# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

Public

ORGANON

# Gentamicin (8%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 30.09.2023 |
|---|---|---|---|
| 4.0 | 06.04.2024 | 1847027-00016 | Date of first issue: 25.07.2017 |

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

### 1.1 Product identifier

Trade name : Gentamicin (8%) Injection Formulation

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

Use of the Sub-stance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

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

Company : Organon & Co.
30 Hudson Street, 33nd floor
07302 Jersey City, New Jersey, U.S.A

Telephone : +1-551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

### 1.4 Emergency telephone number

+1-215-631-6999

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008)**

| | |
|---|---|
| Reproductive toxicity, Category 1A | H360D: May damage the unborn child. |
| Specific target organ toxicity - repeated exposure, Category 2 | H373: May cause damage to organs through prolonged or repeated exposure. |
| Short-term (acute) aquatic hazard, Category 1 | H400: Very toxic to aquatic life. |
| Long-term (chronic) aquatic hazard, Category 2 | H411: Toxic to aquatic life with long lasting effects. |

### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :

Signal word : Danger

Hazard statements :

| | |
|---|---|
| H360D | May damage the unborn child. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H410 | Very toxic to aquatic life with long lasting effects. |

Precautionary statements :

**Prevention:**

| | |
|---|---|
| P201 | Obtain special instructions before use. |
| P273 | Avoid release to the environment. |
| P280 | Wear protective gloves/ protective clothing/ eye protection/ face protection. |

**Response:**

| | |
|---|---|
| P308 + P313 | IF exposed or concerned: Get medical advice/ attention. |
| P391 | Collect spillage. |

**Storage:**

| | |
|---|---|
| P405 | Store locked up. |

**Hazardous components which must be listed on the label:**

Gentamicin

### 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.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

**Components**

| Chemical name | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration (% w/w) |
|---|---|---|---|
| Gentamicin | 1403-66-3<br>215-765-8 | Repr. 1A; H360D<br>STOT RE 1; H372 (Kidney, inner ear)<br>Aquatic Acute 1; H400 | 8 |

| | | | |
|---|---|---|---|
| | | Aquatic Chronic 1; H410<br>M-Factor (Acute aquatic toxicity): 100<br>M-Factor (Chronic aquatic toxicity): 1 | |
| Benzyl alcohol | 100-51-6<br>202-859-9<br>603-057-00-5 | Acute Tox. 4; H302<br>Acute Tox. 4; H332<br>Eye Irrit. 2; H319<br>Acute toxicity estimate<br>Acute oral toxicity: 1,620 mg/kg | 1.5 |

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

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

Risks : May damage the unborn child.
May cause damage to organs through prolonged or repeated

exposure.

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

Treatment : Treat symptomatically and supportively.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

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

Specific hazards during fire-fighting : Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

## SECTION 6: Accidental release measures

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

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages

cannot be contained.

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

| | | |
|---|---|---|
| Methods for cleaning up | : | Soak up with inert absorbent material.<br>For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.<br>Clean up remaining materials from spill with suitable absorbent.<br>Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

| | | |
|---|---|---|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe mist or vapours.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.<br>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

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

| | | |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national |

regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

**Occupational Exposure Limits**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---|---|---|---|---|
| Gentamicin | 1403-66-3 | TWA | 0.1 mg/m3 (OEB 2) | Internal |
| | Further information: OTO | | | |

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|---|---|---|---|---|
| Benzyl alcohol | Workers | Inhalation | Long-term systemic effects | 22 mg/m3 |
| | Workers | Inhalation | Acute systemic effects | 110 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 8 mg/kg bw/day |
| | Workers | Skin contact | Acute systemic effects | 40 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 5.4 mg/m3 |
| | Consumers | Inhalation | Acute systemic effects | 27 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 4 mg/kg bw/day |
| | Consumers | Skin contact | Acute systemic effects | 20 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 4 mg/kg bw/day |
| | Consumers | Ingestion | Acute systemic effects | 20 mg/kg bw/day |

