

## Safety Data Sheet

### WOUND AND EYEWASH SPRAY 0.9 % Phosphate buffered NaCl solution

Issued: 15/11/2019  
Version: 1.0.0

#### SECTION 1: Identification of the substance/preparation and of the company/undertaking

##### 1.1. Product identifier

**Trade name:** WOUND AND EYEWASH SPRAY 0.9 % Phosphate buffered NaCl solution

**Other Information:** The product is a medical device covered by Council Directive 93/42/EEC on medical devices. Consequently, the product does not require a safety data sheet and therefore this data sheet does not fully meet the statutory requirements for a safety data sheet.

##### Article no

Article no	Description
4556	200 ml

##### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended uses:** Wound and eyewash spray.  
This safety data sheet contains general information concerning the chemical, but specific instructions and guidelines are indicated on the product label and in the instructions for use.

##### 1.3. Details of the supplier of the safety data sheet

###### Manufacturer

**Company:** Aurena Laboratories AB

**Address:** Fjärrviksvägen 22

**Zip code:** 653 50

**City:** Karlstad

**Country:** SWEDEN

###### Distributor

**Company:** Plum A/S

**Address:** Frederik Plums Vej 2

**Zip code:** 5610

**City:** Assens

**Country:** DENMARK

##### 1.4. Emergency Telephone Number

Members of the public: 111 (NHS 111 (Scotland: NHS 24)) The emergency telephone is open 24 hours.

#### SECTION 2: Hazards identification

##### 2.1. Classification of the substance or mixture

**CLP-classification:** Aerosol 3;H229

**Most serious harmful effects:** Pressurised container: May burst if heated.

##### 2.2. Label elements

**Signal word:** Warning

**H-phrases**

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#### P-phrases

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 Protect from sunlight.

P412 Do not expose to temperatures exceeding 50°C/122°F.

#### 2.3. Other hazards

PBT/vPvB: Not relevant for inorganic substances.

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

Contains no substances subject to reporting requirements

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

**Inhalation:** The product does not release hazardous vapours. Seek fresh air.

**Ingestion:** Not applicable. Seek medical advice in case of discomfort.

**Skin contact:** The product is intended for first aid.

**Eye contact:** The product is intended for first aid.

**General:** When obtaining medical advice, show the safety data sheet or label.

#### 4.2. Most important symptoms and effects, both acute and delayed

No hazards.

#### 4.3. Indication of any immediate medical attention and special treatment needed

No special immediate treatment required. Treat symptoms.

### SECTION 5: Fire-fighting measures

#### 5.1. Extinguishing media

**Suitable extinguishing media:** Extinguish with powder, foam, carbon dioxide or water mist. Use water or water mist to cool non-ignited stock.

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

CAUTION! Aerosol containers may explode.  
Heating will cause a rise in pressure in packaging with a risk of bursting.  
Hazardous fumes are formed in fire conditions.

#### 5.3. Advice for fire-fighters

If there is a risk of exposure to vapour and flue gases, a self-contained breathing apparatus must be worn.  
Move containers from danger area if it can be done without risk. Avoid inhalation of vapour and flue gases - seek fresh air.

### SECTION 6: Accidental release measures

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

**For non-emergency personnel:** Keep unnecessary personnel away. Smoking and naked flames prohibited.

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**For emergency responders:** In addition to the above: Normal protective clothing equivalent to EN 469 is recommended.

#### 6.2. Environmental precautions

Avoid unnecessary release to the environment.

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

Contain and absorb spill with sand or other absorbent material and transfer to suitable waste containers. Wipe up minor spills with a cloth.

#### 6.4. Reference to other sections

See section 8 for type of protective equipment. See section 13 for instructions on disposal.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Smoking and naked flames prohibited.

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

Storage temperature: 10-30 °C.

Pressurized container: Protect from sunlight and do not expose to temperatures exceeding 50°C.

