

## Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH)

Version 2, Revision Date: 10-JUL-2023

Print Date: 10-JUL-2023

### **SECTION 1 Identification of the Substance/Mixture and of the Company/Undertaking**

#### **1.1. Product identifier**

Product Names: Penicillin-Streptomycin-Nystatin Solution 100X  
Product Options: contains 10,000 units/ml of penicillin, 10 mg/ml streptomycin and 1250 units/ml Nystatin in 0.85 % saline. Sterile filtered.  
Product Code: RAL-007-100ML  
REACH No. This product is a mixture. REACH Registration Number see section 3.

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

Identified uses: Laboratory chemicals, Manufacture of substances

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

Company: Serana Europe GmbH  
Dorfstrasse 17A  
14641 Pessin  
Germany  
Phone: +49 (0)332 3785 9253  
E-Mail: info@serana-europe.com

#### **1.4. Emergency telephone number**

Emergency Phone: Regular Office Hours +49 (0)332 3785 9253

### **SECTION 2 Hazards Identification**

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

**Classification according to Regulation (EC) No 1272/2008**

Specific target organ toxicity - repeated exposure (Category 2), H373

For the full text of the H-Statements mentioned in this Section, see Section 16.

#### **2.2. Label elements**

**CLP Regulation (EC) No 1272/2008:**

Pictogram



Signal word

Warning

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Hazard statement(s)

H373: May cause damage to organs through prolonged or repeated exposure.

Precautionary statement(s)

P260: Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.

P314: Get medical advice/ attention if you feel unwell.

P501: Dispose of contents/ container to an approved waste disposal plant.

Supplemental Hazard Statements

None

Contains: Potassium penicillin G. May produce an allergic reaction.

### Reduced Labeling (<= 125 ml)

Pictogram



Signal word

Warning

Hazard statement(s)

None

Precautionary statement(s)

None

Supplemental Hazard Statements

None

### 2.3. Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Caution: Physiologically highly active substance. The substance must be handled with the care required for hazardous materials.

## SECTION 3 Composition/Information on Ingredients

### 3.1. Substances

Non-applicable

### 3.2. Mixtures

**Chemical characterization:** water-based mixture of antibiotic compounds.

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Chemical name	Identification	Classification	Concentration
Streptomycin sulphate*	CAS: 3810-74-0 EC: 223-286-0	Acute Tox. 4. Repr. 2; H302, H361fd	10,000 µg/ml
Penicillin G sodium salt*	CAS: 69-57-8 EC: 200-710-2	Skin Sens. 1; H317	10,000 units/ml
Nystatin dihydrate*	CAS: 1400-61-9 EC: 215-749-0	-	1250U/ml

\* A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline. For the full text of the H-Statements mentioned in this Section, see Section 16.

**SECTION 4 First Aid Measures****4.1. Description of first aid measures**

In either case, seek medical attention if the symptoms get worse or persist. showing the SDS of this product.

**If inhaled**

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

**In case of skin contact**

Take off immediately all contaminated clothing. Wash off with soap and plenty of water.

**In case of eye contact**

Flush eyes with water as a precaution. Call in ophthalmologist. Remove contact lenses.

**If swallowed**

Never give anything by mouth to an unconscious person. Rinse mouth with water. (two glasses at most). Consult a physician.

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

Acute and delayed effects are listed in section 2 and 11.

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

No data available.

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### **SECTION 5 Firefighting Measures**

#### **5.1. Extinguishing media**

##### **Suitable extinguishing media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment (e.g. ABC powder).

##### **Unsuitable extinguishing media**

For this substance/mixture no limitations of extinguishing agents are given.

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

Not combustible.

Fire may cause evolution of: nitrogen oxides

Sulfur oxides

Ambient fire may liberate hazardous vapours.

