SAFETY DATA SHEET

Benzylpenicillin / Neomycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	11119517-00006	Date of first issue: 2022/12/07

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Benzylpenicillin / Neomycin 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

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H361d Suspected of damaging the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P284 Wear respiratory protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

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

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 2.5 %

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.
White mineral oil (petroleum)	8042-47-5	>= 70 - < 80	9-1700
Benzylpenicillin	61-33-6	>= 10 - < 20	-

Neomycin, sulfate (salt)	1405-10-3	>= 3 - < 10	-
Aluminum tristearate	637-12-7	>= 1 - < 10	2-625

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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. 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.
Most important symptoms and effects, both acute and delayed	:	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Suspected of damaging the unborn child. Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
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 (CO2) 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 Metal 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 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	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe vapours. Do not swallow.

Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.
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.
Contaminated work clothing should not be allowed out of the workplace.
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.

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 / Concentration standard / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	TWA (Inhalable particulate matter)	5 mg/m3	ACGIH
Benzylpenicillin	61-33-6	TWA	600 µg/m3 (OEB 2)	Internal
	Further information: RSEN, DSEN			
		Wipe limit	100 µg/100 cm2	Internal
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m3 (OEB 1)	Internal

	Further information: DSEN, OTO			
		Wipe limit	0.1 mg/100 cm²	Internal
Aluminum tristearate	637-12-7	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
		TWA (Respirable particulate matter)	1 mg/m3 (Aluminium)	ACGIH

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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 : Combined particulates and organic vapour 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 : cream

Colour : white

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Lower explosion limit and upper explosion limit / flammability limit		
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Decomposition temperature	:	No data available
pH	:	7
Evaporation rate	:	No data available
Auto-ignition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available
Density and / or relative density		
Relative density	:	No data available
Density	:	0.9 g/cm³
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	:	Not applicable

10. STABILITY AND REACTIVITY

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:

White mineral oil (petroleum):

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhalation toxicity
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity

Benzylpenicillin:

Acute oral toxicity	:	LD50 (Rat): 8,000 mg/kg LD50 (Mouse): > 5,000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Mouse): 3,500 mg/kg Application Route: Intraperitoneal LD50 (Mouse): 329 mg/kg Application Route: Intravenous

Neomycin, sulfate (salt):

Acute oral toxicity	:	LD50 (Mouse): 2,880 mg/kg LD50 (Rat): 2,750 mg/kg
Acute toxicity (other routes of	:	LD50 (Rat): 633 mg/kg

administration)	Application Route: Subcutaneous LD50 (Mouse): 116 mg/kg Application Route: Intraperitoneal LD50 (Mouse): 27.6 mg/kg Application Route: Intravenous LD50 (Mouse): 275 mg/kg Application Route: Subcutaneous

Aluminum tristearate:

Acute oral toxicity	:	LD50 (Rat, female): > 2,000 mg/kg Remarks: Based on data from similar materials
Acute inhalation toxicity	:	LC50 (Rat): > 5.15 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

White mineral oil (petroleum):

Species	:	Rabbit
Result	:	No skin irritation

Neomycin, sulfate (salt):

Species	:	Rabbit
Result	:	Mild skin irritation

Aluminum tristearate:

Species	:	reconstructed human epidermis (RhE)
Method	:	OECD Test Guideline 439
Remarks	:	Based on data from similar materials
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

White mineral oil (petroleum):

Species	:	Rabbit
Result	:	No eye irritation

Neomycin, sulfate (salt):

Species	:	Rabbit
Result	:	No eye irritation

Aluminum tristearate:

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405
Remarks	:	Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:

White mineral oil (petroleum):

Test Type	:	Buehler Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Benzylpenicillin:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Dermal
Species	:	Mouse
Result	:	Weak sensitizer

Test Type	:	Maximisation Test
Exposure routes	:	Dermal
Species	:	Guinea pig
Result	:	positive
Remarks	:	Based on data from similar materials

Result	:	Strong sensitizer
Remarks	:	Based on human experience.

Neomycin, sulfate (salt):

Exposure routes	:	Dermal
Species	:	Humans
Result	:	positive

Aluminum tristearate:

Test Type	:	Local lymph node assay (LLNA)

Exposure routes	:	Skin contact
Species	:	Mouse
Method	:	OECD Test Guideline 429
Result	:	negative
Remarks	:	Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

White mineral oil (petroleum):

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

Benzylpenicillin:

Germ cell mutagenicity - Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

Neomycin, sulfate (salt):

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative Test Type: Chromosomal aberration Test system: Human lymphocytes Result: positive Test Type: in vitro micronucleus test Result: negative
Genotoxicity in vivo	:	Test Type: Cytogenetic assay Species: Mouse Cell type: Bone marrow Application Route: Intravenous injection Result: negative

Aluminum tristearate:

Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test

		Method: OECD Test Guideline 476 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Application Route: Ingestion Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

White mineral oil (petroleum):

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	24 Months
Result	:	negative

Neomycin, sulfate (salt):

Species	:	Rat
Exposure time	:	2 Years
Result	:	negative

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

White mineral oil (petroleum):

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Skin contact Result: negative
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative

Benzylpenicillin:

Effects on fertility	:	Test Type: Fertility Species: Mouse Result: No effects on fertility Test Type: Fertility Species: Rat Result: No effects on fertility Test Type: Fertility Species: Rabbit Result: No effects on fertility
Effects on foetal development	:	Test Type: Development Species: Mouse Result: No effects on foetal development Test Type: Development Species: Rat Result: No effects on foetal development Test Type: Development Species: Rabbit Result: No effects on foetal development

Neomycin, sulfate (salt):

Effects on fertility	:	Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity - Parent: NOAEL: 25 mg/kg body weight Result: No effects on fertility and early embryonic development were detected.
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Oral Embryo-foetal toxicity: NOAEL: 275 mg/kg body weight Result: No adverse effects, No teratogenic effects Test Type: Development Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 6 mg/kg body weight Result: positive
Reproductive toxicity - Assessment	:	Some evidence of adverse effects on development, based on animal experiments.

Aluminum tristearate:

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

		Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Neomycin, sulfate (salt):

Target Organs	:	Kidney, inner ear
Assessment	:	May cause damage to organs through prolonged or repeated exposure.
Remarks	:	Based on human experience.

Repeated dose toxicity

Components:

White mineral oil (petroleum):

Species	:	Rat
LOAEL	:	160 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

Species	:	Rat
LOAEL	:	>= 1 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	4 Weeks
Method	:	OECD Test Guideline 412

Neomycin, sulfate (salt):

Species	:	Mouse
LOAEL	:	30 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	14 d
Target Organs	:	Kidney

Species	:	Guinea pig
NOAEL	:	50 mg/kg
LOAEL	:	100 mg/kg
Application Route	:	Intramuscular

Exposure time	:	30 - 60 Weeks
Target Organs	:	ear

Species	:	Guinea pig
NOAEL	:	10 mg/kg
Application Route	:	Oral
Exposure time	:	90 d
Remarks	:	No significant adverse effects were reported

Species	:	Guinea pig
LOAEL	:	100 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	34 d

Species	:	Dog
LOAEL	:	24 mg/kg
Application Route	:	Intramuscular
Exposure time	:	30 d
Target Organs	:	Kidney

Species	:	Rat
LOAEL	:	25 mg/kg
Application Route	:	oral (feed)
Exposure time	:	84 Weeks
Target Organs	:	ear
Symptoms	:	hearing loss
Remarks	:	mortality observed

Species	:	Dog
LOAEL	:	20 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	90 d
Target Organs	:	Kidney

Aluminum tristearate:

Species	:	Rat
NOAEL	:	>= 5,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Remarks	:	Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Benzylpenicillin:

Inhalation	:	Symptoms: Allergic reactions, Abdominal pain, bronchospasm, skin rash

Neomycin, sulfate (salt):

Skin contact	:	Symptoms: Sensitisation Remarks: May irritate skin.
Eye contact	:	Remarks: May cause eye irritation.
Ingestion	:	Symptoms: Nausea, Vomiting, Diarrhoea, tinnitus, hearing loss, Loss of balance

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

White mineral oil (petroleum):

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l Exposure time: 28 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 1,000 mg/l Exposure time: 21 d

Benzylpenicillin:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 hrs Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 3.6 mg/l Exposure time: 48 hrs Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201 NOEC (Raphidocelis subcapitata (freshwater green alga)): 50

		mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201 EC50 (blue-green algae): 0.74 mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201 NOEC (blue-green algae): 0.14 mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to microorganisms	:	EC50: > 500 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC: 5 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

Neomycin, sulfate (salt):

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 72 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 LC50 (Americamysis): 39 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035
Toxicity to algae/aquatic plants	:	EC50 (Anabaena flos-aquae (cyanobacterium)): 0.00075 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0003 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 EC50 (Pseudokirchneriella subcapitata (green algae)): 0.0099 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0022 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic tox-	:	1,000

icity)		
M-Factor (Chronic aquatic toxicity)	:	10
Toxicity to microorganisms	:	EC50 (Natural microorganism): 107.6 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 EC10 (Natural microorganism): 2.8 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

Aluminum tristearate:

Ecotoxicology Assessment

Acute aquatic toxicity	:	Toxic effects cannot be excluded
Chronic aquatic toxicity	:	Toxic effects cannot be excluded

Persistence and degradability

Components:

White mineral oil (petroleum):

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 31 % Exposure time: 28 d

Benzylpenicillin:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 70.10 % Exposure time: 28 d Method: OECD Test Guideline 301B

Neomycin, sulfate (salt):

Biodegradability	:	Result: rapidly degradable Biodegradation: 50 % Exposure time: 1.2 d Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

Neomycin, sulfate (salt):

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

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. (Neomycin, sulfate (salt), Benzylpenicillin)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

IATA-DGR

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Neomycin, sulfate (salt), Benzylpenicillin)
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. (Neomycin, sulfate (salt), Benzylpenicillin)
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

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

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

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Mineral oil	>=70 - <80	-

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Mineral oil	-

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)
Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)
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

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

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

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

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA	:	8-hour, time-weighted average

AIIC - 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 - 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