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

None.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

**Occupational exposure limit:** Contains no substances subject to reporting requirements

**Legal basis:** EH40/2005 Workplace exposure limits. Last amended August 2018.

**Other Information:** The product requires no special exposure control.

#### 8.2. Exposure controls

**Appropriate engineering controls:** Wear the personal protective equipment specified below.

**Personal protective equipment, eye/face protection:** Not required.

**Personal protective equipment, skin protection:** Not required.

**Personal protective equipment, hand protection:** Not required.

**Personal protective equipment, respiratory protection:** Not required.

**Environmental exposure controls:** Ensure compliance with local regulations for emissions.

### SECTION 9: Physical and chemical properties

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#### 9.1. Information on basic physical and chemical properties

Parameter	Value/unit
State	Aerosol
Colour	Clear Colourless
Odour	Neutral
Solubility	Soluble in the following: Water.
Explosive properties	Non-explosive
Oxidising properties	N/A

Parameter	Value/unit	Remarks
pH (solution for use)	No data	
pH (concentrate)	6 - 8	
Melting point	No data	
Freezing point	No data	
Initial boiling point and boiling range	~ 100 °C	
Flash Point	No data	
Evaporation rate	No data	
Flammability (solid, gas)	No data	
Flammability limits	No data	
Explosion limits	No data	
Vapour pressure	~ 5000 mbar	
Vapour density	No data	
Relative density	No data	
Partition coefficient n-octanol/water	No data	
Auto-ignition temperature	No data	
Decomposition temperature	No data	
Viscosity	No data	
Odour threshold	No data	

#### 9.2 Other information

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Not reactive.

#### 10.2. Chemical stability

The product is stable when used in accordance with the supplier's directions.

#### 10.3. Possibility of hazardous reactions

None known.

#### 10.4. Conditions to avoid

Avoid direct sunlight. Avoid heating and contact with ignition sources.

#### 10.5. Incompatible materials

None known.

#### 10.6. Hazardous decomposition products

None known.

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#### SECTION 11: Toxicological information

##### 11.1. Information on toxicological effects

<b>Acute toxicity - oral:</b>	No hazards. The product does not have to be classified.
<b>Acute toxicity - dermal:</b>	The product does not have to be classified.
<b>Acute toxicity - inhalation:</b>	The product does not have to be classified.
<b>Skin corrosion/irritation:</b>	The product does not have to be classified.
<b>Serious eye damage/eye irritation:</b>	The product does not have to be classified.
<b>Respiratory sensitisation or skin sensitisation:</b>	The product does not have to be classified.
<b>Germ cell mutagenicity:</b>	The product does not have to be classified.
<b>Carcinogenic properties:</b>	The product does not have to be classified.
<b>Reproductive toxicity:</b>	The product does not have to be classified.
<b>Single STOT exposure:</b>	The product does not release hazardous vapours. The product does not have to be classified.
<b>Repeated STOT exposure:</b>	The product does not have to be classified.
<b>Aspiration hazard:</b>	The product does not have to be classified.

#### SECTION 12: Ecological information

##### 12.1. Toxicity

The product does not have to be classified.

##### 12.2. Persistence and degradability

Expected to be biodegradable.

##### 12.3. Bioaccumulative potential

No bioaccumulation expected.

##### 12.4. Mobility in soil

Test data are not available.

##### 12.5. Results of PBT and vPvB assessment

No assessment required, as the product contains inorganic matter only.

##### 12.6. Other adverse effects

None known.

#### SECTION 13: Disposal considerations

##### 13.1. Waste treatment methods

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Do not dispose of aerosol sprays in refuse collection, even when empty. The sprays must be sent to the municipal chemical waste collection facility.

**Category of waste:** 16 05 05 gases in pressure containers other than those mentioned in 16 05 04

#### SECTION 14: Transport information

##### Land transport (ADR/RID)

<b>14.1. UN-No.:</b>	1950	<b>14.4. Packing group:</b>	
<b>14.2. UN proper shipping name:</b>	AEROSOLS	<b>14.5. Environmental hazards:</b>	The product should not be labelled as an environmental hazard (symbol: fish and tree).
<b>14.3. Transport hazard class(es):</b>	2.2		
<b>Hazard label(s):</b>	2.2		
<b>Hazard identification number:</b>		<b>Tunnel restriction code:</b>	E

