

SAFETY DATA SHEET



Ribavirin Liquid Formulation

Version 3.0 Revision Date: 06.04.2024 SDS Number: 402762-00020 Date of last issue: 30.09.2023 Date of first issue: 10.12.2015

Section 1: Identification

Product identifier : Ribavirin Liquid Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD
Address : 50 Tuas West Drive
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

Germ cell mutagenicity : Category 2
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Blood)

GHS Label elements, including precautionary statements

Hazard pictograms	:
Signal word	: Danger
Hazard statements	: H341 Suspected of causing genetic defects. H360Df May damage the unborn child. Suspected of damaging fertility. H373 May cause damage to organs (Blood) through prolonged or repeated exposure if swallowed.
Precautionary statements	: Prevention: P201 Obtain special instructions before use.

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P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe mist or vapours.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

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.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 30 -< 50
Glycerine	56-81-5	>= 20 -< 30
Ribavirin	36791-04-5	>= 1 -< 10

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 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.
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.

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Most important symptoms and effects, both acute and delayed

Risks : Suspected of causing genetic defects.
May damage the unborn child. Suspected of damaging fertility.
May cause 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.

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 : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Special protective actions for fire-fighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

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 protective 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).

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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 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.

Section 7: Handling and storage**Precautions for safe 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.

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 locked up.

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Materials to avoid : Keep tightly closed.
Store in accordance with the particular national regulations.
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 parame- ters / Permissible concentration	Basis
Sucrose	57-50-1	PEL (long term)	10 mg/m ³	SG OEL
		TWA	10 mg/m ³	ACGIH
Glycerine	56-81-5	PEL (long term) (Mist)	10 mg/m ³	SG OEL
Ribavirin	36791-04-5	Wipe limit	400 µg/100 cm ²	Internal
		TWA	40 µg/m ³ (OEB 3)	Internal

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. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

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. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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

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Filter type : Combined particulates and organic vapour type
Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Section 9: Physical and chemical properties

Appearance : liquid

Colour : clear

Odour : No data available

Odour Threshold : No data available

pH : 4.8 - 5.5

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 : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

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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.
Particle characteristics		
Particle size	:	Not applicable

Section 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.

Section 11: Toxicological information

Information on likely routes of exposure	:	Inhalation
		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

Components:

Sucrose:

Acute oral toxicity	:	LD50 (Rat): 29,700 mg/kg
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Glycerine:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
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Acute dermal toxicity	:	LD50 (Guinea pig): > 5,000 mg/kg
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Acute oral toxicity	:	LD50 (Rat): 4,116 - 5,584 mg/kg
		LD50 (Mouse): > 10,000 mg/kg
		LD50 (Dog): >= 1,500 mg/kg
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available
Acute toxicity (other routes of administration)	:	LD50 (Rat): 1,554 - 1,758 mg/kg Application Route: Intraperitoneal
		LD50 (Mouse): 1,268 mg/kg Application Route: Intraperitoneal

Skin corrosion/irritation

Not classified based on available information.

Components:

Glycerine:

Species	:	Rabbit
Result	:	No skin irritation

Ribavirin:

Remarks	:	No data available May irritate skin.
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Serious eye damage/eye irritation

Not classified based on available information.

Components:

Glycerine:

Species	:	Rabbit
Result	:	No eye irritation

Ribavirin:

Remarks	:	No data available May irritate eyes.
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Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

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Components:

Ribavirin:

||| Remarks : No data available

Germ cell mutagenicity

Suspected of causing genetic defects.

Components:

Sucrose:

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

Glycerine:

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

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Ribavirin:

||| Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: Rodent cell line
Result: positive

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: negative

||| Genotoxicity in vivo : Test Type: dominant lethal test
Species: Rat
Result: negative

Test Type: Mouse Lymphoma
Species: Mouse
Result: positive

Test Type: Micronucleus test
Species: Mouse
Result: positive

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Germ cell mutagenicity - Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Carcinogenicity

Not classified based on available information.

Components:

Glycerine:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Ribavirin:

Species : Mouse
Application Route : Oral
Exposure time : 6 Months
LOAEL : 75 mg/kg body weight
Result : negative
Target Organs : Blood, Testes
Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Rat
Application Route : Oral
Exposure time : 2 Years
NOAEL : 10 mg/kg body weight
Result : negative
Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Mouse
Application Route : Oral
Exposure time : 18 Months
Result : negative
Remarks : The mechanism or mode of action may not be relevant in humans.

Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

Components:

Glycerine:

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

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Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative
Ribavirin:	
Effects on fertility	: Test Type: Fertility Species: Rat, male Application Route: Intraperitoneal injection Fertility: LOAEL: < 20 mg/kg body weight Symptoms: Reduced fertility Result: positive
	Test Type: Fertility Species: Mouse, male Application Route: Oral Fertility: LOAEL: 35 mg/kg body weight Symptoms: Reduced fertility Result: positive
	Test Type: Fertility Species: Rat, females Application Route: Oral Fertility: NOAEL: 10 mg/kg body weight Result: Animal testing did not show any effects on fertility.
	Test Type: Fertility Species: Rat, male Application Route: Oral Fertility: NOAEL: 160 mg/kg body weight Result: Animal testing did not show any effects on fertility.
Effects on foetal development	: Test Type: Development Species: Rat, female Application Route: Oral Developmental Toxicity: LOAEL: <= 1 mg/kg body weight Symptoms: Reduced body weight, Reduced number of viable fetuses, Skeletal malformations Result: Embryotoxic effects and adverse effects on the offspring were detected.
	Test Type: Development Species: Rabbit, female Application Route: Oral General Toxicity Maternal: LOAEL: 1 mg/kg body weight Developmental Toxicity: LOAEL: 1 mg/kg body weight Symptoms: Reduced body weight, Skeletal malformations Result: Embryotoxic effects and adverse effects on the offspring were detected.
	Test Type: Development Species: Hamster

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Application Route: Oral
Developmental Toxicity: LOAEL: 2.5 mg/kg body weight
Symptoms: Skeletal and visceral variations, Total Resorptions / resorption rate
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: 0.3 mg/kg body weight
Embryo-foetal toxicity: LOAEL: 1 mg/kg body weight
Symptoms: Skeletal malformations
Result: positive

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

Components:**Ribavirin:**

Assessment : May cause respiratory irritation.

STOT - repeated exposure

May cause damage to organs (Blood) through prolonged or repeated exposure if swallowed.

Components:**Ribavirin:**

Exposure routes : Ingestion
Target Organs : Blood
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Glycerine:**

Species : Rat
NOAEL : 0.167 mg/l
LOAEL : 0.622 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 13 Weeks

Species : Rat
NOAEL : 8,000 - 10,000 mg/kg

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Application Route : Ingestion
Exposure time : 2 yr

Species	Rabbit
NOAEL	5,040 mg/kg
Application Route	Skin contact
Exposure time	45 Weeks

Ribavirin-

Species : Monkey
LOAEL : 30 mg/kg
Exposure time : 10 d
Target Organs : Blood, Gastrointestinal tract

Species	:	Rat
NOAEL	:	7.6 mg/kg
Application Route	:	Inhalation
Exposure time	:	90 d
Target Organs	:	Blood, Lungs

Species : Dog
NOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 1 yr
Target Organs : Blood, Gastrointestinal tract

Species	: Mouse
NOAEL	: 20 mg/kg
Application Route	: Oral
Exposure time	: 18 Months
Target Organs	: Blood, Cardio-vascular system

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ribavirin:

Inhalation	: Symptoms: Headache, Dizziness Remarks: Based on Human Evidence
Skin contact	: Remarks: May cause eye irritation. Based on Human Evidence
Eye contact	: Remarks: May cause eye irritation. Based on Human Evidence
Ingestion	: Symptoms: blood effects, immune system effects, anorexia, Dizziness, insomnia, Fatigue, Headache, Itching, Rash, liver function change, Gastrointestinal disturbance

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Section 12: Ecological information

Toxicity

Components:

Glycerine:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1,955 mg/l Exposure time: 48 h
Toxicity to microorganisms	:	NOEC (Pseudomonas putida): > 10,000 mg/l Exposure time: 16 h Method: DIN 38 412 Part 8

Ribavirin:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 119 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 117 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 119 mg/l Exposure time: 96 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 6.9 mg/l Exposure time: 96 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

Components:

Glycerine:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 92 % Exposure time: 30 d Method: OECD Test Guideline 301D
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Bioaccumulative potential

Components:

Sucrose:

Partition coefficient: n-octanol/water : Pow: < 1

Glycerine:

Partition coefficient: n-octanol/water : log Pow: -1.75

Ribavirin:

Partition coefficient: n-octanol/water : log Pow: 0.971

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 handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG

UN number : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
UN proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable

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Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
UN proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

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 : Not applicable
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable
Regulations

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 : Internal technical data, data from raw material SDSs, OECD
compile the Safety Data eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>
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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
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, 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.

SG / EN