

Revision Date 11-Feb-2014

Revision Number 1

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**1.1. Product identifier**

Product Description:	Amikacin disulfate salt
Cat No. :	455190000, 45519050, 455190250
CAS-No	39831-55-5
EC-No.	254-648-6
Molecular Formula	C ₂₂ H ₄₃ N ₅ O ₁₃ . 2 H ₂ S O ₄

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

Recommended Use	Laboratory chemicals
Uses advised against	No Information available

1.3. Details of the supplier of the safety data sheet

Company	Acros Organics BVBA Janssen Pharmaceuticaaan 3a 2440 Geel, Belgium
E-mail address	begel.sdsdesk@thermofisher.com

1.4. Emergency telephone number

For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11
Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99
CHEMTREC Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

SECTION 2: HAZARDS IDENTIFICATION**2.1. Classification of the substance or mixture****CLP Classification - Regulation (EC) No 1272/2008****Physical hazards**

Based on available data, the classification criteria are not met

Health hazards

Based on available data, the classification criteria are not met

Environmental hazards

Based on available data, the classification criteria are not met

Classification according to EU Directives 67/548/EEC or 1999/45/EC**R-phrases(s)** none

For the full text of the R-phrases and H-Statements mentioned in this Section, see Section 16

2.2. Label elements

Hazard Statements**Precautionary Statements****2.3. Other hazards**

No information available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Component	CAS-No	EC-No.	Weight %	CLP Classification - Regulation (EC) No 1272/2008	DSD Classification - 67/548/EEC
Amikacin sulfate	39831-55-5	EEC No. 254-648-6	>95	-	-

For the full text of the R-phrases and H-Statements mentioned in this Section, see Section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. Get medical attention immediately if symptoms occur.
Ingestion	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.
Inhalation	Move to fresh air. Get medical attention immediately if symptoms occur.
Protection of First-aiders	No special precautions required.

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

None reasonably foreseeable.

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

Notes to Physician Treat symptomatically

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media**Suitable Extinguishing Media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Extinguishing media which must not be used for safety reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors

Hazardous Combustion Products

Carbon monoxide (CO), Carbon dioxide (CO₂), Nitrogen oxides (NO_x), Sulfur oxides.

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1. Personal precautions, protective equipment and emergency procedures**

Ensure adequate ventilation. Use personal protective equipment. Avoid dust formation.

6.2. Environmental precautions

Should not be released into the environment.

6.3. Methods and material for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation.

6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE**7.1. Precautions for safe handling**

Wear personal protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid ingestion and inhalation. Avoid dust formation.

7.2. Conditions for safe storage, including any incompatibilities

Keep refrigerated. Keep container tightly closed in a dry and well-ventilated place.

7.3. Specific end use(s)

Use in laboratories

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control parameters****Exposure limits**

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

Derived No Effect Level (DNEL) No information available.

Amikacin disulfate salt

<u>Route of exposure</u>	<u>Acute effects (local)</u>	<u>Acute effects (systemic)</u>	<u>Chronic effects (local)</u>	<u>Chronic effects (systemic)</u>
Oral Dermal Inhalation				

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering Measures

None under normal use conditions..

Personal protective equipment

Eye Protection

Safety glasses with side-shields (European standard - EN 166)

Hand Protection

Protective gloves

<u>Glove material</u>	<u>Breakthrough time</u>	<u>Glove thickness</u>	<u>EU standard</u>	<u>Glove comments</u>
Natural rubber Nitrile rubber Neoprene PVC	See manufacturers recommendations	-	EN 374	(minimum requirement)

Skin and body protection

Long sleeved clothing

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion. Remove gloves with care avoiding skin contamination.

Respiratory Protection

No protective equipment is needed under normal use conditions.

Large scale/emergency use

Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced..
Recommended Filter type: Particle filter.

Small scale/Laboratory use

Maintain adequate ventilation

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice

Environmental exposure controls

No information available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance

Physical State

Solid.

Odor

No information available

Odor Threshold

No data available

pH

No information available.

