

SAFETY DATA SHEET



Ertugliflozin Formulation

Version
12.0

Revision Date:
2025/04/14

SDS Number:
2338013-00020

Date of last issue: 2024/09/28
Date of first issue: 2017/12/13

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Ertugliflozin Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Serious eye damage/eye irritation : Category 1

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H318 Causes serious eye damage.

Precautionary statements : **Prevention:**
P280 Wear eye protection/ face protection.

Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

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Other hazards which do not result in classification

Important symptoms and outlines of the emergency assumed : Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) | ENCS No. |
|------------------|--------------|-----------------------|---------------|
| Cellulose | 9004-34-6 | >= 50 - < 60 | |
| Ertugliflozin | 1210344-83-4 | >= 5 - < 10 | - |
| Titanium dioxide | 13463-67-7 | >= 0.1 - < 1 | 1-558, 5-5225 |

4. 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 if symptoms occur.

In case of skin contact : Wash with water and soap.
Get medical attention if symptoms occur.

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 immediately.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.
Causes serious eye damage.

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 : None known.

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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.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Metal oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
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 : 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.

7. HANDLING AND STORAGE

Handling

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| | |
|-----------------------------|---|
| 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. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin. 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. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment. |
| Avoidance of contact | : Oxidizing agents |
| Hygiene measures | : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |
| Storage | |
| Conditions for safe storage | : Keep in properly labelled containers. 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 |
| Packaging material | : Unsuitable material: None known. |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Concentra- tion standard / Permissible con- centration | Basis |
|---------------|--------------|-------------------------------------|---|----------|
| Cellulose | 9004-34-6 | TWA | 10 mg/m3 | ACGIH |
| Ertugliflozin | 1210344-83-4 | TWA | 10 µg/m3 (OEB 3) | Internal |

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| | | Wipe limit | 100 µg/100 cm ² | Internal | |
|------------------|------------|--|---|----------------|--|
| Titanium dioxide | 13463-67-7 | OEL-M (Respirable particulate matter) | 1.5 mg/m ³ (Titanium) | JP OEL JSOH | |
| | | Further information: Group 2B: possibly carcinogenic to humans | | | |
| | | OEL-M (Total particulate matter) | 2 mg/m ³ (Titanium) | JP OEL JSOH | |
| | | Further information: Group 2B: possibly carcinogenic to humans | | | |
| | | TWA (Respirable particulate matter) | 2.5 mg/m ³ (Titanium dioxide) | ACGIH | |

This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

Titanium dioxide

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 containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type

Hand protection

Material

Remarks

Eye protection

Skin and body protection

: Particulates type

: Chemical-resistant gloves

: Consider double gloving.

: 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.

: Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially contaminated clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

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|--|---|
| Physical state | : powder |
| Colour | : No data available |
| Odour | : No data available |
| Odour Threshold | : No data available |
| Melting point/freezing point | : No data available |
| Boiling point, initial boiling point and boiling range | : No data available |
| Flammability (solid, gas) | : May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : No data available |
| Lower explosion limit and upper explosion limit / flammability limit | |
| Upper explosion limit / Up- per flammability limit | : No data available |
| Lower explosion limit / Lower flammability limit | : No data available |
| Flash point | : Not applicable |
| Decomposition temperature | : No data available |
| pH | : No data available |
| Evaporation rate | : Not applicable |
| Auto-ignition temperature | : No data available |
| Viscosity | |
| Viscosity, kinematic | : Not applicable |
| Solubility(ies) | |
| Water solubility | : No data available |
| Partition coefficient: n-octanol/water | : Not applicable |
| Vapour pressure | : Not applicable |
| Density and / or relative density | |
| Relative density | : No data available |
| Density | : No data available |
| Relative vapour density | : Not applicable |

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Explosive properties : Not explosive

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

Particle characteristics
Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : 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.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

Product:

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

Components:

Cellulose:

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

Ertugliflozin:

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| | |
|---------------------------|------------------------------|
| Acute oral toxicity | : LD50 (Rat): 500 mg/kg |
| Acute inhalation toxicity | : Remarks: No data available |
| Acute dermal toxicity | : Remarks: No data available |

Titanium dioxide:

| | |
|---------------------------|--|
| Acute oral toxicity | : LD50 (Rat): > 5,000 mg/kg |
| Acute inhalation toxicity | : LC50 (Rat): > 6.82 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhalation toxicity |

Skin corrosion/irritation

Not classified based on available information.

Product:

| | |
|------------|----------------------|
| Assessment | : No skin irritation |
| Method | : EpiDerm |
| Result | : Not corrosive |

Components:**Ertugliflozin:**

| | |
|--------|-------------|
| Result | : Corrosive |
|--------|-------------|

Titanium dioxide:

| | |
|---------|----------------------|
| Species | : Rabbit |
| Result | : No skin irritation |

Serious eye damage/eye irritation

Causes serious eye damage.

Components:**Ertugliflozin:**

| | |
|--------|---------------------|
| Result | : Severe irritation |
|--------|---------------------|

Titanium dioxide:

| | |
|---------|---------------------|
| Species | : Rabbit |
| Result | : No eye irritation |

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

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Respiratory sensitisation

Not classified based on available information.

Components:

Ertugliflozin:

| | | |
|-----------|---|-------------------------------|
| Test Type | : | Local lymph node assay (LLNA) |
| Result | : | Not a skin sensitizer. |

Titanium dioxide:

| | | |
|-----------------|---|-------------------------------|
| Test Type | : | Local lymph node assay (LLNA) |
| Exposure routes | : | Skin contact |
| Species | : | Mouse |
| Result | : | negative |

Germ cell mutagenicity

Not classified based on available information.