#### **5.3. Advice for firefighters**

Wear self-contained breathing apparatus for fire-fighting if necessary. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

#### **5.4. Further information**

Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

### **SECTION 6 Accidental Release Measures**

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

Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. For personal protection see section 8.

#### **6.2. Environmental precautions**

Do not let the product enter drains.

#### **6.3. Methods and materials for containment and cleaning up**

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area.

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### 6.4. Reference to other sections

For disposal see section 13

## SECTION 7 Handling and Storage

### 7.1. Precautions for safe handling

#### Advice on safe handling

Work under hood. Do not inhale substance/mixture. Avoid generation of vapours/aerosols.

#### Hygiene measures

Change contaminated clothing. Preventive skin protection recommended. Wash hands after working with substance. For precautions see section 2.2.

For precautions see section 2.

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

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Recommended storage temperature: -5 to -20 °C

### 7.3. Specific end uses

Apart from the uses mentioned in section 1.2. no other specific uses are stipulated.

## SECTION 8 Exposure Controls/Personal Protection

### 8.1. Control parameters

Ingredients with workplace control parameters

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

General industrial hygiene practice. Ensure adequate ventilation, especially in confined areas.

#### 8.2.2. Individual protection measures

##### Eye/face protection

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Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

### **Skin protection**

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves.

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: > 480 min

### **Body protection**

Impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

### **Respiratory protection**

Required when vapours/aerosols are generated. Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system. Recommended Filter type: Filter type ABEK The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

### **8.2.3. Environmental expose controls**

Do not let product enter drains.

## **SECTION 9 Physical and Chemical Properties**

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

Appearance:                      Form: liquid

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Odor: No data available.  
pH: No data available.  
Water solubility: No data available.

### 9.2. Other safety information

No data available

## **SECTION 10 Stability and Reactivity**

### 10.1. Reactivity

No data available.

### 10.2. Chemical stability

Stable under recommended storage conditions.

### 10.3. Possibility of hazardous reactions

No data available.

### 10.4. Conditions to avoid

No data available.

### 10.5. Incompatible materials

Avoid alkalis or strong bases and strong acids.

### 10.6. Hazardous decomposition products

Other decomposition products: No data available.

## **SECTION 11 Toxicological Information**

### 11.1. Information on toxicological effects

#### Mixture

#### Acute toxicity

Acute toxicity estimate Oral - > 2.000 mg/kg (Calculation method)

Inhalation No data available

Dermal No data available

#### Skin corrosion/irritation

No data available

#### Serious eye damage/eye irritation

No data available

#### Respiratory or skin sensitization

Mixture may produce an allergic reaction.

#### Germ cell mutagenicity

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No data available

### **Carcinogenicity**

No data available

### **Reproductive toxicity**

No data available

### **Specific target organ toxicity - single exposure**

No data available

### **Specific target organ toxicity - repeated exposure**

Mixture may cause damage to organs through prolonged or repeated exposure.

### **Aspiration hazard**

No data available

### **Components**

#### **Streptomycin sulphate**

#### **Acute toxicity**

LD50 Oral - Rat - 430 mg/kg

Remarks: (RTECS)

Inhalation: No data available

Dermal: No data available

#### **Skin corrosion/irritation**

No data available

#### **Serious eye damage/eye irritation**

No data available

#### **Respiratory or skin sensitization**

No data available

#### **Germ cell mutagenicity**

No data available

#### **Carcinogenicity**

No data available

#### **Reproductive toxicity**

Suspected of damaging the unborn child. Suspected of damaging fertility.

#### **Specific target organ toxicity - single exposure**

No data available

#### **Specific target organ toxicity - repeated exposure**

No data available

#### **Aspiration hazard**

No data available



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### **Penicillin G sodium salt**

#### **Acute toxicity**

LD50 Oral - Rat - 6916 mg/kg

Remarks: (RTECS)

Inhalation: No data available

Dermal: No data available

#### **Skin corrosion/irritation**

No data available

#### **Serious eye damage/eye irritation**

No data available

#### **Respiratory or skin sensitization**

May cause sensitization by skin contact.

