



Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Indinavir 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 : Pharmaceutical Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Serious eye damage/eye irri-

tation

Category 2A

Reproductive toxicity : Category 2

GHS label elements

Hazard pictograms



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

H361d Suspected of damaging the unborn child.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.





Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

attention.

P337 + P313 If eye irritation persists: Get medical advice/ at-

tention.

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

Important symptoms and outines of the emergency as-

sumed

May form explosive dust-air mixture during processing, han-

dling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Indinavir	157810-81-6	>= 70 - < 80	
Magnesium stearate	557-04-0	>= 1 - < 10	2-611

4. 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.

In case of skin contact : In case of contact, immediately flush skin with 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 : In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.





Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

Causes serious eye irritation.

delaved

Suspected of damaging the unborn child.

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 None known.

Unsuitable extinguishing

media

Specific hazards during fire-

fighting

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Metal oxides

Specific extinguishing meth-

ods

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.

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 emer-

gency procedures

Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. 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

Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are re-





Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

> leased into the atmosphere in sufficient concentration. 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 : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres. Use only with adequate ventilation.

Local/Total ventilation Advice on safe handling

Do not get on skin or clothing.

Do not breathe dust. Do not swallow.

Do not get in eyes.

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

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

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.

Storage

Conditions for safe storage : Keep in properly labelled containers.

Store locked up.

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





Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible concentration	Basis
Indinavir	157810-81-6	TWA	1,000 µg/m3	Internal
Magnesium stearate	557-04-0	TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH

Engineering measures : Ensure adequate ventilation, especially in confined areas.

Minimize workplace exposure concentrations. Apply measures to prevent dust explosions.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

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

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the

end of workday.

Eye protection : Wear the following personal protective equipment:

Safety goggles

Skin and body protection : Select appropriate protective clothing based on chemical

resistance data and an assessment of the local exposure

potential.

Skin contact must be avoided by using impervious protective

clothing (gloves, aprons, boots, etc).

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder



Indinavir Formulation

Version SDS Number: Date of last issue: 2023/04/04 **Revision Date:** 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

Colour white

Odour odourless

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) May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- :

per flammability limit

No data available

Lower explosion limit /

Lower flammability limit

No data available

Flash point No data available

Decomposition temperature No data available

No data available pΗ

Evaporation rate No data available

Auto-ignition temperature No data available

Viscosity

No data available Viscosity, dynamic

Viscosity, kinematic No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

No data available

No data available Vapour pressure

Density and / or relative density

Density No data available

Relative vapour density No data available



Indinavir Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

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

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation. Oxidizing agents

Incompatible materials

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:

Indinavir:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

LD50 (Mouse): > 5,000 mg/kg

Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-

icity

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Remarks: Based on data from similar materials



Indinavir Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

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Skin corrosion/irritation

Not classified based on available information.

Components:

Indinavir:

Species : Rabbit

Result : Mild skin irritation
Remarks : slight irritation

Magnesium stearate:

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Indinavir:

Species : Bovine cornea Remarks : Severe eye irritation

Magnesium stearate:

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Magnesium stearate:

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.





Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

Components:

Indinavir:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Alkaline elution assay

Result: negative

Genotoxicity in vivo : Test Type: Mammalian bone marrow sister chromatid ex-

change

Application Route: Intraperitoneal injection

Result: negative

Magnesium stearate:

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

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

Indinavir:

Species : Rat Application Route : Oral

NOAEL : 640 mg/kg body weight

Result : negative

Species : Mouse
Application Route : Oral
Result : negative

Reproductive toxicity

Suspected of damaging the unborn child.





Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

Components:

Indinavir:

Effects on fertility : Test Type: Fertility

Species: Rat

Result: No effects on mating performance

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Monkey

Developmental Toxicity: LOAEL: 160 mg/kg body weight

Result: Effects on foetal development

Test Type: Embryo-foetal development

Species: Rat

Developmental Toxicity: NOAEL: 40 mg/kg body weight

Result: Effects on foetal development

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Oral

Embryo-foetal toxicity: NOAEL: 240 mg/kg body weight

Result: No effects on foetal development

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

Magnesium stearate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal 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.

Repeated dose toxicity

Components:

Indinavir:



Indinavir Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

Species : Rat

NOAEL : 10 mg/kg

Application Route : Oral

Exposure time : 53 Weeks

Remarks : No significant adverse effects were reported

Species: DogNOAEL: 10 mg/kgApplication Route: OralExposure time: 53 Weeks

Remarks : No significant adverse effects were reported

Species : Monkey
NOAEL : 80 mg/kg
Application Route : Oral
Exposure time : 5 Weeks

Remarks : No significant adverse effects were reported

Magnesium stearate:

Species : Rat

NOAEL : > 100 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:

Indinavir:

Ingestion : Symptoms: Nausea, Abdominal pain, Headache, Kidney dis-

orders, liver function change

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Indinavir:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 20 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: No toxicity at the limit of solubility

LC50 (Oncorhynchus mykiss (rainbow trout)): 438 mg/l

Exposure time: 96 h





Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

Method: OECD Test Guideline 203

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 20 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic

plants

NOEC (Pseudokirchneriella subcapitata (green algae)): 6.47

mg/l

Exposure time: 10 d

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50: > 20 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Remarks: No toxicity at the limit of solubility

NOEC: 10 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Remarks: No toxicity at the limit of solubility

Magnesium stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l

Exposure time: 48 h Method: DIN 38412

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 47 h

Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials

No toxicity at the limit of solubility

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

No toxicity at the limit of solubility

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1

ma/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials





Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l

Exposure time: 16 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Persistence and degradability

Components:

Indinavir:

Stability in water : Hydrolysis: 50 %(651 d)

Magnesium stearate:

Biodegradability : Result: Not biodegradable

Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Indinavir:

Partition coefficient: n-

octanol/water

log Pow: 2.66

Magnesium stearate:

Partition coefficient: n-

octanol/water

log Pow: > 4

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations



Indinavir Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

IATA-DGR

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

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

IMDG-Code

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

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

Not applicable

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



Indinavir Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

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
Magnesium stearate	>=1 - <10	-

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Magnesium stearate	-

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

Indinavir Formulation



Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not 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 cy, 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.

Internal technical data, data from raw material SDSs, OECD

eChem Portal search results and European Chemicals Agen-

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



Indinavir Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 42770-00022 Date of first issue: 2015/01/07

- 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