##### Inland water ways transport (ADN)

<b>14.1. UN-No.:</b>	1950	<b>14.4. Packing group:</b>	
<b>14.2. UN proper shipping name:</b>	AEROSOLS	<b>14.5. Environmental hazards:</b>	The product should not be labelled as an environmental hazard (symbol: fish and tree).
<b>14.3. Transport hazard class(es):</b>	2.2		
<b>Hazard label(s):</b>	2.2		
<b>Transport in tank vessels:</b>			

##### Sea transport (IMDG)

<b>14.1. UN-No.:</b>	1950	<b>14.4. Packing group:</b>	
<b>14.2. UN proper shipping name:</b>	AEROSOLS	<b>14.5. Environmental hazards:</b>	The product is not a Marine Pollutant (MP).
<b>14.3. Transport hazard class(es):</b>	2.2	<b>Environmental Hazardous Substance Name(s):</b>	
<b>Hazard label(s):</b>	2.2		
<b>EmS:</b>	F-D, S-U	<b>IMDG Code segregation group:</b>	- None -

##### Air transport (ICAO-TI / IATA-DGR)

<b>14.1. UN-No.:</b>	1950	<b>14.4. Packing group:</b>	
<b>14.2. UN proper shipping name:</b>	AEROSOLS, NON-FLAMMABLE	<b>14.5. Environmental hazards:</b>	
<b>14.3. Transport hazard class(es):</b>	2.2		
<b>Hazard label(s):</b>	2.2		

##### 14.6. Special precautions for user

None.

##### 14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable.

**Other Information:** May be transported in limited quantities if placed in outer packaging according to ADR 3.4, when max. 1 liter/inner packaging and max. 30 kg total gross mass. Shrink- or stretch wrapped trays may be used and shall not exceed 20 kg total gross mass/tray.  
May be transported in limited quantities if placed in outer packaging according to IMDG 3.4, when max. 1 liter/inner packaging and max. 30 kg total gross mass. Shrink- or stretch

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wrapped trays may be used and shall not exceed 20 kg total gross mass/tray.

#### SECTION 15: Regulatory information

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

**Special Provisions:** The product is covered by Council Directive 93/42/EEC on medical devices. Consequently, the product is not covered by Regulation (EC) no 1272/2008 of the European Parliament and the Council on classification, labelling and packaging of substances and mixtures. cf. Article 1 (5d). Regulation 1907/2006 EC of the European Parliament and Council on registration, evaluation, authorisation and restriction of chemicals (REACH) states in Article 2 (6c) that section IV regarding requirements for safety data sheets does not apply to medical equipment. Consequently, there is no requirement stating that the product mentioned above should be provided with a safety data sheet to meet the requirements of the above regulation.  
European Agreement concerning the International Carriage of Dangerous Goods by Road (UN ADR 2019).  
COUNCIL DIRECTIVE of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (75/324/EEC)

##### 15.2. Chemical Safety Assessment

**Other Information:** Chemical safety assessment has not been performed.

#### SECTION 16: Other information

##### Version history and indication of changes

Version	Revision date	Responsible	Changes
1.0.0	15/11/2019	Plum A/S (SKP)	New

**Abbreviations:** DNEL: Derived No Effect Level  
PNEC: Predicted No Effect Concentration  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: Very Persistent and Very Bioaccumulative  
STOT: Specific Target Organ Toxicity

**Other Information:** Expiry date for unopened, sealed bottles: At least three years from the manufacturing date. Additional information can be obtained by contacting info@plum.dk or by telephone +45 6471 2112.

**Vendor notes:** If defects or adverse side effects are found during use, please report such defects or side effects to Plum A/S, info@plum.dk by phone +45 6471 2112, so that the necessary remedies can be initiated and the obligation to report serious adverse effects according to Appendix VII item 4 of the Directive can be observed. Serious adverse effects should always be reported to the Board of Health in the state in which the side effect has occurred.

**Date:** 15/11/2019

##### List of relevant H-statements

H229 Pressurised container: May burst if heated.

##### SDS is prepared by

**Company:** Plum A/S  
**Address:** Frederik Plums Vej 2  
**Zip code:** 5610

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