

## Raltegravir Pediatric Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 20356-00029      Date of last issue: 12/06/2025  
Date of first issue: 10/09/2014

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### SECTION 1. IDENTIFICATION

Product name : Raltegravir Pediatric 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

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### 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 : Category 3  
- single exposure

#### 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

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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

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Raltegravir	No data available	871038-72-1*	>= 10 - <= 30	TSC

\* Indicates that the identifier is a CAS No.

TSC- the 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.

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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 (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  
Chlorine compounds  
Sulfur oxides  
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.

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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.

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### 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

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### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Raltegravir	871038-72-1	TWA	1000 (µg/m <sup>3</sup> ) (OEB 1)	Internal

**Engineering measures** : Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### 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

Hand protection

Material : Chemical-resistant gloves

Eye protection

: Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection

: Work uniform or laboratory coat.

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.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : yellow-orange

Odor : No data available

Odor Threshold : No data available

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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
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 characteristics Particle size	:	No data available

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### SECTION 10. STABILITY AND REACTIVITY

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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.

#### 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

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Raltegravir:

Species : Rabbit  
Result : No skin irritation

#### Serious eye damage/eye irritation

Causes serious eye damage.

#### Components:

##### Raltegravir:

Species : Bovine cornea  
Result : Severe irritation

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### 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

### 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

### Carcinogenicity

Not classified based on available information.

#### Components:

##### Raltegravir:

Species	:	Mouse, male and female
Exposure time	:	104 weeks
Result	:	negative

### Reproductive toxicity

Suspected of damaging the unborn child.

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### 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: LOEL F1: 300 mg/kg body weight Symptoms: Skeletal malformations. Result: positive
		Species: Rabbit General Toxicity Maternal: NOAEL: $\geq$ 1,000 mg/kg body 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.

#### **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

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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

### 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

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	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

### 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

### Bioaccumulative potential

#### Components:

##### Raltegravir:

Partition coefficient: n-octanol/water	: log Pow: -0.328
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### Mobility in soil

No data available

### Other adverse effects

No data available

### Endocrine disrupting properties

No data available

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### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
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.

#### Domestic regulation

##### TDG

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

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### SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

CA. DSL : not determined

CN IECSC : not determined

#### Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

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### SECTION 16. OTHER INFORMATION

#### Full text of other abbreviations

AICC - 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 -

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Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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, Authorization and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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/>

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

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