following skin contact:	No specific treatment is necessary since this material is not likely to be hazardous.
	Following eye contact:	Immediately flush eyes with plenty of water while keeping eyelids open (at least 5 minutes).
	Following ingestion:	No specific treatment is necessary. If large quantities are accidentally ingested: drink water and seek medical advice.
	Self-protection of the first aider	-
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	-
	Following skin contact:	-
	Following eye contact:	Contact with eyes can cause irritation (redness, tearing).
	Following ingestion:	-
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures

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:	-
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).	
5.4.	Additional information	
	-	

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:	-
	Emergency procedures:	Keep away from sources of ignition and/or heat. No smoking! Prevent access to unauthorised personnel.
6.1.2.	For emergency responders:	
	Use personal protective equipment.	
6.2.	Environmental precautions:	
	-	
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, universal binder, sawdust) and collect in containers for waste disposal. Small quantities: can be mopped up with dry cloth.
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:	-
	Measures to prevent aerosol and dust generation:	-
	Measures to protect the environment:	-
	Other measures:	Keep out of reach of children.
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. Keep out of the reach of children.
	Packaging materials:	Store only in original container.
	Requirements for storage rooms and vessels:	-
	Advices for storage equipment:	-
	Further information on storage conditions:	-
7.3.	Specific end use(s)	
	Recommendations:	-
	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^3	

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

DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	No information.	No information.	No information.	No information.
Inhalation	No information.	No information.	No information.	No information.
Dermal	No information.	No information.	No information.	No information.
Critical physical parameters: solubility, flammability, corrosivity:				
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	No information.	No information.	No information.	No information.
Inhalation	No information.	No information.	No information.	No information.
Dermal	No information.	No information.	No information.	No information.

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

-

8.2.	Exposure controls	
8.2.1.	Appropriate engineering controls	
	Substance/mixture related measures to prevent exposure during identified uses:	No information.
	Structural measures to prevent exposure:	No information.
	Organisational measures to prevent exposure:	Use good personal hygiene practices – wash hands at breaks and when done working with material.
	Technical measures to prevent exposure:	No information.
8.2.2.	Personal protection equipment:	
8.2.2.1.	Eye and face protection:	No requirements under normal use conditions. If there is risk of splashing into eyes, wear safety glasses with side shields (EN 166). Avoid contact with eyes.
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:	No requirements under normal use conditions.
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	No information.
	Structural measures to prevent exposure:	No information.
	Organisational measures to prevent exposure:	No information.
	Technical measures to prevent exposure:	No information.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

		Value	Method
	Physical state:	liquid	-
	Colour:	clear, colourless	Organoleptic
	Odour/odour threshold:	odourless	Organoleptic
	Melting point / freezing point;	No data.	-
	Boiling point or initial boiling point and boiling range:	No data.	-
	Flammability:	No data.	-
	Lover and upper explosion limit:	No data.	-
	Flash point:	No data.	-
	Auto-ignition temperature:	No data.	-
	Decomposition temperature:	No data.	-
	pH:	6,0 – 8,5	Ph .Eur. 2.2.3.
	Kinematic viscosity:	No data.	-
	Solubility:	No data.	-
	Partition coefficient n-octanol/water (log value):	No data.	-
	Vapour pressure:	No data.	-
	Relative density	No data.	-
	Relative vapour density:	No data.	-
	Particle characteristics:	No data.	-

9.2. Other information

Osmolality: 270 – 376 mOsmol/kg (Ph.Eur. 2.2.35.)
Sterility: solution must be sterile (Ph. Eur. 2.6.1.)

SECTION 10.: Stability and reactivity

10.1.	Reactivity:	No data.

10.2.	Chemical stability:	Product is stable under normal conditions of use, recommended handling and storage conditions.
10.3.	Possibility of hazardous reactions:	No data.
10.4.	Conditions to avoid:	No data.
10.5.	Incompatible materials:	No data.
10.6.	Hazardous decomposition products:	No data.

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_{50}/LC_{50} or $ATE_{mixture}$	Exposure time	Results
Oral:	No information.	No information.	No information.	No information.	No information.
Dermal:	No information.	No information.	No information.	No information.	No information.
Inhalation:	No information.	No information.	No information.	No information.	No information.

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

	Specific effects	Target organ	Note
Oral:	No information.	No information.	No information.
Dermal:	No information.	No information.	No information.
Inhalation:	No information.	No information.	No information.

Aspiration hazard:

No information.

Irritation and corrosion:

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation	No information.	No information.	No information.	No information.	No information.
Serious eye damage/irritation	No information.	No information.	No information.	No information.	No information.

Sensitization

Skin sensitization:	No information.
Respiratory sensitization:	No information.

