

Enalapril / Hydrochlorothiazide Formulation

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|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 30.09.2023 |
| 6.0 | 06.04.2024 | 402636-00020 | Date of first issue: 07.01.2016 |

Section 1: Identification

Product identifier : Enalapril / Hydrochlorothiazide Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable


Manufacturer or supplier's details

Company : Organon & Co.
Address : 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302
Telephone : +1-551-430-6000
Emergency telephone number : +1-215-631-6999
E-mail address : EHSSTEWARD@organon.com

Section 2: Hazard identification**Classification of the substance or mixture**

Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure : Category 1 (Kidney, Parathyroid gland)
Specific target organ toxicity - repeated exposure : Category 2 (Cardio-vascular system)

GHS Label elements, including precautionary statements

| | | |
|--------------------------|---|--|
| Hazard pictograms | : |  |
| Signal word | : | Danger |
| Hazard statements | : | H360D May damage the unborn child. H372 Causes damage to organs (Kidney, Parathyroid gland) through prolonged or repeated exposure. H373 May cause damage to organs (Cardio-vascular system) through prolonged or repeated exposure. |
| Precautionary statements | : | Prevention: |

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P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

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

Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

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

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--|------------|-----------------------|
| Hydrochlorothiazide | 58-93-5 | >= 10 -< 20 |
| Starch | 9005-25-8 | >= 10 -< 20 |
| (S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate | 76095-16-4 | >= 1 -< 10 |

Section 4: First-aid measures**Description of necessary 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.

If inhaled : If inhaled, remove to fresh air.
 Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
 Remove contaminated clothing and shoes.
 Get medical attention.
 Wash clothing before reuse.
 Thoroughly clean shoes before reuse.

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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.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

Risks : May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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).

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

Section 5: Fire-fighting measures**Extinguishing media**

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

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 (NO_x)
Chlorine compounds
Sulphur oxides
Metal oxides

Special protective actions for fire-fighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
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**Personal precautions, protective equipment and emergency procedures**

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

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.

Methods and materials 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.

Section 7: Handling and storage**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 : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.

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Hygiene measures : Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
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.

Conditions for safe storage, including any incompatibilities

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
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

Section 8: Exposure controls/personal protection**Control parameters****Occupational Exposure Limits**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|--|------------|-------------------------------|--|----------|
| Hydrochlorothiazide | 58-93-5 | TWA | 100 µg/m ³ (OEB 2) | Internal |
| Starch | 9005-25-8 | PEL (long term) | 10 mg/m ³ | SG OEL |
| | | TWA | 10 mg/m ³ | ACGIH |
| (S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate | 76095-16-4 | TWA | 50 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 500 µg/100 cm ² | Internal |

Appropriate engineering control 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 containment devices).
Minimize open handling.

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Individual protection measures, such as personal protective equipment (PPE)

| | | |
|------------------------|---|--|
| Eye/face 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 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. |
| Respiratory protection | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. |
| Filter type | : | Particulates type |
| Hand protection | : | |
| Material | : | Chemical-resistant gloves |
| Remarks | : | Consider double gloving. |

Section 9: Physical and chemical properties

| | | |
|--|---|---|
| Appearance | : | powder |
| 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 explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |

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|--|---|--|
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | No data available |
| 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. |
| Particle characteristics Particle size | : | No data available |

Section 10: Stability and reactivity

| | | |
|------------------------------------|---|--|
| Reactivity | : | Not classified as a reactivity hazard. |
| Chemical stability | : | Stable under normal conditions. |
| Possibility of hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents. |
| Conditions to avoid | : | Heat, flames and sparks. Avoid dust formation. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

Section 11: Toxicological information

| | | |
|--|---|--|
| Information on likely routes of exposure | : | Inhalation Skin contact Ingestion Eye contact |
|--|---|--|

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Acute toxicity

Not classified based on available information.

