

Date of issue: 2024-03-27

Revision 5

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

1.1 Product identifier	Unbuffered Saline Solution
REF no	REF 2001-X Wound Wash REF 2002-X* Wound and Eye Wash REF 2003-X* Eye Wash REF 2010-X* Nasal Spray, Isotonic REF 2011-X Nasal Spray, Aloe Vera and/or Chamomile, Hypertonic REF 2013-X* Ear Spray REF 2016-X Sparkling Nasal Spray Isotonic REF 2017-X Sparkling Nasal Spray, Hypertonic REF 2018-X* Nasal Spray, Hypertonic REF 2020-X Nasal Spray, Aloe Vera and/or Chamomile, Isotonic <i>*Does not apply to REF 2002-2, REF 2003-2, REF 2010-2, REF 2013-6, REF 2018-2</i>
1.2 Relevant identified uses of the substance or mixture and uses advised against	Medical device For external use only. Do not use for injections.
1.3 Details of the supplier of the safety data sheet	Aurena Laboratories AB
Address	Fjärrviksvägen 22 653 50 Karlstad, Sweden
Telephone	+46 54 44 44 800
E-mail /Homepage	info@aurenalabs.com / www.aurenalabs.com
1.4 Emergency telephone number	For poison information call, NHS 111 (England), NHS 24 (Scotland) or NHS Direct (Wales), in emergencies call 999.

**SECTION 2: Hazards identification**

**2.1 Classification of the substance or mixture**

Classification CLP (1272/2008/EC)

Not classified as dangerous according to CLP.- Not relevant, medical device. (Art.1.5d)

75/324/EEC, 2013/10/EC, 2016/2037/EC

Aerosol 3 H229

**2.2 Label elements**

**Pictogram**

None

**Signal word:** Warning

**Containing substances**

Sodium chloride

**Hazard statement Code(s)**

H229 Pressurised container: may burst if heated.

**Precautionary statements**

P102 Keep out of reach of children.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P251 Do not pierce or burn, even after use.

P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

Date of issue: 2024-03-27

Revision 5

**SECTION 2: Hazards identification**

**2.3 Other hazards**

This product is not considered to contain any substances that meet the criteria for classification as PBT or vPvB substances. Contains no fluorocarbons. Not flammable. For external use only. Do not use for injections. Does not contain an endocrine disruptor (EDC) in a concentration of  $\geq 0.1\%$ . Follow local regulations for safe disposal of contents/pressurized containers.

**SECTION 3: Composition/information on ingredients**

**3.2 Mixtures**

Components	CAS-No EC-No Reg-No	Conc.%	Hazard Class & Category Code*	Hazard statement Code(s)*
Ingredients not listed are classified as non-hazardous or at a concentration below reportable levels.	-	-	-	-

\* The full text of Hazard statement Codes are listed under section 16.

The classification is based on data from the chemical supplier and [www.echa.europa.eu](http://www.echa.europa.eu) (databases)

**SECTION 4: First aid measures**

**4.1 Description of first aid measures**

**General information**

In all cases of doubt, or when symptoms persist, seek medical advice.

**Inhalation**

Fresh air.

**Skin contact**

Not relevant. The product is used as eye, wound, nasal spray etc

**Eye contact**

Not relevant. The product is used as eye, wound, nasal spray etc

**Ingestion**

Not relevant. The product is used as eye, wound, nasal spray etc

**4.2 Most important symptoms and effects, both acute and delayed**

**Inhalation:** No symptoms are expected.

**Skin contact:** No symptoms are expected.

**Eye contact:** No symptoms are expected.

**Ingestion:** No symptoms are expected.

**4.3 Indication of any immediate medical attention and special treatment needed**

No additional information available

Date of issue: 2024-03-27

Revision 5

#### SECTION 5: Firefighting measures

##### 5.1 Extinguishing media

Foam, powder, sand, carbon dioxide, water spray, fog or mist.

##### 5.2 Special hazards arising from the substance or mixture

Aerosol. Pressurised container: may burst if heated. Do not breathe fumes. During fire, gases hazardous to health may be formed.

##### 5.3 Special protective equipment

Wear appropriate breathing apparatus and protective clothing.

##### Additional information

Cool endangered containers with water in case of fire.

Move containers from fire area if it can be done without risk.

#### SECTION 6: Accidental release measures

##### 6.1 Personal precautions, protective equipment and emergency procedures

Avoid sparks, flames, heat and smoking.

##### 6.2 Environmental precautions

Do not flush larger amounts into surface water or sanitary sewer system.

##### 6.3 Methods and material for containment and cleaning up

Small quantities may be wiped up with a cloth.

##### 6.4 Reference to other sections

See section 7 for proper handling and storage.

For personal protection see section 8.

For disposal of spillage, see section 13.

#### SECTION 7: Handling and storage

##### 7.1 Precautions for safe handling

Normal precautions taken when handling chemicals should be observed.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Comply with the health and safety at work laws.

##### 7.2 Conditions for safe storage, including any incompatibilities

For comfortable use, store between 15°C (59°F) and 30°C (86°F).

Storage/transport temperature: -20°C (-4°F) to 40°C (104°F).

Protect from direct sunlight

##### 7.3 Specific end use(s)

-

Date of issue: 2024-03-27

Revision 5

**SECTION 8: Exposure controls/personal protection**

**8.1 Control parameters**

**Appropriate engineering controls**

No specific

Swedish limit values (AFS 2018:1/2020:6) or limit values according to the European commission.

None established.

**8.2 Exposure controls**

**General protective and hygiene measures**

The usual precautionary measures for the handling of chemicals have to be observed.