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	No information.
Dermal exposure:	No information.
Inhalation exposure:	No information.
Eye exposure:	No information.

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	Repeated dose toxicity (subacute, subchronic, chronic)					
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information.	No information.	No information.	No information.	No information.	No information.
Subacute dermal	No information.	No information.	No information.	No information.	No information.	No information.
Subacute inhalation	No information.	No information.	No information.	No information.	No information.	No information.
Subchronic oral	No information.	No information.	No information.	No information.	No information.	No information.
Subchronic dermal	No information.	No information.	No information.	No information.	No information.	No information.
Subchronic inhalation	No information.	No information.	No information.	No information.	No information.	No information.
Chronic oral	No information.	No information.	No information.	No information.	No information.	No information.
Chronic dermal	No information.	No information.	No information.	No information.	No information.	No information.
Chronic inhalation	No information.	No information.	No information.	No information.	No information.	No information.

	Specific target organ toxicity – repeated exposure (STOT RE):		
	Specific effects	Target organ	Note
Subacute oral	No information.	No information.	No information.
Subacute dermal	No information.	No information.	No information.
Subacute inhalation	No information.	No information.	No information.
Subchronic oral	No information.	No information.	No information.
Subchronic dermal	No information.	No information.	No information.
Subchronic inhalation	No information.	No information.	No information.
Chronic oral	No information.	No information.	No information.
Chronic dermal	No information.	No information.	No information.
Chronic inhalation	No information.	No information.	No information.

	CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	
	Carcinogenicity:	No information.
	Mutagenicity *in-vitro*:	No information.
	Genotoxicity:	No information.
	Mutagenicity *in-vivo*:	No information.

	Germ cell mutagenicity :	No information.
	Reproductive toxicity:	No information.
	Summary of evaluation of the CMR properties; :	No information.
11.2.	Information on other hazards:	
11.2.1.	Endocrine disrupting properties:	
	No information.	
11.2.2.	Other informations:	
	No information.	

SECTION 12. Ecological information

12.1. Toxicity

Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish:	LC_{50}	96 hours	No information.	No information.	No information.	No information.
Crustacea:	EC_{50}	48 hours	No information.	No information.	No information.	No information.
Algae/aquatic plants:	IC_{50}	72 hours	No information.	No information.	No information.	No information.
Other organisms:			No information.	No information.	No information.	No information.
Chronic (long-term) toxicity	Doza	Exposure time	Species	Method	Evaluation	Note
Fish:	LC_{50}	96 hours	No information.	No information.	No information.	No information.
Crustacea:	EC_{50}	48 hours	No information.	No information.	No information.	No information.
Algae/aquatic plants:	IC_{50}	72 hours	No information.	No information.	No information.	No information.
Other organisms:	No information.	No information.	No information.	No information.	No information.	No information.

12.2. Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information.	No information.	No information.	No information.
Fresh water	No information.	No information.	No information.	No information.
Air	No information.	No information.	No information.	No information.
Soil	No information.	No information.	No information.	No information.

Biodegradation

% Degradation	Time (days)	Method	Evaluation	Note

No information.	No information.	No information.	No information.	No information.

12.3.	Bioaccumulative potential
	Octanol-water partition coefficient (log Kow)

Value	Concentration	pH	°C	Method	Evaluation	Note
No information.	No information.	No information.	No information.	No information.	No information.	No information.

	Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note
No information.	No information.	No information.	No information.	No information.

	Chronic ecotoxicity

Vrijednost	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC_{50}	No information.	No information.	No information.	No information.	No information.
Chronic toxicity on crustacea (Daphnia)	EC_{50}	No information.	No information.	No information.	No information.	No information.

12.4.	Mobility in soil
	Known or predicted distribution in environmental compartments:
	No information.
	Surface tension:

Value	°C	Concentration	Method	Note
No information.	No information.	No information.	No information.	No information.

	Adsorption/desorption

Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-Water	No information.	No information.	No information.	No information.	No information.
Water-Air	No information.	No information.	No information.	No information.	No information.

Soil-Air	No information.	No information.	No information.	No information.	No information.

12.5.	Results of PBT and vPvB assessment
	No evaluation.
12.6.	Endocrine disrupting properties
	No data.
12.7.	Other adverse effects
	-

SECTION 13. Disposal considerations	
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:
	-

SECTION 14. Transport information	
	Transporting/shipment by road (ADR)
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:	-

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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:	-

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	
	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:	Zakon o kemikalijama NN18/13, NN115/18, NN37/20, Zakon o prijevozu opasnih tvari NN79/07, waste control regulations
15.2.	Chemical safety assessment	

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	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:	MSDS for raw materials Specification drug product SpecDP001559/3 (internal document)
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
-