SECTION 1. IDENTIFICATION

Product name: Raltegravir Pediatric Granules Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Serious eye damage: Category 1
Reproductive toxicity: Category 2
Specific target organ toxicity - single exposure: 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.

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.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P304 + P340 + P312 IF INHALED: Remove person to fresh air
and keep comfortable for breathing. Call a 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.
P308 + P313 IF exposed or concerned: Get medical attention.

**Storage:**
P405 Store locked up.

**Disposal:**
P501 Dispose of contents and container to an approved waste disposal plant.

**Other hazards**
Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Raltegravir</td>
<td>No data available</td>
</tr>
<tr>
<td>Cellulose</td>
<td>No data available</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

### SECTION 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: Contact with dust can cause mechanical irritation or drying of the skin. Causes serious eye damage. May cause respiratory irritation. Suspected of damaging the unborn child.

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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 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: Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air. Add excess liquid to allow the material to enter into solution.
Soak up with inert absorbent material. 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. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

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 sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers. 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 labeled 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.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameter</th>
<th>Basis</th>
</tr>
</thead>
</table>

4 / 17
### 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

**Material**: Chemical-resistant gloves

**Remarks**: Choose gloves to protect hands against chemicals depending on the concentration 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:

---

<table>
<thead>
<tr>
<th>Material</th>
<th>(Form of exposure)</th>
<th>TWA / Permissible concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltegravir</td>
<td>871038-72-1</td>
<td>TWA</td>
</tr>
<tr>
<td></td>
<td>1000 µg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Inhalable)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable)</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
</tr>
</tbody>
</table>
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:
powder

Color:
off-white

Odor:
odorless

Odor 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

Vapor pressure:
No data available

Relative vapor density:
No data available

Relative density:
No data available

Solubility(ies):
Water solubility:
No data available
SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.

Chemical stability: Stable under normal conditions.

Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks.

Incompatible materials: Avoid dust formation.

Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 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

**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

**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

**Respiratory or skin sensitization**

**Skin sensitization**
Not classified based on available information.
### Respiratory sensitization
Not classified based on available information.

### Components:

#### Raltegravir:

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

#### Magnesium stearate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</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
  - 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**
  - 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

### 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**
  - **Species:** Rat, male and female
  - **Application Route:** Oral
  - **General Toxicity Parent:** NOAEL: 600 mg/kg body weight
  - **Result:** negative

- **Effects on fetal development**
  - **Species:** Rat
  - **Application Route:** Oral
  - **General Toxicity Maternal:** NOAEL: \( \geq 600 \) mg/kg body weight
  - **Teratogenicity:** LOAEL F1: 300 mg/kg body weight
  - **Symptoms:** Skeletal malformations
  - **Result:** positive

- **Species:** Rabbit
General Toxicity Maternal: NOAEL: \( \geq 1,000 \text{ mg/kg body weight} \)
Teratogenicity: NOAEL: \( \geq 1,000 \text{ mg/kg body weight} \)
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 fetal 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 fetal development**
  - Test Type: Embryo-fetal development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
  - Remarks: Based on data from similar materials

**STOT-single exposure**

May cause respiratory irritation.

**Components:**

**Raltegravir:**

- Routes of exposure: 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, Diarrhea, Headache, Fever, Rash, Skin irritation
## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

**Raltegravir:**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td></td>
<td>LC50 (Cyprinodon variegatus (sheepshead minnow)): &gt; 100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 66 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 3.8 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Pimephales promelas (fathead minnow)): 9.3 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 33 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Daphnia magna (Water flea)): 9.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 211</td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50: &gt; 1,000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
<tr>
<td></td>
<td>NOEC: 1,000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Oryzias latipes (Japanese medaka)): &gt; 100 mg/l</td>
</tr>
<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:**
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
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants: EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms: EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

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

### SECTION 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.

### SECTION 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.

**Domestic regulation**

**TDG**
- Not regulated as a dangerous good

**Special precautions for user**
- Not applicable

### SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
- **AICS**: not determined
- **DSL**: not determined
SAFETY DATA SHEET

Raltegravir Pediatric Granules Formulation

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWA EV : Time-weighted average exposure value

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

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.