**Individual protection measures, such as personal protective equipment**

Always consult a competent person/supplier when selecting personal protective equipment

**Respiratory protection**

None required for normal use.

**Eye protection**

None required for normal use.

**Hand protection**

None required for normal use.

**Body protection**

None required for normal use.

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

Physical state	Liquid.
Colour	Colourless
Odour	None
Melting point/freezing point	Not determined
Boiling point or initial boiling point and boiling range	~100
Flammability	Not determined
Lower and upper explosion limit	Not determined
Flash point	Not determined
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
pH	5 - 8
Kinematic viscosity	Not determined
Solubility	Soluble
Partition coefficient n-octanol/water	Not determined
Vapour pressure	5 bar ± 0,5
Density and/or relative density	Not determined
Relative vapour density	Not determined
Particle characteristics	Not relevant. The product is a liquid.

**9.2 Other information**

No additional information available.

Date of issue: 2024-03-27

Revision 5

**SECTION 10: Stability and reactivity**

**10.1 Reactivity**

Stable under recommended storage and handling conditions

**10.2 Chemical stability**

Stable under recommended storage and handling conditions.

**10.3 Possibility of hazardous reactions**

No known.

**10.4 Conditions to avoid**

Direct sunlight. Open flame.

**10.5 Incompatible materials**

No known.

**10.6 Hazardous decomposition products**

No known.

**SECTION 11: Toxicological information**

**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

See also section 4. (Most important symptoms and effects, both acute and delayed)

**Irritating/corrosive properties**

Not classified as irritant/corrosive according to CLP.

**Acute toxicity**

Not classified as acutely toxic according to CLP

**Toxicology data**

Information/data about this preparation is not available.

**STOT-single exposure -repeated exposure.**

None

**Routes of exposure**

Inhalation, eyes and skin, ingestion.

**Allergenic potential**

The product is not classified as allergenic by inhalation or skin contact.

**Carcinogenicity, mutagenicity and toxicity for reproduction**

This product is not classified as carcinogen, mutagen and toxic for reproduction.

**Aspiration hazard**

No aspiration hazard expected.

**11.2. Information on other hazards**

Does not contain an endocrine disruptor (EDC) in a concentration of  $\geq 0.1\%$ .

Date of issue: 2024-03-27

Revision 5

**SECTION 12: Ecological information**

This product is not classified as dangerous for the environment.

**12.1 Toxicity**

Information about this preparation is not available.

**12.2 Persistence and degradability**

Expected to be readily biodegradable.

**12.3 Bioaccumulative potential**

Not expected to bioaccumulate.

**12.4 Mobility in soil**

No information available.

**12.5 Results of PBT and vPvB assessment**

This product is not considered to contain any substances that meet the criteria for classification as PBT or vPvB substances.

**12.6 Endocrine disrupting properties**

Does not contain an endocrine disruptor (EDC) in a concentration of  $\geq 0.1\%$ .

**12.7 Other adverse effects**

No additional information available

**SECTION 13: Disposal considerations**

**13.1 Waste treatment methods**

This product or residues of this product are not classified as hazardous waste.

Dispose of in accordance with local authority requirements.

**Disposal of Packaging**

Empty packaging can be recycled, provided that all risks have been eliminated.

**SECTION 14: Transport information**

Classified as dangerous goods according to ADR/RID, IMDG, IATA-DGR.

**14.1 UN number or ID number**

1950

**14.2 UN proper shipping name**

Aerosols.

**14.3 Transport hazard class(es)**

2, ( Label 2,2)

**14.4 Packing group**

Not applicable

**14.5 Environmental hazards**

Marine Pollutant: No

**14.6 Special precautions for user**

-

**14.7 Maritime transport in bulk according to IMO instruments**

-

**Tunnel restriction code**

(E)

LQ

1L

'This product has a content that are less than 1 Liter

Limited Quantity are recommended to use

Date of issue: 2024-03-27

Revision 5

#### SECTION 15: Regulatory information

##### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The product is classified as a Medical Device class IIa according to MDR 2017/745/EEC.  
Classification according to CLP (1272/2008/EC) - Not relevant, medical device. (Art.1.5d)  
Reach (1907/2006/EC), 75/324/EEC, 2013/10/EC, 2016/2037/EC

##### 15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

#### SECTION 16: Other information

##### The full text of Hazard statement codes listed under section 3:

-

This information is provided for health and safety assessments by an industrial user. Reference should be made to any relevant local or national health, safety, and environmental legislation.

##### Sources

Safety data sheet provided by the manufacturer.  
CLP-regulation, [www.kemi.se](http://www.kemi.se), EH40/2005. [www.echa.europa.eu](http://www.echa.europa.eu) (Databases)

##### Revision 1: 2024-03-27

Safety data sheet according to Regulation (EC) No. 1907/2006 annex II and EC/2020/878.

##### Abbreviations explanations

ADR::International Carriage of Dangerous Goods by Road  
BCF: Bio Concentration Factor  
CAS-nr: Chemical Abstracts Service number  
DNEL: Derived No Effect Level  
EC<sub>50</sub>: Effect Concentration  
EG-nr: A substance number i Einescs, Elincs or in No-Longer Polymers List.  
IMDG: International Maritime Dangerous Goods Code.  
LC<sub>50</sub>: Lethal Concentration  
LD<sub>50</sub>: Lethal Dose  
IC<sub>50</sub>: Median Inhibition Concentration  
NOEC: No Observed Effect Concentration  
NOAEL: No observed adverse effect level  
PBT-substance: Persistent, Bio accumulative and Toxic substances.  
PNEC: Predicted No Effect Concentration  
vPvB-substance: Very persistent and Very Bio accumulative substances.