



Amikacin Sulfate Injection

Safety Data Sheet

according to the Hazardous Products Regulation (February 11, 2015)
Issue date: 2022-11-18

SECTION 1: Identification

1.1. Product identifier

Product form : Mixture
Product name : Amikacin Sulfate Injection

1.2. Recommended use and restrictions on use

Recommended use : Antibiotics
Restrictions on use : No data available

1.3. Supplier

Omega Laboratories, Ltd.
11177 Hamon St.
Montreal, Quebec H3M 3E4
Canada
T (514) 335-0310

1.4. Emergency telephone number

Emergency number : (514) 335-0310

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

Classification (GHS CA)

Serious eye damage/eye irritation Category 2A	H319	Causes serious eye irritation
Skin sensitization, Category 1	H317	May cause an allergic skin reaction
Specific target organ toxicity (repeated exposure) Category 1	H372	Causes damage to organs through prolonged or repeated exposure

Full text of H statements : see section 16

2.2. GHS Label elements, including precautionary statements

GHS CA labeling

Hazard pictograms (GHS CA) :



Signal word (GHS CA) : Danger

Hazard statements (GHS CA) : H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H372 - Causes damage to organs through prolonged or repeated exposure

Precautionary statements (GHS CA) : P260 - Do not breathe mist, spray, vapors.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective clothing, eye protection, face protection.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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P314 - Get medical advice/attention if you feel unwell.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS CA)

No data available

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Chemical name / Synonyms	Product identifier	Conc. (% w/w)
Amikacin Sulfate	D-Streptamine,O-3-amino-3-deoxy- α -D-glucopyranosyl-(1 \rightarrow 6)-O-[6-amino-6-deoxy- α -D-glucopyranosyl-(1 \rightarrow 4)]-N1-[(2S)-4-amino-2-hydroxy-1-oxobutyl]-2-deoxy- ; Amikacin	CAS-No.: 37517-28-5	21.3
Sodium hydrogensulfite	Sodium hydrogensulfite	CAS-No.: 7631-90-5	0.5

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. If you feel unwell, seek medical advice.

First-aid measures after skin contact : Rinse skin with water/shower. Remove/Take off immediately all contaminated clothing. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Get medical advice/attention. Rinse mouth out with water. Never give anything by mouth to an unconscious person.

First-aid measures general : IF exposed or concerned: Get medical advice/attention.

4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : May cause an allergic skin reaction. Repeated or prolonged contact may cause skin irritation.

Symptoms/effects after eye contact : Causes serious eye irritation.

Symptoms/effects after ingestion : May cause irritation to the digestive tract.

Chronic symptoms : Causes damage to organs through prolonged or repeated exposure.

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4.3. Immediate medical attention and special treatment, if necessary

Other medical advice or treatment : Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Unsuitable extinguishing media

Unsuitable extinguishing media : No data available.

5.3. Specific hazards arising from the hazardous product

Fire hazard : No fire hazard.
Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.4. Special protective equipment and precautions for fire-fighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Ensure adequate ventilation. Wear personal protective equipment. Avoid breathing dust, mist or spray. Mark out the contaminated area with signs and prevent access to unauthorized personnel.

6.2. Methods and materials for containment and cleaning up

For containment : Stop leak, if possible without risk.
Methods for cleaning up : Take up liquid spill into absorbent material. Collect all waste in suitable and labeled containers and dispose according to local legislation.
Other information : Dispose of materials or solid residues at an authorized site.

6.3. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection"

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Do not breathe gas, fumes, vapor or spray.
Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Separate working clothes from town clothes. Launder separately. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Store at room temperature.

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium hydrogensulfite (7631-90-5)	
Canada (Alberta) - Occupational Exposure Limits	
Local name	Sodium bisulfite
OEL TWA	5 mg/m ³
Notations and remarks	Occupational exposure limit is based on irritation effects and its adjustment to compensate for unusual work schedules is not required.
Regulatory reference	Alberta Regulation 191/2021
Canada (Quebec) - Occupational Exposure Limits	
Local name	Sodium bisulfite
VEMP (OEL TWA)	5 mg/m ³
Regulatory reference	S-2.1, r. 13 - Regulation respecting occupational health and safety
Canada (British Columbia) - Occupational Exposure Limits	
Local name	Sodium bisulfite
OEL TWA	5 mg/m ³
Regulatory reference	OHS Guidelines Part 5: Chemical Agents and Biological Agents (WorkSafe BC)
Canada (Manitoba) - Occupational Exposure Limits	
Local name	Sodium bisulfite
OEL TWA	5 mg/m ³
Notations and remarks	TLV® Basis: Skin, eye, & URT irr. Notations: A4 (Not classifiable as a Human Carcinogen)
Regulatory reference	ACGIH 2022
Canada (New Brunswick) - Occupational Exposure Limits	
Local name	Sodium bisulfite
OEL TWA	5 mg/m ³
Notations and remarks	Skin, eye, & URT irr
Canada (Newfoundland and Labrador) - Occupational Exposure Limits	
Local name	Sodium bisulfite
OEL TWA	5 mg/m ³
Notations and remarks	TLV® Basis: Skin, eye, & URT irr. Notations: A4 (Not classifiable as a Human Carcinogen)
Regulatory reference	ACGIH 2022
Canada (Nova Scotia) - Occupational Exposure Limits	
Local name	Sodium bisulfite
OEL TWA	5 mg/m ³
Notations and remarks	TLV® Basis: Skin, eye, & URT irr. Notations: A4 (Not classifiable as a Human Carcinogen)
Regulatory reference	ACGIH 2022
Canada (Nunavut) - Occupational Exposure Limits	
Local name	Sodium bisulphite

