

Pancrelipase (High / Low Lipase) Formulation



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2020/10/10

 1.3
 2021/04/09
 5322081-00004
 Date of first issue: 2019/11/22

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Pancrelipase (High / Low Lipase) Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : JL Raya Pandaan KM. 48

Pandaan, Jawa Timur - Indonesia

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS Classification

Skin corrosion/irritation : Category 2

Serious eye damage/eye irri-

tation

Category 2A

Respiratory sensitisation : Category 1

GHS label elements

Hazard pictograms

Signal word : Danger

Hazard statements : H315 Causes skin irritation.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Precautionary statements : Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ eye protection/ face protection.

P284 Wear respiratory protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water. P304 + P340 IF INHALED: Remove person to fresh air and



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keep comfortable for breathing.

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

P332 + P313 If skin irritation occurs: Get medical advice/ atten-

tion.

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

tention.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

Disposal:

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

Other hazards which do not result in classification

May form combustible dust concentrations in air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Pancrelipase	53608-75-6	>= 60 -<= 100
Talc	14807-96-6	< 10
Starch	9005-25-8	< 10
Sucrose	57-50-1	< 10
Diethyl phthalate	84-66-2	< 10

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.

If not breathing, give artificial respiration.

If breathing is difficult, give oxygen.

Get medical attention.

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

for at least 15 minutes while removing 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, DO NOT induce vomiting.



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Get medical attention if symptoms occur.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

Causes skin irritation.
Causes serious eye irritation.

and effects, both acute and delayed

May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive airways dysfunction syndrome).

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

: High volume water jet

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.

Do not use a solid water stream as it may scatter and spread

fire.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Nitrogen oxides (NOx)

Sulphur 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, protec-:

tive equipment and emergency 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 : Sweep up or vacuum up spillage and collect in suitable con-



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containment and cleaning up 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 released 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

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.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation.

Do not get on skin or clothing.

Avoid breathing dust, fume, gas, mist, vapours or spray.

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

Keep container tightly closed.

Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.

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.

Conditions for safe storage : Keep in properly labelled containers.

Keep tightly closed.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

In the second se				
Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Pancrelipase	53608-75-6	TWA	OEB 3 (>= 10 <	Internal
·			100 μg/m3)	
Talc	14807-96-6	NAB (Res-	2 mg/m3	ID OEL



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			fied as carcinogenio			
	mans or anin	mans or animals				
		TWA (Respirable particulate matter)	2 mg/m3	ACGIH		
Starch	9005-25-8	NAB	10 mg/m3	ID OEL		
	enough data	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals				
		TWA	10 mg/m3	ACGIH		
Sucrose	57-50-1	NAB	10 mg/m3	ID OEL		
	enough data	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals				
		TWA	10 mg/m3	ACGIH		
Diethyl phthalate	84-66-2	NAB	5 mg/m3	ID OEL		
	enough data	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals TWA 5 mg/m3 ACGIH				
		1	<i>₽</i>			

Engineering measures : 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 con-

tainment devices).

Minimize open handling.

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. Combined particulates and organic vapour type

Filter 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, dis-



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posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the work-

ing 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form combustible dust concentrations in air.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available



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Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

Molecular weight : No data available

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-

the second strict of the secon

uons

May form combustible dust concentrations in air.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents

No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

InhalationSkin contact

Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Pancrelipase:

Acute oral toxicity : LD50 (Rat): > 10,000 mg/kg

Talc:

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

Remarks: Based on data from similar materials

Starch:

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



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

Sucrose:

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

Diethyl phthalate:

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

Acute inhalation toxicity : LC50 (Rat): > 4.64 mg/l

Exposure time: 6 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rat): > 11,181 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:

Pancrelipase:

Species : Rabbit

Method : OECD Test Guideline 404

Result : Skin irritation

Remarks : Based on data from similar materials

Talc:

Species : Rabbit

Result : No skin irritation

Diethyl phthalate:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Pancrelipase:

Result : Irritation to eyes, reversing within 21 days Remarks : Based on data from similar materials

Talc:

Species : Rabbit

Result : No eye irritation

Starch:

Species : Rabbit

Result : No eye irritation



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Diethyl phthalate:

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

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

Components:

Pancrelipase:

Exposure routes : Inhalation
Species : Humans
Result : positive

Remarks : Based on data from similar materials

Assessment : May cause sensitisation by inhalation.

Talc:

Exposure routes : Skin contact Species : Humans Result : negative

Starch:

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

Diethyl phthalate:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Pancrelipase:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test



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Method: OECD Test Guideline 476

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

Talc:

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: negative

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

Species: Rat

Application Route: Ingestion

Result: negative

Starch:

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

Result: negative

Sucrose:

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

Result: negative

Diethyl phthalate:

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

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Talc:

Species : Mouse

Application Route : inhalation (dust/mist/fume)

Exposure time : 2 Years
Result : negative



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Diethyl phthalate:

Species : Rat

Application Route : Skin contact Exposure time : 103 weeks Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Pancrelipase:

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

Species: Rat

Application Route: Ingestion

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

Talc:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Diethyl phthalate:

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: Rat

Application Route: Ingestion

Result: negative

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Skin contact

Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.



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Repeated dose toxicity

Components:

Pancrelipase:

Species : Rat

NOAEL : > 100 mg/kg Application Route : Ingestion Exposure time : 13 Weeks

Method : OECD Test Guideline 408

Remarks : Based on data from similar materials

Starch:

Species : Rat

NOAEL : >= 2,000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days

Method : OECD Test Guideline 410

Diethyl phthalate:

Species : Rat
NOAEL : 150 mg/kg
Application Route : Ingestion
Exposure time : 16 Weeks

Aspiration toxicity

Not classified based on available information.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Pancrelipase:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10 - 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 1 -

10 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): > 1 mg/l

Exposure time: 72 h



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Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Talc:

Toxicity to fish LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l

Exposure time: 24 h

Diethyl phthalate:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 12 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

LC50 (Daphnia magna (Water flea)): 90 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): 45 mg/l

Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 9 mg/l

Exposure time: 72 h

Toxicity to fish (Chronic tox-

icity)

NOEC (Cyprinus carpio (Carp)): 5 mg/l

Exposure time: 28 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 25 mg/l

Exposure time: 21 d

Persistence and degradability

Components:

Pancrelipase:

Biodegradability Result: Readily biodegradable.

Diethyl phthalate:

Biodegradability Result: Readily biodegradable.

> Biodegradation: 94.6 % Exposure time: 28 d

Bioaccumulative potential

Components:

Pancrelipase:

octanol/water

Partition coefficient: n-

 $\log Pow: < 4$

Sucrose:

Partition coefficient: n-

octanol/water

Pow: < 1

Diethyl phthalate:

Partition coefficient: nlog Pow: 2.2



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octanol/water

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mix-

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable



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Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials

Type of Hazardous Materials Restricted to Import, : Not applicable

Distribution and Supervision

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 Agen-

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average ID OEL / NAB : Long term exposure limit

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; 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.

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