

Gentamicin (10%) Injection Formulation

Version 6.0 Revision Date: 2023/09/30 SDS Number: 804046-00019 Date of last issue: 2023/04/04
Date of first issue: 2016/07/15

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Gentamicin (10%) Injection Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use



Recommended use : Veterinary product
Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Kidney, inner ear)
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 2

GHS label elements

Hazard pictograms :  

Signal word : Danger

Hazard statements : H360D May damage the unborn child.
H372 Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

Gentamicin (10%) Injection Formulation

Version 6.0 Revision Date: 2023/09/30 SDS Number: 804046-00019 Date of last issue: 2023/04/04
 Date of first issue: 2016/07/15

Precautionary statements

:

Prevention:

P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe mist or vapours.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 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.

Disposal:

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

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Gentamicin	1403-66-3	10	
Ethylenediaminetetraacetic acid disodium salt	139-33-3	0.01	2-1265

4. 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.

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.

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

In case of eye contact	:	Thoroughly clean shoes before reuse. 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.
Most important symptoms and effects, both acute and delayed	:	May damage the unborn child. Causes damage to organs through prolonged or repeated exposure if swallowed.
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).
Notes to physician	:	Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
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.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
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.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.

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.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

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.
Do not breathe mist or vapours.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment. |
| Avoidance of contact | : | Oxidizing agents |
| 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.
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. |

Storage

- | | | |
|-----------------------------|---|--|
| Conditions for safe storage | : | Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:
Strong oxidizing agents |
| Packaging material | : | Unsuitable material: None known. |

Gentamicin (10%) Injection Formulation

Version 6.0 Revision Date: 2023/09/30 SDS Number: 804046-00019 Date of last issue: 2023/04/04
 Date of first issue: 2016/07/15

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

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

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

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection
 Material : Chemical-resistant gloves

Eye 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.

Skin and body protection : Work uniform or laboratory coat.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid

Colour : clear

Odour : odourless

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : > 100 °C

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Up- : No data available
per flammability limit

Lower explosion limit / : No data available
Lower flammability limit

Flash point : No data available

Decomposition temperature : No data available

pH : 3.0 - 5.5

Evaporation rate : 1

Auto-ignition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : soluble

Partition coefficient: n- : No data available
octanol/water

Vapour pressure : No data available

Density and / or relative density
Relative density : No data available

Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics
Particle size : No data available

10. STABILITY AND REACTIVITY

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure :

- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity

Not classified based on available information.

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

Ethylenediaminetetraacetic acid disodium salt:

Acute oral toxicity	:	LD50 (Rat): 2,800 mg/kg
Acute inhalation toxicity	:	LC50 (Rat, male): > 1 mg/l
		Exposure time: 6 h
		Test atmosphere: dust/mist
		Method: OECD Test Guideline 412

Skin corrosion/irritation

Not classified based on available information.

Gentamicin (10%) Injection Formulation

Version 6.0 Revision Date: 2023/09/30 SDS Number: 804046-00019 Date of last issue: 2023/04/04
Date of first issue: 2016/07/15

Components:**Gentamicin:**

Species : Rabbit
Result : Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Gentamicin:**

Species : Rabbit
Result : Mild eye irritation

Ethylenediaminetetraacetic acid disodium salt:

Species : Rabbit
Result : No eye irritation

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

Ethylenediaminetetraacetic acid disodium salt:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:**Gentamicin:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative
Test Type: Chromosome aberration test in vitro

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

		Result: equivocal
	Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intravenous injection Result: negative

Ethylenediaminetetraacetic acid disodium salt:

	Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials
		Test Type: In vitro mammalian cell gene mutation test Result: negative
		Test Type: Chromosome aberration test in vitro Result: negative Remarks: Based on data from similar materials
	Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Gentamicin:**

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

Ethylenediaminetetraacetic acid disodium salt:

Species		: Rat
Application Route		: Ingestion
Exposure time		: 103 weeks
Result		: negative
Remarks		: Based on data from similar materials

Reproductive toxicity

May damage the unborn child.

Components:**Gentamicin:**

Effects on fertility		: Test Type: Two-generation reproduction toxicity study Species: Rat
----------------------	--	---

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

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

Ethylenediaminetetraacetic acid disodium salt:

Effects on fertility	:	Test Type: Four-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Components:**Gentamicin:**

|| Target Organs : Kidney, inner ear

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

Assessment : Causes damage to organs through prolonged or repeated exposure.

Ethylenediaminetetraacetic acid disodium salt:

Exposure routes : inhalation (dust/mist/fume)
 Target Organs : Respiratory Tract
 Assessment : May cause 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

Ethylenediaminetetraacetic acid disodium salt:

Species : Rat
 NOAEL : 500 mg/kg
 Application Route : Ingestion

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

Exposure time	:	13 Weeks
Species	:	Rat
LOAEL	:	0.03 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	4 Weeks
Method	:	OECD Test Guideline 412

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Gentamicin:**

Ingestion	:	Target Organs: Kidney
		Target Organs: inner ear
		Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Gentamicin:**

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 86 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
		LC50 (Americamysis): 30 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l Exposure time: 72 h Method: OECD Test Guideline 201
		EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

	Exposure time: 72 h
	Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	: 100
M-Factor (Chronic aquatic toxicity)	: 1
Toxicity to microorganisms	: EC50: 288.7 mg/l
	Exposure time: 3 h
	Test Type: Respiration inhibition
	Method: OECD Test Guideline 209

Ethylenediaminetetraacetic acid disodium salt:

Toxicity to fish	: LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l
	Exposure time: 96 h
	Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 140 mg/l
	Exposure time: 48 h
	Method: DIN 38412
Toxicity to algae/aquatic plants	: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
	Exposure time: 72 h
	Method: OECD Test Guideline 201
	Remarks: Based on data from similar materials
	EC10 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
	Exposure time: 72 h
	Method: OECD Test Guideline 201
	Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 25 mg/l
	Exposure time: 21 d
Toxicity to microorganisms	: EC10 (activated sludge): > 500 mg/l
	Exposure time: 30 min
	Method: OECD Test Guideline 209

Persistence and degradability**Components:****Gentamicin:**

Biodegradability	: Result: rapidly degradable
	Biodegradation: 100 %
	Exposure time: 28 d
	Method: OECD Test Guideline 314

Ethylenediaminetetraacetic acid disodium salt:

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

Biodegradability : Result: Not readily biodegradable.
 Biodegradation: 2 %
 Exposure time: 28 d
 Method: OECD Test Guideline 301D

Bioaccumulative potential**Components:****Gentamicin:**

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

Ethylenediaminetetraacetic acid disodium salt:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
 Bioconcentration factor (BCF): < 500
 Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: -4.3

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
 Do not dispose of waste into sewer.
 Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
 If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number : UN 3082
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
 Class : 9
 Packing group : III
 Labels : 9
 Environmentally hazardous : yes

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

IATA-DGR

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964
Packing instruction (passenger aircraft)	:	964
Environmentally hazardous	:	yes

IMDG-Code

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

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.

ERG Code	:	171
-----------------	---	-----

15. REGULATORY INFORMATION**Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law**Priority Assessment Chemical Substance**

Chemical name	Number
Sodium salt of 2,2',2'',2'''-(ethane-1,2-diylidinitrilo)tetraacetic acid	268

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

Industrial Safety and Health Law**Harmful Substances Prohibited from Manufacture**

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

|| Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION**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/>

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

Date format : yyyy/mm/dd

Full text of other abbreviations

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA

Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	804046-00019	Date of first issue: 2016/07/15

- 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

JP / EN