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Sodium hydrogensulfite (7631-90-5)	
OEL TWA	5 mg/m ³
OEL STEL	10 mg/m ³
Regulatory reference	Occupational Health and Safety Regulations, Nu Reg 003-2016 (Amendment R-044-2021)
Canada (Northwest Territories) - Occupational Exposure Limits	
Local name	Sodium bisulphite
OEL TWA	5 mg/m ³
OEL STEL	10 mg/m ³
Regulatory reference	Occupation Health and Safety Regulations R-039-2015 (R-013-2020)
Canada (Ontario) - Occupational Exposure Limits	
Local name	Sodium bisulfite
OEL TWA	5 mg/m ³
Regulatory reference	Ontario Occupational Exposure Limits under Regulation 833
Canada (Prince Edward Island) - Occupational Exposure Limits	
Local name	Sodium bisulfite
OEL TWA	5 mg/m ³
Notations and remarks	TLV® Basis: Skin, eye, & URT irr. Notations: A4 (Not classifiable as a Human Carcinogen)
Regulatory reference	ACGIH 2022
Canada (Saskatchewan) - Occupational Exposure Limits	
Local name	Sodium bisulphite
OEL TWA	5 mg/m ³
OEL STEL	10 mg/m ³
Regulatory reference	The Occupational Health and Safety Regulations, 2020. Chapter S-15.1 Reg 10
USA - ACGIH - Occupational Exposure Limits	
Local name	Sodium bisulfite
ACGIH OEL TWA	5 mg/m ³
Remark (ACGIH)	TLV® Basis: Skin, eye, & URT irr. Notations: A4 (Not classifiable as a Human Carcinogen)
Regulatory reference	ACGIH 2022

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.
Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Protective gloves

Eye protection:

Safety glasses

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Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Wear respiratory protection.

Personal protective equipment symbol(s):



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Colourless to pale yellow liquid.
Color	: Colourless to pale yellow
Odor	: No data available
Odor threshold	: No data available
pH	: 3.5 – 5.5
Relative evaporation rate (butyl acetate=1)	: No data available
Relative evaporation rate (ether=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Density	: 1.173 g/ml
Solubility	: Miscible with water.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Explosion limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

Reactivity	: No additional information available
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: No dangerous reactions known under normal conditions of use.
Conditions to avoid	: No additional information available
Incompatible materials	: Strong acids. Strong bases. Strong oxidizing agents.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.
Hardening time:	: No additional information available

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Sodium hydrogensulfite (7631-90-5)	
LD50 oral rat	1420 mg/kg Source: ECHA
LD50 dermal rat	> 2000 mg/kg Source: ECHA
LC50 Inhalation - Rat	> 5.5 mg/l air Animal: rat, Animal sex: male, Guideline: OECD Guideline 403 (Acute Inhalation Toxicity)
LC50 Inhalation - Rat (Dust/Mist)	> 5.5 mg/l Source: ECHA

Skin corrosion/irritation : Not classified
pH: 3.5 – 5.5
Serious eye damage/irritation : Causes serious eye irritation.
pH: 3.5 – 5.5
Respiratory or skin sensitization : May cause an allergic skin reaction.
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified

Sodium hydrogensulfite (7631-90-5)	
IARC group	3 - Not classifiable

Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Causes damage to organs through prolonged or repeated exposure.
Aspiration hazard : Not classified
Likely routes of exposure : Dermal. Ingestion. Inhalation.
Symptoms/effects after inhalation : May cause respiratory irritation.
Symptoms/effects after skin contact : May cause an allergic skin reaction. Repeated or prolonged contact may cause skin irritation.
Symptoms/effects after eye contact : Causes serious eye irritation.
Symptoms/effects after ingestion : May cause irritation to the digestive tract.
Chronic symptoms : Causes damage to organs through prolonged or repeated exposure.

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified
Hazardous to the aquatic environment, long-term (chronic) : Not classified

Sodium hydrogensulfite (7631-90-5)	
LC50 - Fish [1]	215 – 464 mg/l Source: ECHA
EC50 - Crustacea [1]	230 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	43.8 mg/l Source: ECHA
NOEC chronic fish	≥ 316 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio) Duration: '34 d'
NOEC (chronic)	> 10 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

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12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Amikacin Sulfate (37517-28-5)

Partition coefficient n-octanol/water (Log Pow)	-8.78 Source: EPISUITE
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12.4. Mobility in soil

Amikacin Sulfate (37517-28-5)

Mobility in soil	0.00000126 Source: EPISUITE
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12.5. Other adverse effects

Ozone : Not classified

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
Additional information : Flammable vapors may accumulate in the container.

SECTION 14: Transport information

In accordance with TDG / DOT / IMDG / IATA

TDG	DOT	IMDG	IATA
14.1. UN number			
Not regulated for transport			
14.2. Proper Shipping Name			
Not applicable	Not applicable	Not applicable	Not applicable
Transport document description			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available			

14.6. Special precautions for user

TDG

No data available

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DOT

No data available

IMDG

No data available

IATA

No data available

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

Not applicable

SECTION 15: Regulatory information

15.1. National regulations

Amikacin Sulfate (37517-28-5)

Listed on the Canadian DSL (Domestic Substances List)

Sodium hydrogensulfite (7631-90-5)

Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: Other information

Issue date : 11-18-2022

Full text of H-phrases:

H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H372	Causes damage to organs through prolonged or repeated exposure

Safety Data Sheet (SDS), Canada

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.