SAFETY DATA SHEET

Amikacin Sulfate Injection, USP

Section 1. Identification

GHS product identifier : Amikacin Sulfate Injection, USP

Chemical name : Amikacin

Synonyms : Amikacin Sulfate Injection, USP 500mg/2ml, Amikacin Sulfate Injection, USP 1 gram/4ml, Amikin®, Amicacin, Antibiotic BB-K 8, BB-K 8

Product code : Not available.

Chemical family : Aminoglycoside (semisynthetic)

Product type : Regulated prescription drug.

Container information : Packaged in 2mL and 5mL flint vials with rubber stoppers.

Identified uses

Pharmaceuticals.

Supplier's details : Hikma Pharmaceuticals USA Inc.
246 Industrial Way West
Eatontown, New Jersey (NJ) 07724

Emergency telephone number (with hours of operation) : CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887
24/7

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture : SKIN CORROSION/IRRITATION - Category 2
SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2
SKIN SENSITIZATION - Category 1

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : Causes serious eye irritation.
Causes skin irritation.
May cause an allergic skin reaction.

Precautionary statements

Prevention : Wear protective gloves. Wear eye or face protection. Avoid breathing vapor. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace.

Section 2. Hazards identification

Response : IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.

Storage : Not applicable.

Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Chemical name : Amikacin

Other means of identification : Amikacin Sulfate Injection, USP 500mg/2ml, Amikacin Sulfate Injection, USP 1 gram/4ml, Amikin®, Amicacin, Antibiotic BB-K 8, BB-K 8

CAS number/other identifiers

CAS number : Not applicable.

Product code : Not available.

Ingredient name	%	CAS number
Amikacin bis(sulphate)	10 - 30	39831-55-5
Sodium metabisulphite	0.1 - 1	7681-57-4
Trisodium citrate	1 - 5	68-04-2
Sulfuric acid	5 - 10	7664-93-9
Water	60 - 100	7732-18-5

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Section 4. First aid measures

Ingestion : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : Causes serious eye irritation.

Inhalation : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Skin contact : Causes skin irritation. May cause an allergic skin reaction.

Ingestion : Irritating to mouth, throat and stomach.

Over-exposure signs/symptoms

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation : No known significant effects or critical hazards.

Skin contact : Adverse symptoms may include the following:
irritation
redness

Ingestion : No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments : If over-dosage/over-exposure occurs, peritoneal dialysis or hemodialysis will aid in the removal of Amikacin from the blood.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Section 5. Fire-fighting measures

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
Sulfur oxides
metal oxide/oxides

Special protective actions for fire-fighters : No special measures are required.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Spill : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.

Section 7. Handling and storage

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Sulfuric acid	**NIOSH REL (United States, 10/2013).** TWA: 1 mg/m³ 10 hours. **OSHA PEL (United States, 2/2013).** TWA: 1 mg/m³ 8 hours. **ACGIH TLV (United States, 4/2014).** TWA: 0.2 mg/m³ 8 hours. Form: thoracic fraction

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties

Appearance

Physical state : Liquid.

Color : Clear. Colorless to pale yellow.

Odor : Odorless.

Odor threshold : Not available.

pH : 4.5

Melting point : Not available.

Boiling point : 100°C (212°F)

Flash point : Not available.

Evaporation rate : Not available.

Flammability (solid, gas) : Not available.

Lower and upper explosive (flammable) limits : Not available.

Vapor pressure : Similar to water.

Vapor density : Similar to water.

Relative density : Not available.

Solubility : Easily soluble in the following materials: cold water and hot water.

Partition coefficient: n-octanol/water : Not available.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : Not available.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : Product is sable under standard use and storage conditions.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials, reducing materials, organic materials, acids, alkalis and moisture.