Product:

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

Components:**Hydrochlorothiazide:**

Acute oral toxicity : LD50 (Rat): > 2,750 mg/kg
LD50 (Mouse): > 2,830 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 990 mg/kg
Application Route: Intravenous
LD50 (Mouse): 590 mg/kg
Application Route: Intravenous

Starch:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:

Acute oral toxicity : LD50 (Rat): 2,000 - 3,500 mg/kg
LDLo (Rat): 1,775 mg/kg
LD50 (Mouse): 2,000 - 3,500 mg/kg
LDLo (Mouse): 1,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 850 mg/kg
Application Route: Intravenous
LD50 (Mouse): 750 mg/kg
Application Route: Intravenous
LD50 (Dog): > 100 mg/kg
LDLo (Dog): 200 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**Hydrochlorothiazide:**

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Species : Rabbit
Result : No skin irritation

(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Hydrochlorothiazide:**

Species : Rabbit
Result : Mild eye irritation

Starch:

Species : Rabbit
Result : No eye irritation

(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:

Species : Rabbit
Result : Severe irritation

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Starch:**

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

(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : Not a skin sensitizer.

Germ cell mutagenicity

Not classified based on available information.

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Components:**Hydrochlorothiazide:**

| | | |
|-------------------------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro assay Test system: mouse lymphoma cells Result: positive |
| Genotoxicity in vivo | : | Test Type: Chromosomal aberration Species: Chinese hamster Cell type: Bone marrow Result: negative Test Type: in vivo assay Species: Mouse Cell type: Bone marrow Result: negative |
| Germ cell mutagenicity - Assessment | : | Weight of evidence does not support classification as a germ cell mutagen. |

Starch:

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

(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:

| | | |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro sister chromatid exchange assay in mammalian cells Result: negative Test Type: Alkaline elution assay Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative |

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Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)

Species: Mouse

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Hydrochlorothiazide:**

Species : Mouse, female
 Application Route : Oral
 Exposure time : 2 Years
 Result : negative

Species : Mouse, male
 Application Route : Oral
 Exposure time : 2 Years
 Result : equivocal

Species : Rat, male and female
 Application Route : Oral
 Exposure time : 2 Years
 Result : negative

(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:

Species : Rat
 Application Route : Ingestion
 Exposure time : 106 weeks
 NOAEL : 90 mg/kg body weight
 Result : negative

Species : Mouse
 Application Route : Ingestion
 Exposure time : 94 weeks
 NOAEL : 90 - 180 mg/kg body weight
 Result : negative

Reproductive toxicity

May damage the unborn child.

Components:**Hydrochlorothiazide:**

Effects on fertility : Test Type: Fertility
 Species: Rat, male and female
 Application Route: oral (feed)
 Fertility: NOAEL: 4 mg/kg body weight

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| | | |
|--|---|---|
| | | Result: Effects on fertility |
| | | Test Type: Fertility |
| | | Species: Mouse, male and female |
| | | Application Route: oral (feed) |
| | | Fertility: NOAEL: 100 mg/kg body weight |
| | | Result: Effects on fertility |
| Effects on foetal development | : | Test Type: Development |
| | | Species: Mouse |
| | | Application Route: Oral |
| | | Developmental Toxicity: NOAEL: 3,000 mg/kg body weight |
| | | Result: No teratogenic effects |
| | | Test Type: Development |
| | | Species: Rat |
| | | Application Route: Oral |
| | | Developmental Toxicity: NOAEL: 1,000 mg/kg body weight |
| | | Result: No teratogenic effects |
| (S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate: | | |
| Effects on fertility | : | Test Type: Fertility |
| | | Species: Rat, male and female |
| | | Application Route: Ingestion |
| | | Fertility: NOAEL: 90 mg/kg body weight |
| | | Result: No effects on fertility |
| Effects on foetal development | : | Species: Rat |
| | | Application Route: Ingestion |
| | | Developmental Toxicity: NOAEL: 200 mg/kg body weight |
| | | Result: No effects on foetal development |
| | | Species: Rat |
| | | Application Route: Ingestion |
| | | Developmental Toxicity: LOAEL: 1,200 mg/kg body weight |
| | | Result: Fetotoxicity |
| | | Species: Rat |
| | | Application Route: Ingestion |
| | | Developmental Toxicity: LOAEL: 30 mg/kg body weight |
| | | Result: Effects on postnatal development, Effects on newborn, No teratogenic effects |
| | | Species: Rabbit |
| | | Application Route: Ingestion |
| | | General Toxicity Maternal: LOAEL: 1 mg/kg body weight |
| | | Developmental Toxicity: LOAEL: 1 mg/kg body weight |
| | | Result: Fetotoxicity, Maternal toxicity observed., No teratogenic effects |
| Reproductive toxicity - Assessment | : | Positive evidence of adverse effects on development from human epidemiological studies. |

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II

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs (Kidney, Parathyroid gland) through prolonged or repeated exposure.
May cause damage to organs (Cardio-vascular system) through prolonged or repeated exposure.

