SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Raltegravir Pediatric Granules Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Raltegravir Pediatric Granules Formulation

Manufacturer or supplier's details
Company : MSD
Address : 199 Wenhai North Road
          HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone : 908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance : powder
Colour : off-white
Odour : odourless

Causes serious eye damage. May cause respiratory irritation. Suspected of damaging the unborn child. Harmful to aquatic life.

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:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
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.
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.

**Physical and chemical hazards**
Not classified based on available information.

**Health hazards**
Causes serious eye damage. Suspected of damaging the unborn child. May cause respiratory irritation.

**Environmental hazards**
Harmful to aquatic life.

**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

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltegravir</td>
<td>871038-72-1</td>
<td>&gt;= 20 -&lt; 25</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 -&lt; 30</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 -&lt; 10</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. Thoroughly clean shoes before reuse.

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. Rinse mouth thoroughly with water.

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

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 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 method: Use extinguishing measures that are appropriate to local cir-
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

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.

Avoidance of contact : Oxidizing agents

Storage

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

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERScotAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltegravir</td>
<td>871038-72-1</td>
<td>TWA</td>
<td>1,000 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>PC-TWA</td>
<td>10 mg/m³</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Ammonium hydroxide</td>
<td>1336-21-6</td>
<td>TWA</td>
<td>25 ppm (Ammonia)</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>35 ppm (Ammonia)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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
Eye/face 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).
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.
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.
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

Exposure routes: Inhalation
Skin contact

Not available
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**Raltegravir Pediatric Granules Formulation**

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Revision Date: 2020/10/16  
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Date of last issue: 2020/03/23  
Date of first issue: 2014/10/09

**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
Raltegravir Pediatric Granules Formulation

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:
Result: Irreversible effects on the eye
Remarks: Based on skin corrosivity.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Raltegravir:
Test Type: Local lymph node assay (LLNA)
Species: Mouse
Result: negative

Magnesium stearate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials
### Germ cell mutagenicity
Not classified based on available information.

**Components:**

**Raltegravir:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>reverse mutation assay</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Alkaline elution assay</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>
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

Effects on foetal development : 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
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<thead>
<tr>
<th>Version</th>
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</tr>
</thead>
<tbody>
<tr>
<td>3.10</td>
<td>2020/10/16</td>
<td>20440-00016</td>
<td>2020/03/23</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>2014/10/09</td>
</tr>
</tbody>
</table>

---

**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

**STOT - single exposure**

May cause respiratory irritation.

**Components:**

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

#### Ammonium hydroxide:
- **Assessment:** May cause respiratory irritation.
- **Remarks:** Based on the Catalogue of Hazardous Chemicals of China

**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

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>30 mg/kg</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>LOAEL</th>
<th>120 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>189 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Stomach</td>
</tr>
</tbody>
</table>

#### Species: Mouse

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>50 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>500 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>14 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Stomach</td>
</tr>
</tbody>
</table>

#### Species: Rat

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>50 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>200 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>8 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Stomach</td>
</tr>
</tbody>
</table>

#### Cellulose:

- **Species**: Rat  
- **NOAEL**: $\geq 9,000$ 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
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 2020/03/23</th>
<th>Date of first issue: 2014/10/09</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.10</td>
<td>2020/10/16</td>
<td>20440-00016</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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:**

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants:**

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): 66 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

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

**Toxicity to fish (Chronic toxicity):**

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Pimephales promelas (fathead minnow)): 9.3 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>33 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 210</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Daphnia magna (Water flea)): 9.5 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

**Toxicity to microorganisms:**

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50: &gt; 1,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>3 h</td>
</tr>
<tr>
<td>Test Type</td>
<td>Respiration inhibition</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

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

**Cellulose:**

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

**Magnesium stearate:**

- **Toxicity to fish:**
  - LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
  - Exposure time: 48 h
  - Method: DIN 38412
  - Remarks: Based on data from similar materials

- **Toxicity to daphnia and other aquatic invertebrates:**
  - EL50 (Daphnia magna (Water flea)): > 1 mg/l
  - Exposure time: 47 h
  - Test substance: Water Accommodated Fraction
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</tr>
</tbody>
</table>

Remarks: Based on data from similar materials
No toxicity at the limit of solubility

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Toxicity (mg/l)</th>
<th>Exposure time</th>
<th>Test method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EL50 (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 1</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**NOELR (Pseudokirchneriella subcapitata (green algae))**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Toxicity (mg/l)</th>
<th>Exposure time</th>
<th>Test method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>&gt; 1</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Toxicity to microorganisms**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Toxicity (mg/l)</th>
<th>Exposure time</th>
<th>Test method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC10 (Pseudomonas putida)</td>
<td>&gt; 100</td>
<td>16 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Ammonium hydroxide**

**Toxicity to fish**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Toxicity (mg/l)</th>
<th>Exposure time</th>
<th>Test method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 (Pimephales promelas (fathead minnow))</td>
<td>8.2</td>
<td>96 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Toxicity (mg/l)</th>
<th>Exposure time</th>
<th>Test method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Daphnia magna (Water flea))</td>
<td>0.66</td>
<td>48 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

**M-Factor (Acute aquatic toxicity)**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Toxicity (mg/l)</th>
<th>Exposure time</th>
<th>Test method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Ecotoxicology Assessment**

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

### Persistence and degradability

**Components**

**Raltegravir**

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: rapidly degradable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation:</td>
<td>50 %</td>
</tr>
<tr>
<td>Exposure time:</td>
<td>9 d</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 302B</td>
</tr>
</tbody>
</table>

**Stability in water**

<table>
<thead>
<tr>
<th>Hydrolysis (%)</th>
<th>&lt; 10</th>
<th>Method: OECD Test Guideline 111</th>
</tr>
</thead>
</table>

**Cellulose**

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: Readily biodegradable.</th>
</tr>
</thead>
</table>
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 Annex II of MARPOL 73/78 and the IBC Code
   Not applicable for product as supplied.

National Regulations

GB 6944/12268
   Not regulated as a dangerous good

Special precautions for user
   Not applicable
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Raltegravir Pediatric Granules Formulation

Version 3.10
Revision Date: 2020/10/16
SDS Number: 20440-00016
Date of last issue: 2020/03/23
Date of first issue: 2014/10/09

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Determination</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

Sources of key data used to compile the Safety Data Sheet:

Date format: yyyy/mm/dd

Full text of other abbreviations:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>CN OEL</td>
<td>Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>ACGIH / STEL</td>
<td>Short-term exposure limit</td>
</tr>
<tr>
<td>CN OEL / PC-TWA</td>
<td>Permissible concentration - time weighted average</td>
</tr>
</tbody>
</table>

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; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Dose to 50% of a test population; 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 Develop-
Introduction

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.

Disclaimer

CN / EN