according to the Globally Harmonized System



# **Raltegravir Pediatric Formulation**

Version Revision Date: Date of last issue: 26.09.2023 SDS Number: 4.0 28.09.2024 20370-00024 Date of first issue: 09.10.2014

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name Raltegravir Pediatric Formulation

Manufacturer or supplier's details

Company : MSD

Address Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

+1-908-740-4000 Telephone

Emergency telephone number: +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Pharmaceutical Recommended use Restrictions on use Not applicable

## 2. HAZARDS IDENTIFICATION

### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

**GHS Classification** 

Serious eye damage/eye irri-

tation

: Category 1

Reproductive toxicity Category 2

Specific target organ toxicity - : Category 3

single exposure

**GHS** label elements

Hazard pictograms



Signal word

H318 Causes serious eye damage. Hazard statements

H335 May cause respiratory irritation.

H361d Suspected of damaging the unborn child.

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Precautionary statements : Prevention:

P203 Obtain, read and follow all safety instructions before use.

P261 Avoid breathing dust.

P264+P265 Wash hands thoroughly after handling. Do not

touch eyes.

P271 Use only outdoors or with adequate ventilation.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P304 + P340 + P319 IF INHALED: Remove person to fresh air

and keep comfortable for breathing. Get medical help if you feel

unwell

P305 + P354 + P338 + P317 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical help.

P318 IF exposed or concerned, get medical advice.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

#### 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

| 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 ad-

vice 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.

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If easy to do, remove contact lens, if worn.

Get medical attention immediately.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water. Causes serious eye damage.

Most important symptoms

and effects, both acute and

delayed

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 (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Avoid generating dust; fine dust dispersed in air in sufficient

concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx) Fluorine compounds Chlorine compounds Sulphur oxides Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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, protec: :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

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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 problem.

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 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 as-

sessment

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 respira-

tory 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.

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

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Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

| Components  | CAS-No.     | Value type<br>(Form of<br>exposure) | Control parameters / Permissible concentration | Basis    |
|-------------|-------------|-------------------------------------|--|----------|
| Raltegravir | 871038-72-1 | TWA                                 | 1000 μg/m3 (OEB<br>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 designed in a manner to prevent the escape of dust into the work

area (i.e., there is no leakage from the equipment).

If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

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.

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 re-

sistance data and an assessment of the local exposure poten-

tial.

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.

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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

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, han-

dling 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

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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-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation. Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure 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

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.

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# **Components:**

Raltegravir:

Species : Bovine cornea Result : Severe irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

### 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

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Result : negative

# 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 foetal develop-

ment

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

weiaht

Teratogenicity: NOAEL: >= 1,000 mg/kg body weight

Result: negative

Reproductive toxicity - As-

sessment

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: DogNOAEL: 90 mg/kgApplication Route: OralExposure time: 371 dSymptoms: Vomiting

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Species: RatNOAEL: 30 mg/kgLOAEL: 120 mg/kgApplication Route: OralExposure time: 189 dTarget Organs: Stomach

Species: MouseNOAEL: 50 mg/kgLOAEL: 500 mg/kgApplication Route: OralExposure time: 14 WeeksTarget 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

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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 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

Toxicity to fish (Chronic tox-

icity)

NOEC: 9.3 mg/l

Exposure time: 33 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 9.5 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

### 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

### Mobility in soil

No data available

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#### Other adverse effects

No data available

#### 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### 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 IMO instruments

Not applicable for product as supplied.

#### Special precautions for user

Not applicable

#### 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mix-

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

AICS : not determined

DSL : not determined

IECSC : not determined

# **16. OTHER INFORMATION**

Revision Date : 28.09.2024

**Further information** 

Sources of key data used to

compile the Safety Data Sheet eChem Portal search results and European Chemicals Agen-

Internal technical data, data from raw material SDSs, OECD

cy, 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.

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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

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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