# Doravirine Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 06.07.2024 |
|---|---|---|---|
| 5.1 | 28.09.2024 | 9371601-00009 | Date of first issue: 27.08.2021 |

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

### 1.1 Product identifier

Trade name : Doravirine Formulation

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

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

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

Company : MSD
120 Moorgate
EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

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

### 1.4 Emergency telephone number

1-908-423-6000

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Not a hazardous substance or mixture.

### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

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

EUH210 Safety data sheet available on request.

### 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.
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.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration (% w/w) |
|---|---|---|---|
| Doravirine | 1338225-97-0 | | >= 10 - < 20 |
| Substances with a workplace exposure limit : | | | |
| Cellulose | 9004-34-6<br>232-674-9 | | >= 20 - < 30 |
| Silicon, amorphous | 112945-52-5 | | >= 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.
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.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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
Nitrogen oxides (NOx)
Halogenated compounds
Metal 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.

## 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).

### 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.
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 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.

## 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.
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.

**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.

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

No data available

## SECTION 8: Exposure controls/personal protection

**8.1 Control parameters**

**Occupational Exposure Limits**

dust of any kind

10 mg/m3
Value type (Form of exposure): TWA (Inhalable)
Basis: GB EH40

4 mg/m3
Value type (Form of exposure): TWA (Respirable fraction)
Basis: GB EH40

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---|---|---|---|---|
| Cellulose | 9004-34-6 | TWA (inhalable dust) | 10 mg/m3 | GB EH40 |
| | | TWA (Respirable dust) | 4 mg/m3 | GB EH40 |
| | | STEL (inhalable dust) | 20 mg/m3 | GB EH40 |
| Doravirine | 1338225-97-0 | TWA | 500 ug/m3 (OEB2) | Internal |
| Silicon, amorphous | 112945-52-5 | TWA (inhalable dust) | 6 mg/m3 (Silica) | GB EH40 |
| | | TWA (Respirable dust) | 2.4 mg/m3 (Silica) | GB EH40 |

**8.2 Exposure controls**

**Engineering measures**

Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

**Personal protective equipment**

| | | |
|---|---|---|
| Eye/face protection | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Hand protection | | |
| Material | : | Chemical-resistant gloves |
| Skin and body protection | : | Work uniform or laboratory coat. |
| Respiratory protection | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.<br>Equipment should conform to BS EN 143 |
| Filter type | : | Particulates type (P) |

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

| | | |
|---|---|---|
| Appearance | : | powder |
| Colour | : | off-white |
| 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 explosive dust-air mixture during processing, handling or other means. |
| 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 |
| 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. |

**9.2 Other information**

| | | |
|---|---|---|
| Flammability (liquids) | : | No data available |
| Molecular weight | : | No data available |
| Particle size | : | No data available |

## 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.<br>Can react with strong oxidizing agents. |

**10.4 Conditions to avoid**

| | | |
|---|---|---|
| Conditions to avoid | : | Heat, flames and sparks.<br>Avoid dust formation. |

**10.5 Incompatible materials**

| | | |
|---|---|---|
| Materials to avoid | : | Oxidizing agents |

**10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

**11.1 Information on toxicological effects**

| | | |
|---|---|---|
| Information on likely routes of | : | Inhalation |

| | |
|---|---|
| exposure | Skin contact<br>Ingestion<br>Eye contact |

**Acute toxicity**

Not classified based on available information.

**Components:**

**Doravirine:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 750 mg/kg<br>Remarks: No mortality observed at this dose.<br><br>(Rat): Method: Phototoxicity<br>Remarks: No evidence of phototoxicity was observed<br><br>LD50 (Dog): > 1,000 mg/kg<br>Remarks: No mortality observed at this dose.<br><br>LD50 (Mouse): > 450 mg/kg<br>Remarks: No mortality observed at this dose. |

**Cellulose:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 5.8 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg |

**Silicon, amorphous:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg<br>Method: OECD Test Guideline 401<br>Remarks: Based on data from similar materials |
| Acute inhalation toxicity | : | LC50 (Rat): > 2.08 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Assessment: The substance or mixture has no acute inhalation toxicity<br>Remarks: Based on data from similar materials |
| Acute dermal toxicity | : | LD50 (Rabbit): > 5,000 mg/kg<br>Remarks: Based on data from similar materials |

