

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Raltegravir Pediatric Formulation

Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road
HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : 908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance	: powder
Colour	: yellow-orange
Odour	: No data available

Causes serious eye damage. May cause respiratory irritation. Suspected of damaging the unborn child.

GHS Classification

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - single exposure : Category 3

GHS label elements

Hazard pictograms :



Signal word : Danger

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

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/ face protection.

Response:

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.

Physical and chemical hazards

Not classified based on available information.

Health hazards

Causes serious eye damage. Suspected of damaging the unborn child. May cause respiratory irritation.

Environmental hazards

Not classified based on available information.

Other hazards which do not result in classification

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

May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

Chemical name	CAS-No.	Concentration (% w/w)
Raltegravir	871038-72-1	≥ 20 - < 25

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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 _x)

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

Fluorine compounds
Chlorine compounds
Sulphur 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 firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.
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 minimise 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.

7. HANDLING AND STORAGE

Handling

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Avoid breathing dust.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents
- Storage**
- Conditions for safe storage : Keep in properly labelled 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
- Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Raltegravir	871038-72-1	TWA	1000 µg/m3 (OEB 1)	Internal

- 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 de-

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

signed 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 |
| Eye/face 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). |
| Hand protection | : | |
| Material | : | Chemical-resistant gloves |
| Remarks | : | Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday. |
| 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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|------------------------------|---|-------------------|
| Appearance | : | powder |
| Colour | : | yellow-orange |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| pH | : | No data available |
| Melting point/freezing point | : | No data available |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version 4.0	Revision Date: 2024/09/28	SDS Number: 20362-00025	Date of last issue: 2024/04/06 Date of first issue: 2014/10/09
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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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition 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

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	May form explosive dust-air mixture during processing, han-

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

tions	dling or other means. Can react with strong oxidizing agents.
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes	: Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	: Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
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Components:

Raltegravir:

Acute oral toxicity	: LD50 (Mouse, male and female): > 2,000 mg/kg
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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

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

Respiratory sensitisation

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.

Components:

Raltegravir:

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

Effects on fertility	: Test Type: Fertility/early embryonic development Species: Rat, male and female Application Route: Oral General Toxicity - Parent: NOAEL: 600 mg/kg body weight Result: negative
Effects on foetal development	: Species: Rat Application Route: Oral General Toxicity Maternal: NOAEL: $\geq$ 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 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:

Exposure routes	: Inhalation
Target Organs	: Respiratory Tract
Assessment	: May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Raltegravir:

Species	: Dog
NOAEL	: 90 mg/kg
Application Route	: Oral
Exposure time	: 371 d
Symptoms	: Vomiting

Species	: Rat
NOAEL	: 30 mg/kg
LOAEL	: 120 mg/kg
Application Route	: Oral
Exposure time	: 189 d

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

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, Diarrhoea, Headache, Fever, Rash, Skin irritation

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Raltegravir:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 66 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

		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

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no

IATA-DGR

UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo aircraft)	:	Not applicable
Packing instruction (passenger aircraft)	:	Not applicable

IMDG-Code

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

GB 6944/12268

UN number	:	Not applicable
Proper shipping name	:	Not applicable

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

Class	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Marine pollutant	: no

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals	: This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.
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Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)	: Not listed
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Hazardous Chemicals for Priority Management under SAWS	: Not listed
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Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals	: Not listed
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Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export	: Not listed
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Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals	: Not listed
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Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

AICS	: not determined
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DSL	: not determined
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IECSC	: not determined
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SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

16. OTHER INFORMATION

Revision Date : 2024/09/28

Further information

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

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

Date format : yyyy/mm/dd

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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

Disclaimer

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	20362-00025	Date of first issue: 2014/10/09

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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