Components:**Hydrochlorothiazide:**

| | |
|---------------|---|
| Target Organs | : Kidney, Parathyroid gland |
| Assessment | : Causes damage to organs through prolonged or repeated exposure. |

(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:

| | |
|---------------|---|
| Target Organs | : Kidney, Cardio-vascular system |
| Assessment | : Causes damage to organs through prolonged or repeated exposure. |

Repeated dose toxicity**Components:****Hydrochlorothiazide:**

| | |
|-------------------|-----------------------------|
| Species | : Rat, male and female |
| LOAEL | : 10 mg/kg |
| Application Route | : Oral |
| Exposure time | : 2 yr |
| Target Organs | : Kidney, Parathyroid gland |

| | |
|-------------------|--|
| Species | : Mouse, male and female |
| NOAEL | : 300 - 550 mg/kg |
| Application Route | : Oral |
| Exposure time | : 2 yr |
| Remarks | : No significant adverse effects were reported |

| | |
|-------------------|---------------------|
| Species | : Dog |
| | : 50 - 200 mg/kg |
| Application Route | : Oral |
| Exposure time | : 9 Months |
| Target Organs | : Parathyroid gland |

Starch:

| | |
|-------------------|---------------------------|
| Species | : Rat |
| NOAEL | : >= 2,000 mg/kg |
| Application Route | : Skin contact |
| Exposure time | : 28 Days |
| Method | : OECD Test Guideline 410 |

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(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:

| | |
|-------------------|-------------|
| Species | : Dog |
| NOAEL | : 15 mg/kg |
| LOAEL | : 30 mg/kg |
| Application Route | : Ingestion |
| Exposure time | : 1 yr |
| Target Organs | : Kidney |

| | |
|-------------------|--|
| Species | : Rat |
| NOAEL | : 90 mg/kg |
| Application Route | : Oral |
| Exposure time | : 1 yr |
| Remarks | : No significant adverse effects were reported |

| | |
|-------------------|--|
| Species | : Monkey |
| NOAEL | : 30 mg/kg |
| Application Route | : Oral |
| Exposure time | : 1 Months |
| Remarks | : No significant adverse effects were reported |

Aspiration toxicity

Not classified based on available information.

Components:**Hydrochlorothiazide:**

|| No aspiration toxicity classification

Experience with human exposure**Components:****Hydrochlorothiazide:**

| | |
|-------------|---|
| Eye contact | : Symptoms: Eye irritation |
| Ingestion | : Symptoms: Dizziness, Headache, Fatigue, Nausea, Abdominal pain, hypotension, dry mouth, electrolyte imbalance, eye pain |

(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:

| | |
|-----------|--|
| Ingestion | : Target Organs: Cardio-vascular system Symptoms: hypotension, Cough, Dizziness, Headache, Blurred vision, Fatigue, Oedema, Nausea, hyperkalemia, fainting, Weakness, skin rash Remarks: May cause harm to the unborn child. |
|-----------|--|

Section 12: Ecological information**Toxicity****Components:****Hydrochlorothiazide:**

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Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 500 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h

(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 346 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to microorganisms : EC50 (Natural microorganism): > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability**Components:****Hydrochlorothiazide:**

Stability in water : Hydrolysis: 46.2 %(96 h)

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Section 13: Disposal considerations**Disposal methods**

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.

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**International Regulations**

UNRTDG

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UN number : Not applicable
 UN proper shipping name : Not applicable
 Transport hazard class(es) : Not applicable
 Subsidiary risk : Not applicable
 Packing group : Not applicable
 Labels : Not applicable
 Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
 UN 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
 UN 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 IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

Section 15: Regulatory information
Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable
 Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable
 Regulations

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

AICS : not determined

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DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 06.04.2024

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 : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
 SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average
 SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

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; KECl - 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 Tem-

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perature; 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.

SG / EN