Components:

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 |

Ertugliflozin:

| | | |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
| | | Test Type: Chromosome aberration test in vitro Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Result: negative |

Titanium dioxide:

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

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Result: negative**Carcinogenicity**

Not classified based on available information.

Components:**Cellulose:**

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

Ertugliflozin:

| | | |
|------------------------------|---|--|
| Species | : | Mouse |
| Application Route | : | Oral |
| Exposure time | : | 2 Years |
| Result | : | negative |
| Species | : | Rat |
| Application Route | : | Oral |
| Exposure time | : | 2 Years |
| Result | : | negative |
| Carcinogenicity - Assessment | : | Weight of evidence does not support classification as a carcinogen |

Titanium dioxide:

| | | |
|------------------------------|---|--|
| Species | : | Rat |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 2 Years |
| Method | : | OECD Test Guideline 453 |
| Result | : | positive |
| Remarks | : | The mechanism or mode of action may not be relevant in humans. This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard. |
| Carcinogenicity - Assessment | : | Limited evidence of carcinogenicity in inhalation studies with animals. |

Reproductive toxicity

Not classified based on available information.

Components:**Cellulose:**

| | | |
|----------------------|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study Species: Rat |
|----------------------|---|---|

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Application Route: Ingestion
Result: negative

Effects on foetal development

: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Ertugliflozin:

Effects on fertility

: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: NOAEL: 250 mg/kg body weight
Remarks: Maternal toxicity observed.
No significant adverse effects were reported

Test Type: Fertility/early embryonic development
Species: Rabbit
Application Route: Oral
Fertility: NOAEL: 200 mg/kg body weight
Remarks: No significant adverse effects were reported

Effects on foetal development

: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 50 mg/kg body weight
Remarks: Adverse developmental effects were observed

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 250 mg/kg body weight
Remarks: No significant adverse effects were reported

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:**Ertugliflozin:**Exposure routes
Target Organs
Assessment

: Oral
: Kidney, Stomach, Prostate
: May cause damage to organs through prolonged or repeated exposure.

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Repeated dose toxicity**Components:****Cellulose:**

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

Ertugliflozin:

| | | |
|-------------------|---|-----------|
| Species | : | Rat |
| LOAEL | : | 500 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 30 d |

| | | |
|-------------------|---|-----------|
| Species | : | Rat |
| LOAEL | : | 250 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 30 d |
| Target Organs | : | Kidney |

| | | |
|-------------------|---|-----------------------|
| Species | : | Rat |
| LOAEL | : | 25 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 180 d |
| Target Organs | : | Kidney, Bone, Stomach |

| | | |
|---------------|---|--|
| Species | : | Rat |
| LOAEL | : | 25 mg/kg |
| Exposure time | : | 90 d |
| Target Organs | : | Kidney, Gastrointestinal tract, Prostate |

| | | |
|-------------------|---|--|
| Species | : | Dog |
| NOAEL | : | 150 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 270 d |
| Remarks | : | No significant adverse effects were reported |

| | | |
|-------------------|---|--|
| Species | : | Mouse |
| NOAEL | : | 100 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 90 d |
| Remarks | : | No significant adverse effects were reported |

| | | |
|-------------------|---|--|
| Species | : | Mouse |
| NOAEL | : | 100 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 28 d |
| Target Organs | : | Bone |
| Remarks | : | No significant adverse effects were reported |

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Titanium dioxide:

| | | |
|-------------------|---|--------------|
| Species | : | Rat |
| NOAEL | : | 24,000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 28 Days |

| | | |
|-------------------|---|-----------------------------|
| Species | : | Rat |
| NOAEL | : | 10 mg/m ³ |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 2 yr |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ertugliflozin:

| | | |
|-----------|---|---|
| Ingestion | : | Symptoms: The most common side effects are:, Headache, constipation, Diarrhoea, Nausea, urinary tract infection, muscle pain, upper respiratory tract infection |
|-----------|---|---|

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

| | | |
|------------------|---|--|
| Toxicity to fish | : | LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials |
|------------------|---|--|

Ertugliflozin:

| | | |
|----------------------------------|---|---|
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 77 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
|----------------------------------|---|---|

| | | |
|--|--|---|
| | | NOEC (Pseudokirchneriella subcapitata (green algae)): 50 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
|--|--|---|

| | | |
|-------------------------------------|---|--|
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 1 mg/l Exposure time: 32 d Method: OECD Test Guideline 210 Remarks: No toxicity at the limit of solubility |
|-------------------------------------|---|--|

| | | |
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| Toxicity to daphnia and other | : | NOEC (Daphnia magna (Water flea)): 2.14 mg/l |
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aquatic invertebrates (Chronic toxicity)
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

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

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Titanium dioxide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Persistence and degradability**Components:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

Ertugliflozin:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 40.8 %
Exposure time: 28 d

Bioaccumulative potential**Components:****Ertugliflozin:**

Partition coefficient: n-octanol/water : log Pow: 2.47

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Mobility in soil

Components:

Ertugliflozin:

Distribution among environmental compartments : log Koc: 2.88

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

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

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable

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Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

| Chemical name | Concentration (%) | Remarks |
|--------------------|-------------------|---------|
| Titanium(IV) oxide | >=0.1 - <1 | - |

Substances Subject to be Indicated Names

Not applicable

Skin and Eye Damage Substances (ISHL MO Art. 594-2)

Not applicable

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Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

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DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

ACGIH / TWA : 8-hour, time-weighted average

JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

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, Evalu-

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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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

JP / EN