

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

| | | | |
|---------------|---|----------------------|------------------------|
| Trade name: | Aqua Maris Plus, 30 ml - Aqua Maris Plus, 100% Natural Seawater Nose Mouisturizer for Nasal Mucosa Regeneration, Saline Nasal Mucosa Spray with d-panthenol (provitamin B5), Adults and Children, 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 Plus, 30 ml - Aqua Maris Plus, 100% Natural Seawater Nose Mouisturizer for Nasal Mucosa Regeneration, Saline Nasal Mucosa Spray with d-panthenol (provitamin B5), Adults and Children, 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, nasal spray |
| | 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 Plus, nasal spray solution, 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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|---|
| - |
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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 | |
| | - | |

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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: - |
| | 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. | Bundling, 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 at temperature not more than 30°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: Shelf-life: 36 months. |
| 7.3. | Specific end use(s) |
| | Recommendations: - |
| | Industrial sector specific solutions: - |

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| 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: | | | | |
| 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. | | |

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| | | |
|----------|---|--|
| | 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: | 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: | 5,0 – 6,5 | Ph.Eur. |
| | 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 | | |

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|---|
| Osmolality: 280 – 325 mOsmol/kg (Ph.Eur.) Sterility: solution must be sterile (Ph. Eur.) |
|---|

| 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. | | | | |

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| 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. | | | | | |
| | | | | | | |
| 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. | |

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|--|----------------------------------|
| 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 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 |

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| 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: | - |

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|--|---|
| 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: | - |

| 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: - |

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| 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 | 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 SpecDP000997/2 (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

-