

# **Raltegravir Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.0
 28.09.2024
 741567-00018
 Date of first issue: 06.06.2016

#### **SECTION 1. IDENTIFICATION**

Product identifier : Raltegravir Formulation

Manufacturer or supplier's details

Company : MSD

Address : Avenue Comendador Antônio Loureiro Ramos,

nº 1500 - Distrito Industrial

Montes Claros - MG, Brazil 39404-620

Telephone : +55 (38) 3229 7000

Emergency telephone : +55 (38) 3201 5670

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

GHS Classification in accordance with ABNT NBR 14725 Standard

Acute toxicity (Oral) : Category 5

Serious eye damage : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - :

single exposure

Category 3

Short-term (acute) aquatic

hazard

Category 3

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :







Signal Word : Danger

Hazard Statements : H303 May be harmful if swallowed.

H318 Causes serious eye damage. H335 May cause respiratory irritation.

H361d Suspected of damaging the unborn child.



# **Raltegravir Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.0
 28.09.2024
 741567-00018
 Date of first issue: 06.06.2016

H402 Harmful to aquatic life.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P261 Avoid breathing dust.

P271 Use only outdoors or in a well-ventilated area.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P301 + P312 IF SWALLOWED: Call a POISON CENTER/ doc-

tor if you feel unwell.

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.

### 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.

### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Raltegravir	871038-72-1	Acute Tox. (Oral), 5 Eye Dam., 1 Repr., 2 STOT SE, 3 Aquatic Acute, 3	>= 50 -< 70
Cellulose	9004-34-6		>= 10 -< 20
Magnesium stearate	557-04-0		>= 1 -< 5

#### **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.



# **Raltegravir Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.0 28.09.2024 741567-00018 Date of first issue: 06.06.2016

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

May be harmful if swallowed. Causes serious eye damage. May cause respiratory irritation.

Suspected of damaging the unborn child.

Contact with dust can cause mechanical irritation or drying of

the skin.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during 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

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 fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.





 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.0
 28.09.2024
 741567-00018
 Date of first issue: 06.06.2016

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emer-

gency 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.

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.

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.



# **Raltegravir Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.0
 28.09.2024
 741567-00018
 Date of first issue: 06.06.2016

Take precautionary measures against static discharges.

Take care to prevent spills, waste and minimize release to the

environment.

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.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parameters / Permissible concentration	Basis
Raltegravir	871038-72-1	exposure) TWA	1000 µg/m3 (OEB	Internal
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m³	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.

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

Hand protection

Particulates type

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending



# **Raltegravir Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.0
 28.09.2024
 741567-00018
 Date of first issue: 06.06.2016

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).

## **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state : powder

Color : No data available

Odor : No data available

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 : Not applicable

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

Density : No data available

Solubility(ies)



# **Raltegravir Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.0
 28.09.2024
 741567-00018
 Date of first issue: 06.06.2016

Water solubility : No data available

Partition coefficient: n-

Autoignition temperature

octanol/water

· : 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.

No data available

Molecular weight : No data available

Particle characteristics

Particle size : No data available

#### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

ions

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

Hazardous decomposition

Oxidizing agents

No hazardous decomposition products are known.

products

## **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of:

exposure

Inhalation Skin contact Ingestion

Eye contact

**Acute toxicity** 

May be harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 4.026 mg/kg

Method: Calculation method

**Components:** 

Raltegravir:

Acute oral toxicity : LD50 (Mouse, male and female): > 2.000 mg/kg



# **Raltegravir Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.0
 28.09.2024
 741567-00018
 Date of first issue: 06.06.2016

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

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 tox-

icity

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

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

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.



# **Raltegravir Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.0 28.09.2024 741567-00018 Date of first issue: 06.06.2016

#### Respiratory sensitization

Not classified based on available information.

#### **Components:**

## Raltegravir:

Test Type : Local lymph node assay (LLNA)

Species : Mouse Result : negative

### Magnesium stearate:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

## Germ cell mutagenicity

Not classified based on available information.

#### **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



# **Raltegravir Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.0
 28.09.2024
 741567-00018
 Date of first issue: 06.06.2016

**Application Route: Ingestion** 

Result: negative

Magnesium stearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

### Carcinogenicity

Not classified based on available information.

#### Components:

### Raltegravir:

Species : Mouse, male and female

Exposure time : 104 weeks Result : negative

#### Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

### Reproductive toxicity

Suspected of damaging the unborn child.

### **Components:**

### Raltegravir:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat, male and female

Application Route: Oral

General Toxicity Parent: NOAEL: 600 mg/kg body weight

Result: negative

Effects on fetal development : Species: Rat

Application Route: Oral

General Toxicity Maternal: NOAEL: >= 600 mg/kg body weight

Teratogenicity: LOAEL F1: 300 mg/kg body weight

Symptoms: Skeletal malformations.

Result: positive

Species: Rabbit



# **Raltegravir Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.0
 28.09.2024
 741567-00018
 Date of first issue: 06.06.2016

General Toxicity Maternal: NOAEL: >= 1.000 mg/kg body

weight

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.

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



# **Raltegravir Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.0
 28.09.2024
 741567-00018
 Date of first issue: 06.06.2016

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

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

Species : Mouse

NOAEL : 50 mg/kg

LOAEL : 500 mg/kg

Application Route : Oral

Exposure time : 14 Weeks

Target Organs : Stomach

Species : Rat

NOAEL : 50 mg/kg

LOAEL : 200 mg/kg

Application Route : Oral

Exposure time : 8 Weeks

Target Organs : Stomach

### Cellulose:

Species : Rat

NOAEL : >= 9.000 mg/kg

Application Route : Ingestion Exposure time : 90 Days

## Magnesium stearate:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

## **Aspiration toxicity**

Not classified based on available information.

### **Experience with human exposure**

### **Components:**

## Raltegravir:

Ingestion : Symptoms: Nausea, Diarrhea, Headache, Fever, Rash, Skin

irritation



# **Raltegravir Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.0
 28.09.2024
 741567-00018
 Date of first issue: 06.06.2016

#### **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 tox-

icity)

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 (Chron-

ic 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

### Magnesium stearate:



# **Raltegravir Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.0
 28.09.2024
 741567-00018
 Date of first issue: 06.06.2016

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.

Magnesium stearate:

Biodegradability : Result: Not biodegradable

Remarks: Based on data from similar materials



# **Raltegravir Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.0
 28.09.2024
 741567-00018
 Date of first issue: 06.06.2016

**Bioaccumulative potential** 

**Components:** 

Raltegravir:

Partition coefficient: n-

octanol/water

log Pow: -0,328

Magnesium stearate:

Partition coefficient: n-

octanol/water

: log Pow: > 4

Mobility in soil

No data available

Other adverse effects

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS** 

**Disposal methods** 

Waste from residues : 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.

#### **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** 

ANTT

Not regulated as a dangerous good

Special precautions for user

Not applicable

### **SECTION 15. REGULATORY INFORMATION**

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

National List of Carcinogenic Agents for Humans - : Not applicable

(LINACH)



# **Raltegravir Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.0 28.09.2024 741567-00018 Date of first issue: 06.06.2016

Brazil. List of chemicals controlled by the Federal : Not applicable

Police

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

**Further information** 

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet

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.

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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



# **Raltegravir Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.0 28.09.2024 741567-00018 Date of first issue: 06.06.2016

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.

BR / Z8