Amikacin disulfate salt

Melting Point/Range	220 - 230°C / 428 - 446°F	
Softening Point	No data available	
Boiling Point/Range	No information available.	
Flash Point	No information available.	Method - No information available.
Evaporation Rate	Not applicable	Solid
Flammability (solid,gas)	No information available.	
Explosion Limits	No data available.	
Vapor Pressure	No data available	
Vapor Density	Not applicable	Solid
Specific Gravity / Density	No data available	
Bulk Density	No data available	
Water Solubility	ca 50 g/L	
Solubility in other solvents	No information available.	
Partition Coefficient (n-octanol/water)		
Autoignition Temperature	Not applicable	
Decomposition temperature	No data available	
Viscosity	Not applicable	Solid
Explosive Properties	No information available.	
Oxidizing Properties	No information available.	

9.2. Other information

Molecular Formula	C22 H43 N5 O13 . 2 H2 S O4
Molecular Weight	781.76

SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

None known, based on information available.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions**Hazardous Polymerization
Hazardous Reactions**Hazardous polymerization does not occur.
None under normal processing.**10.4. Conditions to avoid**

Incompatible products, Excess heat, Avoid dust formation.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition productsCarbon monoxide (CO), Carbon dioxide (CO₂), Nitrogen oxides (NO_x), Sulfur oxides.**SECTION 11: TOXICOLOGICAL INFORMATION****11.1. Information on toxicological effects****Product Information****(a) acute toxicity;
Oral**

Based on available data, the classification criteria are not met

Amikacin disulfate salt

Dermal	No data available		
Inhalation	No data available		
Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Amikacin sulfate	>4 g/kg (Rat)		

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;

Respiratory	No data available
Skin	No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; No data available

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity; No data available

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available

Target Organs	No information available.
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(j) aspiration hazard; Not applicable
Solid

Symptoms / effects, both acute and delayed No information available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity**Ecotoxicity effects**

Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants

12.2. Persistence and degradability**Persistence**

Soluble in water, Persistence is unlikely, based on information available.

12.3. Bioaccumulative potential

Bioaccumulation is unlikely

12.4. Mobility in soil

The product is water soluble, and may spread in water systems. Will likely be mobile in the environment due to its water solubility. Highly mobile in soils.

12.5. Results of PBT and vPvB assessment

No data available for assessment

12.6. Other adverse effects**Endocrine Disruptor Information**

This product does not contain any known or suspected endocrine disruptors

Persistent Organic Pollutant

This product does not contain any known or suspected substance

Ozone Depletion Potential

This product does not contain any known or suspected substance

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from Residues / Unused Products

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

Contaminated Packaging

Empty remaining contents. Dispose of in accordance with local regulations. Do not re-use empty containers.

European Waste Catalogue (EWC)

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific

Other Information

Waste codes should be assigned by the user based on the application for which the product was used

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO

Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

ADR

Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

IATA

Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

No hazards identified

14.6. Special precautions for user

No special precautions required

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable, packaged goods

SECTION 15: REGULATORY INFORMATION

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

International Inventories

X = listed

Component	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	ENCS	CHINA	AICS	KECL
Amikacin sulfate	254-648-6	-		-	-	-	-	-	-	X	X

National Regulations

Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

Take note of Dir 94/33/EC on the protection of young people at work

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

SECTION 16: OTHER INFORMATION**Full text of R-phrases referred to under sections 2 and 3**

Not applicable

Legend

CAS - Chemical Abstracts Service

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Existing and Evaluated Chemical Substances

WEL - Workplace Exposure Limit

ACGIH - American Conference of Industrial Hygiene

DNEL - Derived No Effect Level

RPE - Respiratory Protective Equipment

LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration

PBT - Persistent, Bioaccumulative, Toxic

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

ENCS - Japan Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

PNEC - Predicted No Effect Concentration

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

POW - Partition coefficient Octanol:Water

vPvB - very Persistent, very Bioaccumulative

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from Ships

ATE - Acute Toxicity Estimate

VOC - Volatile Organic Compounds

Key literature references and sources for data

Suppliers safety data sheet,
Chemadvisor - LOLI,
Merck index,
RTECS

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Revision Date 11-Feb-2014

Revision Summary

Reason for revision Not applicable

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

Disclaimer

The information provided on this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet