

## Raltegravir Pediatric Granules Formulation

Version 8.8      Revision Date: 10/01/2022      SDS Number: 20462-00021      Date of last issue: 04/09/2022  
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### SECTION 1. IDENTIFICATION

Product name : Raltegravir Pediatric Granules Formulation

#### 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

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Serious eye damage : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity : Category 3  
- single exposure

#### 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

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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.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Raltegravir	871038-72-1	>= 20 - < 30
Cellulose	9004-34-6	>= 20 - < 30
Polyethylene glycol	25322-68-3	>= 1 - < 5
Magnesium stearate	557-04-0	>= 1 - < 5

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.

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Most important symptoms and effects, both acute and delayed	:	Get medical attention. Rinse mouth thoroughly with water. 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.

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### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) 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 (NO <sub>x</sub> ) 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.

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### 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.

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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.<br>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.<br>Do not swallow.<br>Do not get in eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>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.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Keep in a cool, well-ventilated place.<br>Store in accordance with the particular national regulations.   |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents   |

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis
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		exposure)	concentration	
Raltegravir	871038-72-1	TWA	1000 µg/m <sup>3</sup> (OEB 1)	Internal
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
Polyethylene glycol	25322-68-3	TWA (aerosol)	10 mg/m <sup>3</sup>	US WEEL
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH

**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/m<sup>3</sup> - total dust, 5 mg/m<sup>3</sup> - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m<sup>3</sup> - respirable particles, 10 mg/m<sup>3</sup> - 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**

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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: 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.

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### 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	:	No data available

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flammability limit

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Solubility(ies)  
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

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**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.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

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**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

**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 (Rat): > 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



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**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

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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 : 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

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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:  $\geq$  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 mg/kg body

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weight  
 Teratogenicity: NOAEL:  $\geq$  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

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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 :  $\geq 9,000$  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, Diarrhea, Headache, Fever, Rash, Skin irritation

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

**Polyethylene glycol:**

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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  
 Exposure time: 47 h  
 Test substance: Water Accommodated Fraction  
 Method: Directive 67/548/EEC, Annex V, C.2.  
 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.

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**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

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**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.

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**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.

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## Raltegravir Pediatric Granules Formulation

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### Domestic regulation

#### 49 CFR

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

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## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

### 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  
 Reproductive toxicity  
 Serious eye damage or eye irritation  
 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
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#### 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

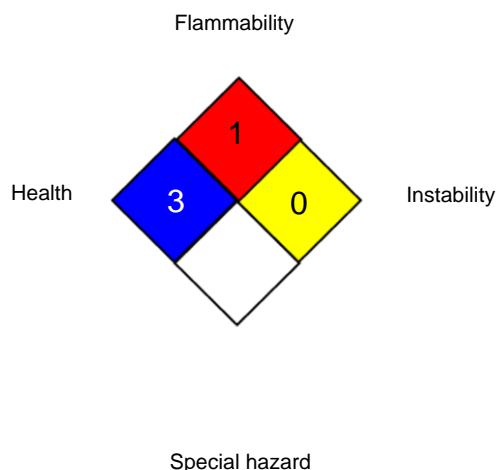
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### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA 704:



##### HMIS® IV:

<b>HEALTH</b>	*	<b>3</b>
<b>FLAMMABILITY</b>	<b>3</b>	
<b>PHYSICAL HAZARD</b>	<b>0</b>	

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

AIIC - Australian Inventory of Industrial Chemicals; 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; 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; 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 (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Oth-

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erwise 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 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; TECI - Thailand Existing Chemicals 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 10/01/2022

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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