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

| Substance name | Environmental Compartment | Value |
|---|---|---|
| Benzyl alcohol | Fresh water | 1 mg/l |

| | | |
|---|---|---|
| | Marine water | 0.1 mg/l |
| | Intermittent use/release | 2.3 mg/l |
| | Sewage treatment plant | 39 mg/l |
| | Fresh water sediment | 5.27 mg/kg |
| | Marine sediment | 0.527 mg/kg |
| | Soil | 0.456 mg/kg |

### 8.2 Exposure controls

**Engineering measures**

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

**Personal protective equipment**

Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection
Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : colourless

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

| | | |
|---|---|---|
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Flash point | : | > 93.3 °C |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | No data available |
| Relative density | : | No data available |
| Density | : | No data available |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle size | : | No data available |

### 9.2 Other information

| | | |
|---|---|---|
| Explosives | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Evaporation rate | : | No data available |
| Molecular weight | : | No data available |

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

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

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

**Components:**

**Gentamicin:**

Acute oral toxicity : LD50 (Rat): 8,000 - 10,000 mg/kg

LD50 (Mouse): 10,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration) : LD50 (Rat): 67 - 96 mg/kg
Application Route: Intravenous

LD50 (Rat): 371 - 384 mg/kg
Application Route: Intramuscular

LDLo (Monkey): 30 mg/kg
Application Route: Intravenous

**Benzyl alcohol:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 1,620 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 4.178 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: OECD Test Guideline 403 |

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Gentamicin:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Mild skin irritation |

**Benzyl alcohol:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 404 |
| Result | : | No skin irritation |

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Gentamicin:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Mild eye irritation |

**Benzyl alcohol:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 405 |
| Result | : | Irritation to eyes, reversing within 21 days |

**Respiratory or skin sensitisation**

**Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:**

**Gentamicin:**

| | | |
|---|---|---|
| Remarks | : | No data available |

**Benzyl alcohol:**

| | | |
|---|---|---|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Method | : | OECD Test Guideline 406 |
| Result | : | negative |

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Gentamicin:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Result: equivocal |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intravenous injection<br>Result: negative |

**Benzyl alcohol:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Result: negative |

**Carcinogenicity**

Not classified based on available information.

**Components:**

**Gentamicin:**

| | | |
|---|---|---|
| Carcinogenicity - Assessment | : | No data available |

**Benzyl alcohol:**

| | | |
|---|---|---|
| Species | : | Mouse |

| | | |
|---|---|---|
| Application Route | : | Ingestion |
| Exposure time | : | 103 weeks |
| Method | : | OECD Test Guideline 451 |
| Result | : | negative |

**Reproductive toxicity**

May damage the unborn child.

**Components:**

**Gentamicin:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Fertility: NOAEL: 20 mg/kg body weight<br>Result: No significant adverse effects were reported |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rabbit<br>Developmental Toxicity: NOAEL: 3.6 mg/kg body weight<br>Result: No embryo-foetal toxicity<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Intraperitoneal<br>Developmental Toxicity: LOAEL: 75 mg/kg body weight<br>Result: Embryo-foetal toxicity<br><br>Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Intraperitoneal<br>Developmental Toxicity: LOAEL: 10 mg/kg body weight<br>Result: foetal mortality, No malformations were observed.<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Intraperitoneal<br>Developmental Toxicity: LOAEL: 50 mg/kg body weight<br>Result: foetal mortality, No malformations were observed. |
| Reproductive toxicity - Assessment | : | Positive evidence of adverse effects on development from human epidemiological studies. |

**Benzyl alcohol:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Ingestion |

Result: negative

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

May cause damage to organs through prolonged or repeated exposure.

