SAFETY DATA SHEET

Raltegravir Pediatric Granules Formulation

Version: 2.4  Revision Date: 16.10.2020  SDS Number: 20448-00016  Date of last issue: 23.03.2020
Date of first issue: 09.10.2014

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Raltegravir Pediatric Granules Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Brihnager - Off Pune Nagar Road
Wagholi - Pune - India  412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Serious eye damage/eye irritation: Category 1
Reproductive toxicity: Category 2
Specific target organ toxicity - single exposure: Category 3
Short-term (acute) aquatic hazard: Category 3

GHS label elements
Hazard pictograms:
Signal word: Danger
Hazard statements:
H318 Causes serious eye damage.
H335 May cause respiratory irritation.
H361d Suspected of damaging the unborn child.
H402 Harmful to aquatic life.
Precautionary statements:

**Prevention:**
- P203 Obtain, read and follow all safety instructions before use.
- P261 Avoid breathing dust.
- P271 Use only outdoors or in a well-ventilated area.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- P304 + P340 + P319 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help if you feel unwell.
- P305 + P354 + P338 + P317 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical help.
- P318 IF exposed or concerned, get medical advice.

**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**
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**

**Components**

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Raltegravir</td>
<td>871038-72-1</td>
<td>&gt;= 20 - &lt; 25</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - 5</td>
</tr>
<tr>
<td></td>
<td>Ammonium hydroxide</td>
<td>1336-21-6</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
</tbody>
</table>

**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.

**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.
**SUMMARY**

**Raltegravir Pediatric Granules Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
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<tr>
<td>2.4</td>
<td>16.10.2020</td>
<td>20448-00016</td>
<td>23.03.2020</td>
<td>09.10.2014</td>
</tr>
</tbody>
</table>

**5. FIREFIGHTING MEASURES**

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

- **Unsuitable extinguishing media:** None known.

- **Specific hazards during firefighting:** 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)
  - Fluorine compounds
  - 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

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:
- Avoid breathing 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.
- Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Keep in a cool, well-ventilated place.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of)</th>
<th>Control parameters / Permissible</th>
<th>Basis</th>
</tr>
</thead>
</table>

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## Engineering measures

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). If sufficient ventilation is unavailable, use with local exhaust ventilation.

## 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**: Particulates type

### Hand protection
- **Material**: Chemical-resistant gloves

### Remarks
- Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

### Eye protection
- Wear the following personal protective equipment:
  - Chemical resistant goggles must be worn.
  - If splashes are likely to occur, wear:
  - Face-shield

### Skin and body protection
- Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Colour: off-white
Odour: odourless
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: No data available
Evaporation rate: 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
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Solubility(ies)
   Water solubility: No data available
Partition coefficient: n-octanol/water: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous 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: > 5,000 mg/kg
Method: Calculation method

Components:
Raltegravir:
Acute oral toxicity : LD50 (Mouse, male and female): > 2,000 mg/kg

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
Magnesium stearate:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

Ammonium hydroxide:
Acute oral toxicity: LD50 (Rat): 350 mg/kg

Acute inhalation toxicity: Assessment: Corrosive to the respiratory tract.

Skin corrosion/irritation
Not classified based on available information.

Components:

Raltegravir:
Species: Rabbit
Result: No skin irritation

Magnesium stearate:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Ammonium hydroxide:
Species: Rabbit
Result: Corrosive after 3 minutes to 1 hour of exposure
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

Serious eye damage/eye irritation
Causes serious eye damage.

Components:

Raltegravir:
Species: Bovine cornea
Result: Severe irritation

Magnesium stearate:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Ammonium hydroxide:
### Respiratory or skin sensitisation

#### Skin sensitisation
Not classified based on available information.

#### Respiratory sensitisation
Not classified based on available information.

### Components:

#### Raltegravir:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local lymph node assay (LLNA)</td>
<td>Mouse</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Magnesium stearate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Raltegravir:

- **Genotoxicity in vitro**: Test Type: reverse mutation assay
  - Result: negative

- **Genotoxicity in vivo**: Test Type: In vivo micronucleus test
  - Species: Mouse
  - Result: negative

#### Cellulose:

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

Magnesium stearate:
Genotoxicity in vitro
: Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

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

Carcinogenicity
Not classified based on available information.

