

Kanamycin Acid Sulfate Formulation

Version **Revision Date:** SDS Number: Date of last issue: 15.12.2023 2.2 06.04.2024 11272792-00005 Date of first issue: 18.09.2023

Section 1: Identification

Product identifier Kanamycin Acid Sulfate Formulation

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product Restrictions on use Not applicable

Manufacturer or supplier's details

: MSD Company

50 Tuas West Drive Address

Singapore - Singapore 638408

Telephone +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

repeated exposure (Oral)

Specific target organ toxicity - : Category 1 (Auditory system)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

GHS Label elements, including precautionary statements

Hazard pictograms



Signal word

H372 Causes damage to organs (Auditory system) through Hazard statements

prolonged or repeated exposure if swallowed.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements Prevention:

P260 Do not breathe mist or vapours.



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P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.

Response:

P314 Get medical advice/ attention if you feel unwell.

P391 Collect spillage.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Kanamycin acid sulfate	64013-70-3	>= 20 -< 25
Phenol	108-95-2	>= 0.1 -< 0.25

Section 4: First-aid measures

Description of necessary first-aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.

Get medical attention if symptoms occur.

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 if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

Risks : 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).

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.



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Section 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Hazardous combustion prod: :

ucts

Exposure to combustion products may be a hazard to health.

Carbon oxides

Special protective actions for fire-fighters

Special protective equipment :

for firefighters

Specific extinguishing meth-

ods

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions

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

Methods for 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 absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items



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employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

Section 7: Handling and storage

Precautions for safe 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 breathe mist or vapours.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

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.

Conditions for safe storage, including any incompatibilities

Conditions for safe storage : Keep in properly labelled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Kanamycin acid sulfate	64013-70-3	TWA	100 μg/m3 (OEB	Internal



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			2)	
Phenol	108-95-2	PEL (long	5 ppm	SG OEL
		term)	19 mg/m3	
		TWA	5 ppm	ACGIH

Biological occupational exposure limits

Components	CAS-No.	Control	Biological	Sam-	Permissible	Basis
		parameters	specimen	pling	concentra-	
				time	tion	
Phenol	108-95-2	Phenol	Urine	End of shift (As soon as possible after	250 mg/g creatinine	ACGIH BEI
				exposure ceases)		

Appropriate engineering control 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.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face 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 protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type
Hand protection

: Particulates type

Material : Chemical-resistant gloves

Section 9: Physical and chemical properties

Appearance : liquid

Colour : colourless

Odour : characteristic

Odour Threshold : No data available

pH : 3.5 - 5.5



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Melting point/freezing point : No data available

Initial boiling point and boiling :

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower :

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.05 - 1.10 g/cm³

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : 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

Section 10: Stability and reactivity



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Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

Section 11: Toxicological information

Information on likely routes of: Inhalation

exposure Skin contact

Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Acute toxicity estimate: > 5 mg/l Acute inhalation toxicity

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Acute toxicity estimate: > 2,000 mg/kg Acute dermal toxicity

Method: Calculation method

Components:

Kanamycin acid sulfate:

Acute oral toxicity LD50 (Rat): > 4,000 mg/kg

LD50 (Mouse): 12,000 mg/kg

LD50 (Rabbit): > 3,000 mg/kg

Phenol:

Acute oral toxicity LD50 (Rat): 650 mg/kg

Method: OECD Test Guideline 401

Acute toxicity estimate (Humans): 140 - 290 mg/kg

Method: Expert judgement

LC0 (Rat): 0.9 mg/l Acute inhalation toxicity

Exposure time: 8 h

Test atmosphere: dust/mist

Assessment: Corrosive to the respiratory tract.



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Acute toxicity estimate (Humans): > 0.9 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Expert judgement

Acute dermal toxicity : LD50 (Rabbit): 660 mg/kg

Method: OECD Test Guideline 402

Acute toxicity estimate (Humans): 300 mg/kg

Method: Expert judgement

Skin corrosion/irritation

Not classified based on available information.

Components:

Kanamycin acid sulfate:

Remarks : No data available

Phenol:

Species : Rabbit

Result : Corrosive after 3 minutes to 1 hour of exposure

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Kanamycin acid sulfate:

Remarks : No data available

Phenol:

Species : Rabbit

Result : Irreversible effects on the eye Method : OECD Test Guideline 405

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Kanamycin acid sulfate:

Test Type : Maximisation Test Species : Guinea pig

Assessment : Did not cause sensitisation on laboratory animals.



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Result : negative

Phenol:

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

Method : OECD Test Guideline 406

Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Kanamycin acid sulfate:

Genotoxicity in vitro : Test Type: Ames test

Result: negative

Test Type: mitotic recombination assay

Test system: Escherichia coli

Result: negative

Test Type: DNA Repair Test system: Escherichia coli

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow

Result: negative

Phenol:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: positive

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: positive

Remarks: Annex VI From 1272/2008

Germ cell mutagenicity -

Assessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity tests.