**Components:**

**Gentamicin:**

| | | |
|---|---|---|
| Target Organs | : | Kidney, inner ear |
| Assessment | : | Causes damage to organs through prolonged or repeated exposure. |

**Repeated dose toxicity**

**Components:**

**Gentamicin:**

| | | |
|---|---|---|
| Species | : | Dog |
| LOAEL | : | 3 mg/kg |
| Application Route | : | Intramuscular |
| Exposure time | : | 12 Months |
| Target Organs | : | Kidney |
| Symptoms | : | Vomiting, Salivation |

| | | |
|---|---|---|
| Species | : | Monkey |
| LOAEL | : | 50 mg/kg |
| Application Route | : | Subcutaneous |
| Exposure time | : | 3 Weeks |
| Target Organs | : | Kidney, inner ear |

| | | |
|---|---|---|
| Species | : | Monkey |
| LOAEL | : | 6 mg/kg |
| Application Route | : | Intramuscular |
| Exposure time | : | 3 Weeks |
| Target Organs | : | Blood, Kidney, inner ear, Liver |

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 5 mg/kg |
| LOAEL | : | 10 mg/kg |
| Application Route | : | Intramuscular |
| Exposure time | : | 52 Weeks |
| Target Organs | : | Kidney, Blood |

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 12.5 mg/kg |
| LOAEL | : | 50 mg/kg |
| Application Route | : | Intramuscular |
| Exposure time | : | 13 Weeks |
| Target Organs | : | Kidney |

**Benzyl alcohol:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 1.072 mg/l |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 28 Days |
| Method | : | OECD Test Guideline 412 |

**Aspiration toxicity**

Not classified based on available information.

### 11.2 Information on other hazards

**Endocrine disrupting properties**

**Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**Experience with human exposure**

**Components:**

**Gentamicin:**

| | | |
|---|---|---|
| Ingestion | : | Target Organs: Kidney<br>Target Organs: inner ear<br>Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness |

## SECTION 12: Ecological information

### 12.1 Toxicity

**Components:**

**Gentamicin:**

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 86 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br><br>LC50 (Americamysis): 30 mg/l<br>Exposure time: 96 h<br>Method: US-EPA OPPTS 850.1035 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l |

| | | |
|---|---|---|
| | | Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| M-Factor (Acute aquatic toxicity) | : | 100 |
| Toxicity to microorganisms | : | EC50 : 288.7 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |
| M-Factor (Chronic aquatic toxicity) | : | 1 |

**Benzyl alcohol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 460 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 230 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 51 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211 |

### 12.2 Persistence and degradability

**Components:**

**Gentamicin:**

| | | |
|---|---|---|
| Biodegradability | : | Result: rapidly degradable<br>Biodegradation: 100 %<br>Exposure time: 28 d |

Method: OECD Test Guideline 314

**Benzyl alcohol:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

### 12.3 Bioaccumulative potential

**Components:**

**Gentamicin:**

Partition coefficient: n-octanol/water : log Pow: < -2

**Benzyl alcohol:**

Partition coefficient: n-octanol/water : log Pow: 1.05

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

**Product:**

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 Endocrine disrupting properties

**Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Do not dispose of waste into sewer.

| | | |
|---|---|---|
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

## SECTION 14: Transport information

### 14.1 UN number or ID number

| | | |
|---|---|---|
| **ADN** | : | UN 3082 |
| **ADR** | : | UN 3082 |
| **RID** | : | UN 3082 |
| **IMDG** | : | UN 3082 |
| **IATA** | : | UN 3082 |

### 14.2 UN proper shipping name

| | | |
|---|---|---|
| **ADN** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Gentamicin) |
| **ADR** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Gentamicin) |
| **RID** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Gentamicin) |
| **IMDG** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Gentamicin) |
| **IATA** | : | Environmentally hazardous substance, liquid, n.o.s.<br>(Gentamicin) |

### 14.3 Transport hazard class(es)

| | | Class | Subsidiary risks |
|---|---|---|---|
| **ADN** | : | 9 | |
| **ADR** | : | 9 | |
| **RID** | : | 9 | |
| **IMDG** | : | 9 | |
| **IATA** | : | 9 | |