#### **Germ cell mutagenicity**

Test Type: Ames test Test

System: *Salmonella typhimurium*

Result: negative

Remarks: (RTECS)

#### **Carcinogenicity**

No data available

#### **Reproductive toxicity**

No data available

#### **Specific target organ toxicity - single exposure**

No data available

#### **Specific target organ toxicity - repeated exposure**

No data available

#### **Aspiration hazard**

No data available

### **Nystatin dihydrate**

#### **Acute toxicity**

No data available

Inhalation: No data available

Dermal: No data available

#### **Skin corrosion/irritation**

No data available

#### **Serious eye damage/eye irritation**

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No data available

**Respiratory or skin sensitization**

No data available

**Germ cell mutagenicity**

No data available

**Carcinogenicity**

No data available

**Reproductive toxicity**

No data available

**Specific target organ toxicity - single exposure**

No data available

**Specific target organ toxicity - repeated exposure**

No data available

**Aspiration hazard**

No data available

### 11.2 Additional Information

Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

## SECTION 12 Ecological Information

### 12.1. Toxicity

**Mixture**

No data available.

### 12.2. Persistence and degradability

No data available.

### 12.3. Bioaccumulative potential

No data available.

### 12.4. Mobility in soil

No data available.

### 12.5. Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6. Other adverse effects

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No data available.

### Components

#### Streptomycin sulphate

Toxicity to fish                      LC50 - Oncorhynchus mykiss (rainbow trout) - > 180 mg/l - 96 h  
Remarks: (Lit.)

Toxicity to daphnia and  
other aquatic invertebrates              EC50 - Ceriodaphnia (water flea) - 487 mg/l - 48 h  
Remarks: (Lit.)

#### Sodium penicillin G

Toxicity to daphnia and  
other aquatic invertebrates              EC50 - Daphnia magna (Water flea) - > 1.000 mg/l - 48 h  
Remarks: (ECOTOX Database)

#### Nystatin dihydrate

No data available

## SECTION 13    Disposal Considerations

### 13.1.    Waste treatment methods

#### Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

#### Contaminated packaging

Dispose as used product.

## SECTION 14    Transport Information

### 14.1.    UN-number

ADR/RID: - IMDG: - IATA: -

### 14.2.    UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

### 14.3.    Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

### 14.4.    Packaging group

ADR/RID: - IMDG: - IATA: -

### 14.5.    Environmental hazards

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ADR/RID: no IMDG Marine pollutant: no IATA: no

### 14.6. Special precautions for user

No data available.

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

No data available.

## SECTION 15 Regulatory Information

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

#### Other regulations

Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where applicable. Take note of Dir 94/33/EC on the protection of young people at work.

### 15.2. Chemical safety assessment

For this product a chemical safety assessment was not carried out.

## SECTION 16 Other Information

### Full text of H-Statements referred to under sections 2 and 3

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.

### Further Information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Serana Europe GmbH shall not be held liable for any damage resulting from handling or from contact with the above product.

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- a) Revised Version:  
First Version, date of issue: 28-JUN-2022
- b) List of Abbreviations:  
ADR: European agreement concerning the international carriage of dangerous goods by road  
IMDG: International maritime dangerous goods code  
IATA: International air transport association  
IBC: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk  
vPvB: very persistent and very bioaccumulative  
LD50: Lethal Dose 50  
LC50: Lethal Concentration 50
- c) References:  
<http://echa.europa.eu>  
<http://eur-lex.europa.eu>
- d) Methods for evaluation of mixtures according to Article 9 of Regulation (EC) No 1272/2008:  
No data available.
- e) List of hazard and precautionary statements:  
If applicable, please see section 2.
- f) Training advice:  
General laboratory instructions are required. No special training advised.

- END OF SAFETY DATA SHEET -