SAFETY DATA SHEET

Raltegravir Pediatric Granules Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Raltegravir Pediatric Granules 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 : EHSDATATESTWARD@msd.com
Emergency telephone number : +1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
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.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
</table>
| Raltegravir         | Chemical name: Raltegravir
|                    | CAS-No.: 871038-72-1
|                    | Concentration (% w/w): >= 20 - < 25
|                    | ENCS No.: 1-314 |
| Cellulose           | Chemical name: Cellulose
|                    | CAS-No.: 9004-34-6
|                    | Concentration (% w/w): >= 20 - < 30
| Magnesium stearate  | Chemical name: Magnesium stearate
|                    | CAS-No.: 557-04-0
|                    | Concentration (% w/w): >= 1 - < 10
|                    | ENCS No.: 2-611 |
| Ammonium hydroxide  | Chemical name: Ammonium hydroxide
|                    | CAS-No.: 1336-21-6
|                    | Concentration (% w/w): >= 0.1 - < 0.25
|                    | ENCS No.: |
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 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.
Methods and materials for containment and cleaning up:

- 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.

- 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

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.

Storage

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
SAFETY DATA SHEET

Raltegravir Pediatric Granules Formulation

5. PRECAUTIONS FOR USE

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/PERSONAL PROTECTION

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

<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>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>Magnesium stearate</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:
Hand protection:
Particulates type

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
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).

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit and upper explosion limit / flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
</tbody>
</table>
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.

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:
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:
Genotoxicity in vitro: Test Type: reverse mutation assay
Result: negative
Test Type: Alkaline elution assay
Test system: rat hepatocytes
Result: negative
Test Type: Chromosomal aberration
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo: Test Type: In vivo micronucleus test
Species: Mouse
Result: negative
Test Type: Chromosomal aberration
Method: OECD Test Guideline 475
Result: negative

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

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

Genotoxicity in vivo:

**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

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

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
  - NOEC (Daphnia magna (Water flea)): 9.5 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

- **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

**Cellulose:**

**Toxicity to fish**

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

**Magnesium stearate:**

**Toxicity to fish**

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

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>EL50 (Daphnia magna (Water flea)):</th>
<th>&gt; 1 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 47 h</td>
<td></td>
</tr>
<tr>
<td>Test substance:</td>
<td>Water Accommodated Fraction</td>
<td></td>
</tr>
<tr>
<td>Remarks:</td>
<td>Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

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

**Ammonium hydroxide:**

**Toxicity to fish**

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

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>EC50 (Daphnia magna (Water flea)):</th>
<th>0.66 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
</tbody>
</table>

**Remarks:**

Based on data from similar materials

No toxicity at the limit of solubility
ECOTHERMAL ASSESSMENT

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

BIOACUMULATIVE 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

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.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
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
Refer to section 15 for specific national regulation.

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

Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
</tr>
<tr>
<td>Ammonia</td>
<td>39</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
</tbody>
</table>
Substances Subject to be Indicated Names

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
</tr>
</tbody>
</table>

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 : Noxious liquid substance(Category Z)
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
SAFETY DATA SHEET

Raltegravir Pediatric Granules Formulation

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16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit

AICL - 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 Civil Aviation Organization; 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 Chemicals in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; 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 Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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
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