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Doravirine:**

Remarks : No data available

**Silicon, amorphous:**

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Doravirine:**

Remarks : No data available

**Silicon, amorphous:**

Species : Rabbit
Method : OECD Test Guideline 405
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:**

**Doravirine:**

Remarks : No data available

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Doravirine:**

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

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Cell type: Bone marrow

Application Route: Oral
Result: negative

**Cellulose:**

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

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

**Silicon, amorphous:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

**Components:**

**Doravirine:**

Species : Mouse
Application Route : Oral
Exposure time : 6 Months
Result : negative
Remarks : No significant adverse effects were reported

**Cellulose:**

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

**Silicon, amorphous:**

Species : Rat
Application Route : Ingestion

| | | |
|---|---|---|
| Exposure time | : | 103 weeks |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |

**Reproductive toxicity**

Not classified based on available information.

**Components:**

**Doravirine:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility<br>Species: Rat, male and female<br>Fertility: NOAEL: 450 mg/kg body weight<br>Result: No effects on fertility |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 450 mg/kg body weight<br>Result: No adverse effects<br><br>Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 300 mg/kg body weight<br>Result: No adverse effects |

**Cellulose:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**Silicon, amorphous:**

| | | |
|---|---|---|
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>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:**

**Doravirine:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 450 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 6 Months |
| Remarks | : | No significant adverse effects were reported |

| | | |
|---|---|---|
| Species | : | Mouse |
| NOAEL | : | > 450 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 3 Months |
| Remarks | : | No significant adverse effects were reported |

| | | |
|---|---|---|
| Species | : | Dog |
| NOAEL | : | > 1,000 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 9 Months |
| Remarks | : | No significant adverse effects were reported |

**Cellulose:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | >= 9,000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

**Silicon, amorphous:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 1.3 mg/l |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 13 Weeks |
| Remarks | : | Based on data from similar materials |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Doravirine:**

| | | |
|---|---|---|
| Ingestion | : | Symptoms: confusion, Headache, Dizziness, Nausea, Rash, abnormal dreams, flushing, Neurological disorders, mental depression |

## SECTION 12: Ecological information

### 12.1 Toxicity

**Components:**

**Doravirine:**

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 39 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>Remarks: No toxicity at the limit of solubility<br><br>EC50 (Americamysis): 9.1 mg/l<br>Exposure time: 96 h |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 5.8 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 5.8 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to microorganisms | : | EC50 : > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br><br>NOEC : 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |
| Toxicity to fish (Chronic toxicity) | : | NOEC: 1 mg/l<br>Exposure time: 32 d<br>Species: Pimephales promelas (fathead minnow)<br>Method: OECD Test Guideline 210<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 6.7 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211<br>Remarks: No toxicity at the limit of solubility |

**Cellulose:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l<br>Exposure time: 48 h |

Remarks: Based on data from similar materials

**Silicon, amorphous:**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 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)): > 1,000 mg/l
Exposure time: 24 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

### 12.2 Persistence and degradability

**Components:**

**Doravirine:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 2 %
Exposure time: 28 d

**Cellulose:**

Biodegradability : Result: Readily biodegradable.

### 12.3 Bioaccumulative potential

**Components:**

**Doravirine:**

Partition coefficient: n-octanol/water : log Pow: 2.08

### 12.4 Mobility in soil

**Components:**

**Doravirine:**

Distribution among environmental compartments : log Koc: 2.86

### 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 Other adverse effects

**Product:**

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

## 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.

## SECTION 14: Transport information

### 14.1 UN 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

**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 Transport in bulk according to Annex II of Marpol and the IBC Code**

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

| | | |
|---|---|---|
| UK REACH List of restrictions (Annex 17) | : | Not applicable |
| UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation | : | Not applicable |
| The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) | : | Not applicable |
| Regulation (EC) on substances that deplete the ozone layer | : | Not applicable |
| UK REACH List of substances subject to authorisation (Annex XIV) | : | Not applicable |
| GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation | : | Not applicable |

Control of Major Accident Hazards Regulations 2015 (COMAH)
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 other abbreviations**

| | | |
|---|---|---|
| GB EH40 | : | UK. EH40 WEL - Workplace Exposure Limits |
| GB EH40 / TWA | : | Long-term exposure limit (8-hour TWA reference period) |
| GB EH40 / STEL | : | Short-term exposure limit (15-minute 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 Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (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 - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; 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; 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; 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

**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/ |

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