Components:

Raltegravir:
Species
: Mouse, male and female
Exposure time
: 104 weeks
Result
: negative

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

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Raltegravir:
Effects on fertility
: Test Type: Fertility/early embryonic development
Species: Rat, male and female
Application Route: Oral
General Toxicity - Parent: NOAEL: 600 mg/kg body weight
Result: negative

Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: >= 600 mg/kg body weight
Teratogenicity: LOAEL F1: 300 mg/kg body weight
Symptoms: Skeletal malformations
Result: positive

Species: Rabbit
General Toxicity Maternal: NOAEL: >= 1,000 mg/kg body weight
Teratogenicity: NOAEL: >= 1,000 mg/kg body weight
Result: negative

Reproductive toxicity - Assessment: Some evidence of adverse effects on development, based on animal experiments.

**Cellulose:**

**Effects on fertility**

Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

**Effects on foetal development**

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

**Magnesium stearate:**

**Effects on fertility**

Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

**Effects on foetal development**

Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

**STOT - single exposure**

May cause respiratory irritation.
Components:

Raltegravir:
Exposure routes: Inhalation
Target Organs: Respiratory Tract
Assessment: May cause respiratory irritation.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Raltegravir:
Species: Dog
NOAEL: 90 mg/kg
Application Route: Oral
Exposure time: 371 d
Symptoms: Vomiting

Species: Rat
NOAEL: 30 mg/kg
LOAEL: 120 mg/kg
Application Route: Oral
Exposure time: 189 d
Target Organs: Stomach

Species: Mouse
NOAEL: 50 mg/kg
LOAEL: 500 mg/kg
Application Route: Oral
Exposure time: 14 Weeks
Target Organs: Stomach

Species: Rat
NOAEL: 50 mg/kg
LOAEL: 200 mg/kg
Application Route: Oral
Exposure time: 8 Weeks
Target Organs: Stomach

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

Magnesium stearate:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks : Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Raltegravir:

Ingestion : Symptoms: Nausea, Diarrhoea, Headache, Fever, Rash, Skin irritation

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Raltegravir:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 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
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 66 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 3.8 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

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

Toxicity to fish (Chronic toxicity) : NOEC: 9.3 mg/l
Exposure time: 33 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC: 9.5 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td></td>
<td>Species: Daphnia magna (Water flea)</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Oryzias latipes (Japanese medaka)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Method: DIN 38412</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EL50 (Daphnia magna (Water flea)): &gt; 1 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 47 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td></td>
<td>NOELR (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC10 (Pseudomonas putida): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 16 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Ammonium hydroxide:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Pimephales promelas (fathead minnow)): 8.2 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 0.66 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
</tbody>
</table>
M-Factor (Acute aquatic toxicity) : 1

Ecotoxicology Assessment
Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Persistence and degradability

Components:

Raltegravir:
Biodegradability : Result: rapidly degradable
Biodegradation: 50 %
Exposure time: 9 d
Method: OECD Test Guideline 302B

Stability in water : Hydrolysis: < 10 % (5 d)
Method: OECD Test Guideline 111

Cellulose:
Biodegradability : Result: Readily biodegradable.

Magnesium stearate:
Biodegradability : Result: Not biodegradable
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Raltegravir:
Partition coefficient: n-octanol/water : log Pow: -0.328

Magnesium stearate:
Partition coefficient: n-octanol/water : log Pow: > 4

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Further information


Date format: dd.mm.yyyy

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)

IN OEL: India. Permissible levels of certain chemical substances in work environment.

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

ACGIH / STEL: Short-term exposure limit

IN OEL / TWA: Time-Weighted Average Concentration (TWA) (8 hrs.)

IN OEL / STEL: Short-term exposure Limit STEL (15 min)

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
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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