Carcinogenicity

Not classified based on available information.



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Components:

Phenol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Kanamycin acid sulfate:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Intravenous injection

Developmental Toxicity: 100 mg/kg body weight

Symptoms: No adverse effects

Test Type: reproductive and developmental toxicity study

Application Route: Intravenous injection

Developmental Toxicity: NOAEL: 400 mg/kg body weight

Symptoms: No adverse effects Target Organs: Auditory system Result: Post-natal toxicity

Test Type: Reproduction/Developmental toxicity screening

test

Species: Guinea pig

Application Route: Intramuscular

Developmental Toxicity: NOAEL: > 100 mg/kg body weight

Target Organs: Auditory system

Remarks: Significant toxicity observed in testing

Phenol:

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

STOT - single exposure

Not classified based on available information.



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STOT - repeated exposure

Causes damage to organs (Auditory system) through prolonged or repeated exposure if swallowed.

Components:

Kanamycin acid sulfate:

Exposure routes : Oral

Target Organs : Auditory system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Phenol:

Target Organs : Central nervous system, Kidney, Liver, Skin

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Kanamycin acid sulfate:

Species : Rat

LOAEL : TDIo = 12000 mg/kg Application Route : Intraperitoneal

Exposure time : 30 d

Target Organs : Kidney, Ureter, Bladder

Remarks : Significant toxicity observed in testing

Species : Dog

LOAEL : TDIo= 6500 mg/kg
Application Route : Subcutaneous

Exposure time : 17 d

Target Organs : Auditory system, Eye, Kidney, olfactory sense organs

Remarks : Significant toxicity observed in testing

Species : Guinea pig
NOAEL : 100 mg/kg
LOAEL : > 200 mg/kg
Application Route : Intramuscular
Exposure time : 4 Weeks
Target Organs : Auditory system

Target Organs : Auditory system

Remarks : Significant toxicity observed in testing

Species : Rabbit, male LOAEL : > 50 mg/kg Application Route : Intramuscular

Exposure time : 30 d

Target Organs : Auditory system, Kidney

Remarks : Significant toxicity observed in testing



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Phenol:

Species : Rat
LOAEL : 300 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Method : OECD Test Guideline 408

Species : Rat

NOAEL : >= 0.1 mg/l

Application Route : inhalation (vapour)

Exposure time : 74 Days

Species : Rabbit
LOAEL : 260 mg/kg
Application Route : Skin contact
Exposure time : 18 Days

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Kanamycin acid sulfate:

General Information : Target Organs: Auditory system

Symptoms: Abdominal pain, altered taste, Dizziness

Remarks: The most common side effects are:

Target Organs: Kidney

Symptoms: Vomiting, skin rash, numbness

Section 12: Ecological information

Toxicity

Components:

Kanamycin acid sulfate:

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

EC50 (Pseudokirchneriella subcapitata (green algae)): 0.74

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.31



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mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (blue-green algae): 0.03 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (blue-green algae): 0.01 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

Toxicity to microorganisms

EC50: > 461 mg/l

10

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 4.9 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic organisms.

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

Phenol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 24.9 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 3.1 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Selenastrum capricornutum (green algae)): 61.1 mg/l

Exposure time: 96 h

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.077 mg/l Exposure time: 60 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 10 mg/l

Exposure time: 16 d

Toxicity to microorganisms : IC50

IC50 (Nitrosomonas sp.): 21 mg/l

Exposure time: 24 h



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Persistence and degradability

Components:

Kanamycin acid sulfate:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 0 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Phenol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 62 % Exposure time: 10 d

Method: OECD Test Guideline 301C

Bioaccumulative potential

Components:

Phenol:

Bioaccumulation : Species: Fish

Bioconcentration factor (BCF): 17.5 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

log Pow: 1.47

Mobility in soil
No data available

Other adverse effects

No data available

Section 13: Disposal considerations

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG

UN number : UN 3082

UN proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.



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(Kanamycin acid sulfate)

Transport hazard class(es) : 9
Packing group : III
Labels : 9
Environmental hazards : yes

IATA-DGR

UN/ID No. : UN 3082

UN proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Kanamycin acid sulfate)

Transport hazard class(es) : 9
Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 964

aircraft)

Packing instruction (passen: 964

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Kanamycin acid sulfate)

Transport hazard class(es) : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

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.

Section 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and

Environmental Protection and Management (Hazard-

ous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not app

Regulations

: Not applicable

Not applicable



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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

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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 Agen-

cy, http://echa.europa.eu/

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

SG OEL : Singapore. Workplace Safety and Health (General Provisions)

Regulations - First Schedule Permissible Exposure Limits of

Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average

SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

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, Evalua-



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tion, 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.

SG / EN