SAFETY DATA SHEET

Raltegravir Pediatric Granules Formulation

Section 1. Identification
Product name: Raltegravir Pediatric Granules Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

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

Section 2. Hazards Identification
GHS classification in accordance with 29 CFR 1910.1200
Combustible dust
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: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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/ face protection.

Response:
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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.

Other hazards
Contact with dust can cause mechanical irritation or drying of the skin.

### SECTION 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; 30</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration 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: 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.

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 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 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 and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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.

**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**: Do not breathe dust. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Already sensitized individuals 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 (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
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<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></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
</tbody>
</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.
Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m³ - total dust, 5 mg/m³ - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m³ - respirable particles, 10 mg/m³ - inhalable particles.

Personal protective equipment
Respiratory protection
General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
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
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.

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)
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<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>
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<tbody>
<tr>
<td>8.1</td>
<td>09/13/2019</td>
<td>20462-00014</td>
<td>04/24/2019</td>
<td>10/09/2014</td>
</tr>
</tbody>
</table>

Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition 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

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.
  Avoid dust formation.
Incompatible materials : Oxidizing agents
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: > 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:
  LD50 (Rat): > 5.8 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Polyethylene glycol:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 423
  Remarks: Based on data from similar materials
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  Remarks: Based on data from similar materials

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

Polyethylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

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

Polyethylene glycol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

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

Polyethylene glycol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

Magnesium stearate:
Test Type: Maximization Test
Routes of exposure: 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.
<table>
<thead>
<tr>
<th>Components:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Raltegravir:</strong></td>
</tr>
</tbody>
</table>
| 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 |
| **Polyethylene glycol:** |
| Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials |
| **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

**IARC**
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

**NTP**
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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 fetal 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 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:**
- 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
**Toxicity to daphnia and other aquatic invertebrates**

EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

NOEC (Daphnia magna (Water flea)): 9.5 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

**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

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

**Polyethylene glycol:**

Toxicity to fish

LC50 (Poecilia reticulata (guppy)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
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
aquatic invertebrates
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.

Polyethylene glycol:
Biodegradability
Result: rapidly degradable
Remarks: Based on data from similar materials

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

Polyethylene glycol:
Partition coefficient: n-octanol/water : log Pow: < 3

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.
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
49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ</th>
<th>Calculated product RQ</th>
</tr>
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</table>
SAFETY DATA SHEET

Raltegravir Pediatric Granules Formulation

Version 8.1  Revision Date: 09/13/2019  SDS Number: 20462-00014  Date of last issue: 04/24/2019  Date of first issue: 10/09/2014

<table>
<thead>
<tr>
<th>Ammonium hydroxide</th>
<th>(lbs)</th>
<th>(lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1336-21-6</td>
<td>1000</td>
<td>*</td>
</tr>
</tbody>
</table>

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards:
- Combustible dust
- Serious eye damage or eye irritation
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)

SARA 313:
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- D-mannitol: 69-65-8
- Raltegravir: 871038-72-1
- Cellulose: 9004-34-6
- Polyvinyl pyrrolidone: 9003-39-8
- Ammonium hydroxide: 1336-21-6

California List of Hazardous Substances
- Polyvinyl pyrrolidone: 9003-39-8

California Permissible Exposure Limits for Chemical Contaminants
- Cellulose: 9004-34-6
- Magnesium stearate: 557-04-0

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

AICS: not determined

DSL: not determined

IECSC: not determined
SAFETY DATA SHEET

Raltegravir Pediatric Granules Formulation

SECTION 16. OTHER INFORMATION

Further information

**NFPA 704:**

Flammability: 1

Health: 3

Instability: 0

Special hazard

**HMIS® IV:**

- **HEALTH:** * 3
- **FLAMMABILITY:** 3
- **PHYSICAL HAZARD:** 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL: USA. NIOSH Recommended Exposure Limits
- OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- US WEEL: USA. Workplace Environmental Exposure Levels (WEEL)
- ACGIH / TWA: 8-hour, time-weighted average
- NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA Z-1 / TWA: 8-hour time weighted average
- US WEEL / TWA: 8-hr TWA

Other abbreviations:

- AIICS - Australian Inventory of Chemical Substances
- ASTM - American Society for the Testing of Materials
- bw - Body weight
- CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act
- CMR - Carcinogen, Mutagen or Reproductive Toxicant
- DIN - Standard of the German Institute for Standardisation
- DOT - Department of Transportation
- DSL - Domestic Substances List (Canada)
- ECx - Concentration associated with x% response
- EHS - Extremely Hazardous Substance
- ELeX - Loading rate associated with x% response
- EmS - Emergency Schedule
- ENCS - Existing and New Chemical Substances (Japan)
- ErCObx - Concentration associated with x% growth rate response
- ERG - Emergency Response Guide
- GHS - Globally Harmonized System
- GLP - Good Laboratory Practice
- HMIS - Hazardous Materials Identification System
- 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 Concentration to 50% of a test population
- LD50 - Lethal Dose to 50% of a test population
- MARPOL - International Convention for the Prevention of Pollution from Ships
- MSHA - Mine Safety and Health Administration
- n.o.s. - Not Otherwise Specified
- NFPA - National Fire Protection Association
- NO(A)EC - No Observed (Adverse) Effect Concentration
- NO(A)EL - No Observed (Adverse) Effect Level
- NOELR - No Observable Effect Loading Rate
- NTP - National Toxicology Program
- NZIoC - New Zealand Inventory of
SAFETY DATA SHEET

Raltegravir Pediatric Granules Formulation

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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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative


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