Hazardous decomposition products : Oxides of sulfer and nitrogen.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Amikacin bis(sulphate)	LD50 Intramuscular	Mouse	1247 mg/kg	-
	LD50 Intraperitoneal	Mouse	2930 mg/kg	-
	LD50 Intravenous	Mouse	181 mg/kg	-
	LD50 Oral	Mouse	>10679 mg/kg	-
	LD50 Oral	Rat	>4000 mg/kg	-
	LD50 Subcutaneous	Mouse	2470 mg/kg	-
Sulfuric acid	LD50 Oral	Rat	2140 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Sulfuric acid	Eyes - Severe irritant	Rabbit	-	250 µg	-
	Eyes - Severe irritant	Rabbit	-	0.5 minutes 5 mg	-

Sensitization

There is no data available.

Carcinogenicity

Classification

Product/ingredient name	OSHA	IARC	NTP
Sulfuric acid	-	1	Known to be a human carcinogen.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Ingestion.

Potential acute health effects

Eye contact : Causes serious eye irritation.

Inhalation : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Skin contact : Causes skin irritation. May cause an allergic skin reaction.

Ingestion : Irritating to mouth, throat and stomach.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation : No known significant effects or critical hazards.

Skin contact : Adverse symptoms may include the following:
irritation
redness

Ingestion : No known significant effects or critical hazards.

Section 11. Toxicological information

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	16819.5 mg/kg

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Sulfuric acid	Acute LC50 42500 µg/L Marine water Acute LC50 42 ppm Fresh water	Crustaceans - Pandalus montagui - Adult Fish - Gambusia affinis - Adult	48 hours 96 hours

Persistence and degradability

There is no data available.

Bioaccumulative potential

There is no data available.

Mobility in soil

Soil/water partition coefficient (K_{OC}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information		-	-

AERG : Not applicable.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) PAIR**: Sodium metabisulphite

TSCA 8(a) CDR Exempt/Partial exemption: Not determined

United States inventory (TSCA 8b): Not determined.

Clean Water Act (CWA) 311: Sulfuric acid

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Section 15. Regulatory information

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Listed

SARA 302/304

Composition/information on ingredients

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
Sulfuric acid	5 - 10	Yes.	1000	66.3	1000	66.3

SARA 304 RQ : 10479.4 lbs / 4757.7 kg

SARA 311/312

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Amikacin bis(sulphate) Sulfuric acid	10 - 30 5 - 10	No. No.	No. No.	No. No.	Yes. Yes.	No. No.

SARA 313

	Product name	CAS number	%
Form R - Reporting requirements	Sulfuric acid	7664-93-9	5 - 10
Supplier notification	Sulfuric acid	7664-93-9	5 - 10

SARA 313 notifications must not be detached from the SDS and any copying and redistribution of the SDS shall include copying and redistribution of the notice attached to copies of the SDS subsequently redistributed.

State regulations

Massachusetts : The following components are listed: Sulfuric acid

New York : The following components are listed: Sulfuric acid

New Jersey : The following components are listed: Sulfuric acid

Pennsylvania : The following components are listed: Sulfuric acid

California Prop. 65

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

Ingredient name	Cancer	Reproductive	No significant risk level	Maximum acceptable dosage level
Amikacin bis(sulphate) Sulfuric acid	No. Yes.	Yes. No.	No. No.	No. No.

International regulations

Section 15. Regulatory information

International lists : **Australia inventory (AICS)**: All components are listed or exempted.
China inventory (IECSC): Not determined.
Japan inventory: Not determined.
Korea inventory: All components are listed or exempted.
Malaysia Inventory (EHS Register): Not determined.
New Zealand Inventory of Chemicals (NZIoC): Not determined.
Philippines inventory (PICCS): Not determined.
Taiwan inventory (CSNN): Not determined.

Chemical Weapons Convention List Schedule I Chemicals : Not listed

Chemical Weapons Convention List Schedule II Chemicals : Not listed

Chemical Weapons Convention List Schedule III Chemicals : Not listed

Section 16. Other information

History

Revision date mm/dd/yyyy : 11/15/2018

Version : 2

Revised Section(s) : Not applicable.

Prepared by : KMK Regulatory Services Inc.

Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
UN = United Nations

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