

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

Page 1 of 13

Trade name:	Aqua Maris Nasal Spray Made of 100% Natural Adriatic Sea Water for Cleaning the Nasal Mucosa, For Daily Use, Adults and Children, 50 ml		
Product code:	-	Date of compilation:	20.01.2023. Version: 3

SECTION 1: Identification of the substance/mixture and of the company/undertaking	
1.1.	Product identifier
	Trade name: Aqua Maris Nasal Spray Made of 100% Natural Adriatic Sea Water for Cleaning the Nasal Mucosa, For Daily Use, Adults and Children, 50 ml
	Chemical name: Not applicable.
	Catalogue number: -
	UFI: -
	Form: Solution
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, Hrvatska
	Telephone number: +385 (0)51 660 700
	Telefax: +385 (0)51 660 777
	e-mail of competent person: sti@jgl.hr
	National contact: -
1.4.	Emergency telephone number
	National Protection and Rescue Directorate: 112
	Medical information: 01-23-48-342
	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: Aerosols
	Hazard statement*: H229
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 Clean Nasal Spray 50 ml
	Identification number: -
	Authorisation number: -
	Hazard pictograms: -
	Signal word: Warning
	Hazard statement: H229 Pressurized container: may burst if heated

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

Page 2 of 13

Trade name:	Aqua Maris Nasal Spray Made of 100% Natural Adriatic Sea Water for Cleaning the Nasal Mucosa, For Daily Use, Adults and Children, 50 ml		
Product code:	-	Date of compilation:	20.01.2023. Version: 3

Precautionary statement:	P210 Keep away from heat/sparks/open flames/hot surfaces. – No smoking. P251 Pressurized container: Do not pierce or burn, even after use. P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50°C. P102 Keep out of reach of children. P501 Dispose of contents/container according to national legislative.
Supplemental hazard information (EU):	-
2.3. Other hazards	-

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 in necessary since this product is not likely to be hazardous by inhalation.
	Following skin contact:	No requirements under normal use conditions.
	Following eye contact:	Immediately flush eyes with plenty of water while keeping eyelids open (at least 5 minutes).
	Following ingestion:	No specific treatment in 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:	No specific symptoms are expected under normal use conditions.
	Following skin contact:	No specific symptoms are expected under normal use conditions.
	Following eye contact:	Contact with eyes can cause irritation (redness, tearing, pain).
	Following ingestion:	No specific symptoms are expected under normal use conditions.
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		

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

Page 3 of 13

Trade name:	Aqua Maris Nasal Spray Made of 100% Natural Adriatic Sea Water for Cleaning the Nasal Mucosa, For Daily Use, Adults and Children, 50 ml		
Product code:	-	Date of compilation:	20.01.2023.
		Version:	3

	Hazardous combustion products:	Do not breathe products of combustion.
5.3.	Advice for firefighters	
	Contains gas under pressure; may explode if heated. In case of fire or heating do not breathe fumes/vapours. Cool containers at risk with water spray. If possible, remove containers from endangered area. 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 unauthorized 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:	Collect the spray cans and hand them over to an authorized waste disposal contractor. Absorb with inert material (sand, universal binder, sawdust). 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:	Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Keep away from sources of ignition – no smoking.
	Measures to prevent aerosol and dust generation:	-
	Measures to protect the environment:	-
	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.	

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

Page 4 of 13

Trade name:	Aqua Maris Nasal Spray Made of 100% Natural Adriatic Sea Water for Cleaning the Nasal Mucosa, For Daily Use, Adults and Children, 50 ml		
Product code:	-	Date of compilation:	20.01.2023. Version: 3

7.2.	Conditions for safe storage, including any incompatibilities		
	Technical measures and storage conditions:	Store in original container at temperatures up to 25°C. Store away from heat, sparks, fire and other surfaces of ignition. Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50°C. 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	
	-	-	- -	-

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: No information.

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.

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

Page 5 of 13

Trade name:	Aqua Maris Nasal Spray Made of 100% Natural Adriatic Sea Water for Cleaning the Nasal Mucosa, For Daily Use, Adults and Children, 50 ml		
Product code:	-	Date of compilation:	20.01.2023.
		Version:	3

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.
	Organizational measures to prevent exposure:	Use good personal hygiene practice – 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).
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:	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	Visual	
Odour:	Odourless.	Organoleptic	
Odour threshold:	No data.	-	
Melting point / freezing point:	No data.	-	
Boiling point or initial boiling point and boiling range:	100°C	Ph.Eur.	

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

Page 6 of 13

Trade name:	Aqua Maris Nasal Spray Made of 100% Natural Adriatic Sea Water for Cleaning the Nasal Mucosa, For Daily Use, Adults and Children, 50 ml		
Product code:	-	Date of compilation:	20.01.2023. Version: 3

	Flammability:	No data.	-
	Lower and upper flammability or explosion limit:	No data.	-
	Flash point:	No data.	-
	Auto-ignition temperature:	No data.	-
	Decomposition temperature:	No data.	-
	pH:	6,0 – 9,0	-
	Kinematic viscosity:	No data.	-
	Solubility:	Soluble in water.	-
	Partition coefficient n-octanol/water (log value):	No data.	-
	Vapour pressure:	No data.	-
	Vapour density:	No data.	-
	Relative density:	1.000 – 1.001	Ph.Eur.
	Relative vapour density:	No data.	-
	Particle characteristics:	No data.	-
9.2.	Other information		
	-		

SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	No information.
10.2.	Chemical stability:	Product is stable under normal conditions of use, recommended handling and storage conditions.
10.3.	Possibility of hazardous reactions:	No information.
10.4.	Conditions to avoid:	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Do not store above 50 °C
10.5.	Incompatible materials:	No information.
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 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	

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

Page 8 of 13

Trade name:	Aqua Maris Nasal Spray Made of 100% Natural Adriatic Sea Water for Cleaning the Nasal Mucosa, For Daily Use, Adults and Children, 50 ml					
Product code:	-	Date of compilation:	20.01.2023.	Version:	3	

Chronic dermal	No information.					
Chronic inhalation	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.
Sub chronic oral	No information.	No information.	No information.
Sub chronic dermal	No information.	No information.	No information.
Sub chronic 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 <i>in-vitro</i> :	No information.
Genotoxicity:	No information.
Mutagenicity <i>in-vivo</i> :	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 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.

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

Page 9 of 13

Trade name:	Aqua Maris Nasal Spray Made of 100% Natural Adriatic Sea Water for Cleaning the Nasal Mucosa, For Daily Use, Adults and Children, 50 ml					
Product code:	-	Date of compilation:	20.01.2023.	Version:	3	

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.

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.				

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

Page 10 of 13

Trade name:	Aqua Maris Nasal Spray Made of 100% Natural Adriatic Sea Water for Cleaning the Nasal Mucosa, For Daily Use, Adults and Children, 50 ml					
Product code:	-	Date of compilation:	20.01.2023.	Version:	3	

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.				

Adsorption/desorption

Transport	A/D coefficient Henry's constant	log K _{ow}	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 information.

12.7. Other adverse effects

No information.

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:

-

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

Page 11 of 13

Trade name:	Aqua Maris Nasal Spray Made of 100% Natural Adriatic Sea Water for Cleaning the Nasal Mucosa, For Daily Use, Adults and Children, 50 ml		
Product code:	-	Date of compilation:	20.01.2023. Version: 3

13.1.5.	Other disposal recommendations:
	-
13.1.6.	Relevant Community provisions:
	National waste disposal regulations.

SECTION 14. Transport information	
Transporting/shipment by road (ADR)	
UN number or ID number:	Not dangerous goods.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	Not dangerous goods.
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:	Not dangerous goods.
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:	Not dangerous goods.
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:	Not dangerous goods.
UN proper shipping name:	-
Transport hazard class(es):	-
Environmental hazards:	-

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

Page 12 of 13

Trade name:	Aqua Maris Nasal Spray Made of 100% Natural Adriatic Sea Water for Cleaning the Nasal Mucosa, For Daily Use, Adults and Children, 50 ml		
Product code:	-	Date of compilation:	20.01.2023. Version: 3

Special precautions for user:	-
Further information:	<p>According to Special Provision 190 not dangerous goods in transporting by road, by train, by sea and by waterways.</p> <p>According to Special Provision A98 not dangerous goods in transporting by air (product not exceeding 50 ml).</p>

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
	National legislation: Zakon o kemikalijama NN18/13, NN115/18, NN37/20, Zakon o prijevozu opasnih tvari NN79/07, waste control regulations
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)
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:
	Section 14. updated transport information
16.2.	Abbreviations and acronyms:
	<p>ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways</p> <p>ADR - Agreement concerning the International Carriage of Dangerous Goods by Road</p> <p>ATE - Acute Toxicity Estimate</p> <p>CAS - Chemical Abstracts Service number</p> <p>CMR - Carcinogen, Mutagen, or Reproductive Toxicant</p> <p>DNEL - Derived No Effect Level</p> <p>EC-Number - EINECS and ELINCS Number</p> <p>IMDG: International Maritime Code for Dangerous Goods;</p> <p>IATA: International Air Transport Association;</p> <p>ICAO: International Civil Aviation Organization;</p> <p>IMDG - International Maritime Dangerous Goods</p> <p>GHS: Globally Harmonized System of Classification and Labelling of Chemicals;</p> <p>LC50: Lethal concentration, 50 percent;</p> <p>LD50: Lethal Dose, 50 percent;</p> <p>PNEC(s) - Predicted No Effect Concentration(s)</p> <p>RID - Regulations concerning the International Carriage of Dangerous Goods by Rail</p> <p>STOT - Specific Target Organ Toxicity (STOT) RE - Repeated Exposure (STOT) SE - Single Exposure</p>

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

Page 13 of 13

Trade name:	Aqua Maris Nasal Spray Made of 100% Natural Adriatic Sea Water for Cleaning the Nasal Mucosa, For Daily Use, Adults and Children, 50 ml		
Product code:	-	Date of compilation:	20.01.2023.
		Version:	3

16.3.	Key literature references and source of data:	MSDS for raw materials
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
	Classification	Classification procedure
	Aerosols	H229
16.5.	Relevant H statements (number and full text)	
	H:	H229 Pressurizes container: may burst if heated
16.6.	Training advice:	-
16.7.	Further information:	-

ANNEX: Exposure scenario resulting to Chemical safety assessment
-