

Buserelin Formulation

Version 7.0 Revision Date: 2023/12/04 SDS Number: 641708-00019 Date of last issue: 2023/09/30
Date of first issue: 2016/05/03

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Buserelin Formulation

Other means of identification : RECEPTAL (A004062)

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuuma 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**

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

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.
Benzyl alcohol	100-51-6	> 0 - < 10	3-1011
Buserelin	68630-75-1	< 0.1	

4. FIRST AID MEASURES

Buserelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2023/12/04	641708-00019	Date of first issue: 2016/05/03

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	:	None known.
Protection of first-aiders	:	No special precautions are necessary for first aid responders.
Notes to physician	:	Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	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	:	Soak up with inert absorbent material.

Buserelin Formulation

Version 7.0	Revision Date: 2023/12/04	SDS Number: 641708-00019	Date of last issue: 2023/09/30 Date of first issue: 2016/05/03
----------------	------------------------------	-----------------------------	---

containment and cleaning up

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

Avoidance of contact : Oxidizing agents

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

When using do not eat, drink or smoke.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Storage

Conditions for safe storage : Keep in properly labelled containers.
Store 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 / Reference concentration /	Basis

Buserelin Formulation

Version 7.0 Revision Date: 2023/12/04 SDS Number: 641708-00019 Date of last issue: 2023/09/30
 Date of first issue: 2016/05/03

			Permissible concentration	
Benzyl alcohol	100-51-6	OEL-C	25 mg/m ³	JP OEL JSH
	Further information: Skin sensitizing agent; Group 2 substances which probably induce allergic reactions in humans.			
Buserelin	68630-75-1	TWA	0.1 µg/m ³ (OEB 5)	Internal
		Wipe limit	1 µg/100 cm ²	Internal

Engineering measures : Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
 No open handling permitted.
 Totally enclosed processes and materials transport systems are required.
 Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

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 : Organic vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.
 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid, Aqueous solution

Colour : colourless

Buserelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2023/12/04	641708-00019	Date of first issue: 2016/05/03

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 : Not applicable

Decomposition temperature : No data available

pH : 5.7 - 6.3

Evaporation rate : No data available

Auto-ignition temperature : Not applicable

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : soluble

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

Vapour pressure : No data available

Density and / or relative density

Relative density : No data available

Density : 1.004 g/cm³

Relative vapour density : No data available

Explosive properties : Not explosive

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

Buserelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2023/12/04	641708-00019	Date of first issue: 2016/05/03

Molecular weight : Not applicable

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 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.

Product:

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

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:**Benzyl alcohol:**

Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Buserelin :

Acute oral toxicity : LD50 (Rat): 400 mg/kg

Buserelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2023/12/04	641708-00019	Date of first issue: 2016/05/03

Acute toxicity (other routes of administration)	LD50 (Mouse): > 1,000 mg/kg
	LD50 (Rat): 36 mg/kg Application Route: Intravenous
	LD50 (Rat): > 500 mg/kg Application Route: Subcutaneous
	LD50 (Mouse): 56 - 78 mg/kg Application Route: Intravenous
	LD50 (Dog): > 100 mg/kg Application Route: Subcutaneous

Skin corrosion/irritation

Not classified based on available information.

Components:**Benzyl alcohol:**

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

Buserelin :

Species	: Rabbit
Result	: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Benzyl alcohol:**

Species	: Rabbit
Result	: Irritation to eyes, reversing within 21 days
Method	: OECD Test Guideline 405

Buserelin :

Species	: Rabbit
Result	: No eye irritation

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Buserelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2023/12/04	641708-00019	Date of first issue: 2016/05/03

Components:**Benzyl alcohol:**

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative

Buserelin :

Exposure routes	: Dermal
Species	: Guinea pig
Result	: Not a skin sensitizer.

Germ cell mutagenicity

Not classified based on available information.

Components:**Benzyl alcohol:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cyto-genetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

Buserelin :

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: unscheduled DNA synthesis assay Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cyto-genetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Benzyl alcohol:**

Species	: Mouse
Application Route	: Ingestion

Buserelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2023/12/04	641708-00019	Date of first issue: 2016/05/03

Exposure time	: 103 weeks
Method	: OECD Test Guideline 451
Result	: negative

Buserelin :

Species	: Rat
Application Route	: Subcutaneous
Exposure time	: 24 Months
Result	: negative
Target Organs	: Uterus (including cervix), Pituitary gland, Testes

Reproductive toxicity

Not classified based on available information.