### 14.4 Packing group

**ADN**

| | | |
|---|---|---|
| Packing group | : | III |
| Classification Code | : | M6 |
| Hazard Identification Number | : | 90 |
| Labels | : | 9 |

**ADR**

| | | |
|---|---|---|
| Packing group | : | III |
| Classification Code | : | M6 |
| Hazard Identification Number | : | 90 |
| Labels | : | 9 |
| Tunnel restriction code | : | (-) |

**RID**

| | | |
|---|---|---|
| Packing group | : | III |
| Classification Code | : | M6 |
| Hazard Identification Number | : | 90 |
| Labels | : | 9 |

**IMDG**

| | | |
|---|---|---|
| Packing group | : | III |
| Labels | : | 9 |
| EmS Code | : | F-A, S-F |

**IATA (Cargo)**

| | | |
|---|---|---|
| Packing instruction (cargo aircraft) | : | 964 |
| Packing instruction (LQ) | : | Y964 |
| Packing group | : | III |
| Labels | : | Miscellaneous |

**IATA (Passenger)**

| | | |
|---|---|---|
| Packing instruction (passenger aircraft) | : | 964 |
| Packing instruction (LQ) | : | Y964 |
| Packing group | : | III |
| Labels | : | Miscellaneous |

### 14.5 Environmental hazards

**ADN**
Environmentally hazardous : yes

**ADR**
Environmentally hazardous : yes

**RID**
Environmentally hazardous : yes

**IMDG**
Marine pollutant : yes

**IATA (Passenger)**
Environmentally hazardous : yes

**IATA (Cargo)**
Environmentally hazardous : yes

### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

| | | |
|---|---|---|
| REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) | : | Conditions of restriction for the following entries should be considered: Number on list 75, 3<br><br>Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.<br><br>If you intend to use this product as tattoo ink, please contact your vendor. |
| REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). | : | Not applicable |
| Regulation (EC) No 1005/2009 on substances that deplete the ozone layer | : | Not applicable |
| Regulation (EU) 2019/1021 on persistent organic pollutants (recast) | : | Not applicable |
| Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals | : | Not applicable |
| REACH - List of substances subject to authorisation (Annex XIV) | : | Not applicable |

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

| | | Quantity 1 | Quantity 2 |
|---|---|---|---|
| E1 | ENVIRONMENTAL HAZARDS | 100 t | 200 t |

**Other regulations:**

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

**The components of this product are reported in the following inventories:**

| | | |
|---|---|---|
| AICS | : | not determined |
| DSL | : | not determined |

| | | |
|---|---|---|
| IECSC | : | not determined |

**15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

| | | |
|---|---|---|
| Other information | : | Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines. |

**Full text of H-Statements**

| | | |
|---|---|---|
| H302 | : | Harmful if swallowed. |
| H319 | : | Causes serious eye irritation. |
| H332 | : | Harmful if inhaled. |
| H360D | : | May damage the unborn child. |
| H372 | : | Causes damage to organs through prolonged or repeated exposure if swallowed. |
| H400 | : | Very toxic to aquatic life. |
| H410 | : | Very toxic to aquatic life with long lasting effects. |

**Full text of other abbreviations**

| | | |
|---|---|---|
| Acute Tox. | : | Acute toxicity |
| Aquatic Acute | : | Short-term (acute) aquatic hazard |
| Aquatic Chronic | : | Long-term (chronic) aquatic hazard |
| Eye Irrit. | : | Eye irritation |
| Repr. | : | Reproductive toxicity |
| STOT RE | : | Specific target organ toxicity - repeated exposure |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office

of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

**Further information**

| | | |
|---|---|---|
| Sources of key data used to compile the Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ |

| **Classification of the mixture:** | | **Classification procedure:** |
|---|---|---|
| Repr. 1A | H360D | Calculation method |
| STOT RE 2 | H373 | Calculation method |
| Aquatic Acute 1 | H400 | Calculation method |
| Aquatic Chronic 2 | H411 | Calculation method |

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IE / EN