

Phosphate Buffered Saline Solution

Date of issue: 2019-03-25

Revision 5

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

1.1 Product identifier	Phosphate Buffered Saline Solution
REF no	REF 1001-X Wound wash, REF 1002-X Wound & Eye Wash, REF 1003-X Eye Wash, REF 1013-X Ear Spray, REF 1010-X Nasal Spray, Isotonic, REF 1018-X Nasal Spray, Hypertonic REF 1011-X Nasal Spray with Aloe & Chamomile, Hypertonic. REF 1020-X Nasal Spray with Aloe & Chamomile, isotonic, REF 1012-X Nasal Spray with Xylitol REF 1014-X Throat Spray with Aloe/Chamomile, REF 1015-X Nebuliser Saline Solution
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	Swedish poison information +46(0)10-4566750 In less acute cases during office hours +46(0)10-4566700

S SECTION 2: Hazards identification

2.1 Classification

Classification CLP (1272/2008/EC)

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

75/324/EEG, 2013/10/EU

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.

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 mix with any other fluid except as directed. Do not use for injections.

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SECTION 3: Composition/information on ingredients

3.2 Chemical composition: Mixture

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 (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

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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.

5.4 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

Store in temperatures below 30°C

Protect from direct sunlight

7.3 Specific end use(s)

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Appropriate engineering controls

No specific

Swedish limit values (AFS 2015:7) 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

Form:	Liquid.
Colour:	Colourless
Odour:	None
Odour threshold:	Not determined
pH :	7-8
Melting point/freezing point (°C):	Not determined
Initial boiling point and boiling range(°C):	~ 100
Flash point(°C):	Not determined
Evaporation rate(°C):	Not determined
Flammability (solid, gas):	Non-flammable
Upper flammability or explosive limits:	Not determined
Lower flammability or explosive limits:	Not determined
Vapour pressure(20°C):	5 bar ± 0,5
Vapour density:	Not determined
Relative density:	Not determined
Solubility in water:	Soluble
Partition coefficient: n-octanol/water:	Not determined
Auto-ignition temperature:	Not determined
Decomposition temperature:	Not determined
Viscosity:	Not determined
Explosive properties:	Not determined
Oxidising properties:	Not determined

9.2 Other information

No additional information available.

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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 toxicological effects

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

Inhalation

Not irritating.

Skin contact

Not irritating.

Eye contact

Not irritating.

Ingestion

Not irritating.

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.

Other information

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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 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, DGR.

14.1 UN 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

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14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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Tunnel restriction code

(E)

LQ

1L

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

Limited Quantity are recommended to use

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SECTION 15: Regulatory information

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

The product is classified as a Sterile Medical device class II a and wound wash Class II b according to MDD 93/42 EEC.

Classification according to CLP (1272/2008/EC) - Not relevant, medical device. (Art.1.5d)

Reach (1907/2006/EC), 75/324/EEG, 2013/10/EU.

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:

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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, www.echa.europa.eu (Databases)

Revision 1: 2015-04-16

Revision 2: 2016-08-10

Revision 3: 2017-09-13

Revision 4: 2018-01-31

Revision 5: 2019-03-25

Safety data sheet according to Regulation (EC) No. 1907/2006 and (EG) 830/2015.

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

EC₅₀: Effect Concentration

EG-nr: A substance number i Einescs, Elincs or in No-Longer Polymers List.

IMDG: International Maritime Dangerous Goods Code.

LC₅₀: Lethal Concentration

LD₅₀: Lethal Dose

IC₅₀: 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.