Components:**Benzyl alcohol:**

Effects on fertility	: Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on foetal development	: Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative

Buserelin :

Effects on fertility	: Test Type: Fertility/early embryonic development Species: Rat Application Route: Subcutaneous Fertility: LOAEL: 0.2 µg/kg Result: Effects on fertility
	: Test Type: Fertility/early embryonic development Species: Mouse, male Application Route: Subcutaneous Fertility: LOAEL: > 1,000 µg/kg Result: Effects on fertility
	: Test Type: Fertility/early embryonic development Species: Mouse, female Application Route: Subcutaneous Fertility: LOAEL: 100 µg/kg Result: Effects on fertility
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Intravenous injection Developmental Toxicity: LOAEL: 0.4 µg/kg body weight

Buserelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2023/12/04	641708-00019	Date of first issue: 2016/05/03

Result: Embryotoxic effects., Effects on early embryonic development

Test Type: Embryo-foetal development

Species: Rabbit

Developmental Toxicity: LOAEL: 0.1 µg/kg body weight

Result: Embryotoxic effects., No specific developmental abnormalities

Test Type: Embryo-foetal development

Species: Mouse

Developmental Toxicity: NOAEL: 0.1 µg/kg body weight

Result: Embryotoxic effects., No effects on F1 offspring

Reproductive toxicity - Assessment : May damage fertility.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Benzyl alcohol:

Species	: Rat
NOAEL	: 1.072 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 28 Days
Method	: OECD Test Guideline 412

Buserelin :

Species	: Rat
LOAEL	: 0.5 ug/kg/day
Application Route	: Subcutaneous
Exposure time	: 14 Days

Species	: Rat
LOAEL	: 0.05 ug/kg/day
Application Route	: Subcutaneous
Exposure time	: 28 Days
Target Organs	: Testis

Species	: Rabbit
NOAEL	: 20 ug/kg/day
Exposure time	: 4 Weeks
Target Organs	: Testis, Prostate, Pituitary gland

Species	: Monkey
LOAEL	: 5 ug/kg/day

Buserelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2023/12/04	641708-00019	Date of first issue: 2016/05/03

Exposure time	: 1 yr
Target Organs	: Ovary, Pituitary gland

Species	: Dog
LOAEL	: 0.05 mg/kg
Application Route	: Subcutaneous
Exposure time	: 30 Days
Target Organs	: Testis, Pituitary gland

Species	: Dog
LOAEL	: 0.05 mg/kg
Application Route	: Subcutaneous
Exposure time	: 6 Months
Target Organs	: Reproductive organs

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Buserelin :**

Inhalation	: Symptoms: male reproductive effects, female reproductive effects, reduced libido, Headache, Rash, Gastrointestinal disturbance, mental depression, Local irritation Remarks: May damage fertility. Based on Human Evidence
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12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Benzyl alcohol:**

Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	: NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h

Buserelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2023/12/04	641708-00019	Date of first issue: 2016/05/03

Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Buserelin :**Ecotoxicology Assessment**

Acute aquatic toxicity : No data available

Chronic aquatic toxicity : No data available

Persistence and degradability**Components:****Benzyl alcohol:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Bioaccumulative potential**Components:****Benzyl alcohol:**

Partition coefficient: n-octanol/water : log Pow: 1.05

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**

Buserelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2023/12/04	641708-00019	Date of first issue: 2016/05/03

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 aircraft) : Not applicable
 Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
 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 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

Buserelin Formulation

Version 7.0 Revision Date: 2023/12/04 SDS Number: 641708-00019 Date of last issue: 2023/09/30
 Date of first issue: 2016/05/03

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
Benzyl alcohol	>0 - <10	-

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
benzyl alcohol	-

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

Buserelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2023/12/04	641708-00019	Date of first issue: 2016/05/03

Explosive Control Law

Not applicable

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 : Noxious liquid substance(Category Z)

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 : 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

JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

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

Buserelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2023/12/04	641708-00019	Date of first issue: 2016/05/03

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