

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Alvimopan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	657612-00020	Date of first issue: 02.05.2016

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Alvimopan Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-  
stance/Mixture : Pharmaceutical

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Innishannon  
County Cork - Ireland

Telephone : 353 214329300

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

#### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008)**

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

**Additional Labelling**

EUH210 Safety data sheet available on request.

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### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Alvimopan	170098-38-1	Acute Tox. 4; H302	>= 1 - < 10

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of 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.
- Protection of first-aiders : No special precautions are necessary for first aid responders.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.
- In case of skin contact : Wash with water and soap.  
Get medical attention if symptoms occur.
- In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.

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Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

### 4.2 Most important symptoms and effects, both acute and delayed

Risks : Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

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 products : Carbon oxides

### 5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary. 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.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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### 6.2 Environmental precautions

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.

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container 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 determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe 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.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
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.

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.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

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Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

dusts non-specific      4 mg/m<sup>3</sup>  
Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust)  
Basis: IE OEL

10 mg/m<sup>3</sup>  
Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust)  
Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Alvimopan	170098-38-1	TWA	10 µg/m <sup>3</sup>	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

### 8.2 Exposure controls

#### 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

Eye/face protection : Wear the following personal protective equipment:  
Safety goggles  
Equipment should conform to I.S. EN 166

Hand protection

Material : Chemical-resistant gloves

Remarks : For prolonged or repeated contact use protective gloves.  
Wash hands before breaks and at the end of workday.

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Skin and body protection	:	Skin should be washed after contact.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143
Filter type	:	Particulates type (P)

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity	:	
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available

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

Vapour pressure : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics  
Particle size : No data available

### 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

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exposure

- Skin contact
- Ingestion
- Eye contact

### Acute toxicity

Not classified based on available information.

#### Product:

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

#### Components:

##### Alvimopan:

Acute oral toxicity : LD50 (Rat): > 500 mg/kg  
LD50 (Mouse): > 4,000 mg/kg

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

Acute toxicity (other routes of administration) : LD50 (Rat): > 20 mg/kg  
Application Route: Intravenous  
Remarks: No significant adverse effects were reported

### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Alvimopan:

Species : Rabbit  
Result : Mild skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Alvimopan:

Species : Rabbit  
Result : Mild eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Alvimopan:



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Test Type : Maximisation Test  
Exposure routes : Dermal  
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Alvimopan:

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  
Test system: mouse lymphoma cells  
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow  
cytogenetic test, chromosomal analysis)  
Species: Mouse  
Application Route: Oral  
Result: negative

### Carcinogenicity

Not classified based on available information.

#### Components:

##### Alvimopan:

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
NOAEL : 500 mg/kg body weight  
Result : negative

Species : Mouse  
Application Route : Oral  
Exposure time : 2 Years  
LOAEL : 4,000 mg/kg body weight  
Result : positive  
Target Organs : Bone, Skin  
Remarks : Benign and malignant tumor(s)  
Adverse effects were observed in females only.  
There is no evidence that these findings are relevant to humans.

### Reproductive toxicity

Not classified based on available information.

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### Components:

#### **Alvimopan:**

- Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Intravenous injection  
Fertility: NOAEL: 5 mg/kg body weight  
Result: No effects on fertility
- Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 200 mg/kg body weight  
Result: No effects on fertility
- Test Type: Fertility/early embryonic development  
Species: Rabbit  
Application Route: Intravenous  
Fertility: NOAEL: 15 mg/kg body weight  
Result: No effects on fertility
- Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 100 mg/kg body weight
- Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 200 mg/kg body weight  
Result: Embryo-foetal toxicity
- Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 10 mg/kg body weight  
Result: No significant adverse effects were reported
- Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 15 mg/kg body weight  
Result: No significant adverse effects were reported

#### **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:

##### **Alvimopan:**

Species : Mouse  
NOAEL : 1000 mg/kg  
Application Route : Oral  
Exposure time : 13 Weeks  
Remarks : No significant adverse effects were reported

Species : Dog  
NOAEL : 1000 mg/kg  
Application Route : Oral  
Exposure time : 39 Weeks  
Remarks : No significant adverse effects were reported

Species : Rat  
NOAEL : 500 mg/kg  
Application Route : Oral  
Exposure time : 1 yr  
Remarks : No significant adverse effects were reported

Species : Dog  
NOAEL : 2 mg/kg  
Application Route : Intravenous  
Exposure time : 1 Months  
Remarks : No significant adverse effects were reported

### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### Experience with human exposure

#### Components:

##### **Alvimopan:**

Ingestion : Symptoms: stomach discomfort, Gastrointestinal disturbance, Nausea, Vomiting, Abdominal pain

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### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Components:

##### **Alvimopan:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 17 mg/l  
Exposure time: 96 h  
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)): > 17 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : EC50 (Scenedesmus subspicatus): > 17 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility

NOEC (Scenedesmus subspicatus): 17 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC50 : > 920 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC : 920 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

#### 12.2 Persistence and degradability

##### Components:

##### **Alvimopan:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 4 %  
Exposure time: 28 d

#### 12.3 Bioaccumulative potential

##### Components:

##### **Alvimopan:**

Partition coefficient: n- : log Pow: 0.52

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octanol/water

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

**Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

**Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.  
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.  
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.

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## SECTION 14: Transport information

### 14.1 UN number or ID number

ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name

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**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.4 Packing group

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA (Cargo)** : Not regulated as a dangerous good  
**IATA (Passenger)** : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

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## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable  
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable  
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable  
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable  
Regulation (EC) No 649/2012 of the European Parliament : Not applicable

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ment and the Council concerning the export and import  
of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable  
(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of  
major-accident hazards involving dangerous substances.  
Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

Other information : Items where changes have been made to the previous version  
are highlighted in the body of this document by two vertical  
lines.

### Full text of H-Statements

H302 : Harmful if swallowed.

### Full text of other abbreviations

Acute Tox. : Acute toxicity

IE OEL : List of Chemical Agents and Carcinogens with Occupational  
Exposure Limit Values - Code of Practice, Schedule 1 and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland  
Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by  
Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Test-  
ing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regula-  
tion (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard  
of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -  
European Chemicals Agency; EC-Number - European Community number; ECx - Concentration  
associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergen-  
cy Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration as-  
sociated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good La-  
boratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air  
Transport Association; IBC - International Code for the Construction and Equipment of Ships car-  
rying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - Interna-  
tional 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 popula-  
tion; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - Interna-

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tional Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### 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/>

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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