according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Raltegravir Pediatric Formulation**

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## SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Raltegravir Pediatric Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-

stance/Mixture

: Pharmaceutical

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Piercetown

A86 HD21 Dunboyne, Ireland

Telephone : 908-740-4000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

### 1.4 Emergency telephone number

1-908-423-6000

#### **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

# Classification (REGULATION (EC) No 1272/2008)

Serious eye damage, Category 1 H318: Causes serious eye damage.

Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child.

Specific target organ toxicity - single ex- H335: May cause respiratory irritation.

posure, Category 3

## 2.2 Label elements

### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word : Danger

Hazard statements : H318 Causes serious eye damage.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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H335 May cause respiratory irritation.

H361d Suspected of damaging the unborn child.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P261 Avoid breathing dust.

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.

#### Hazardous components which must be listed on the label:

Raltegravir

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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**

#### 3.2 Mixtures

Components

Components			
Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Raltegravir	871038-72-1	Eye Dam. 1; H318	>= 20 - < 30
		Repr. 2; H361d	
		STOT SE 3; H335	

For explanation of abbreviations see section 16.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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#### **SECTION 4: First aid measures**

### 4.1 Description of 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.

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).

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, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

## 4.2 Most important symptoms and effects, both acute and delayed

Risks : 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.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## **SECTION 5: Firefighting measures**

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

#### 5.2 Special hazards arising from the substance or mixture

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

#### 5.3 Advice for firefighters

Special protective equipment:

for firefighters

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

Use personal protective equipment.

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.

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

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

tective equipment recommendations (see section 8).

# 6.2 Environmental precautions

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.

## 6.3 Methods and material for containment and cleaning up

Methods for 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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

# **SECTION 7: Handling and storage**

### 7.1 Precautions for safe handling

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.

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 contami-

nated clothing before re-use.

#### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : No data available

## **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

### **Occupational Exposure Limits**

dusts non-specific 4 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable

dust)

Basis: IE OEL

10 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable

dust)

Basis: IE OEL

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

### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
1,2-Benzisothiazol- 3(2H)-one 1,1- dioxide, sodium salt	Workers	Inhalation	Long-term systemic effects	1.68 mg/m3
	Workers	Skin contact	Long-term systemic effects	0.952 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0.414 mg/m3
	Consumers	Skin contact	Long-term systemic effects	0.476 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	

## Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
1,2-Benzisothiazol-3(2H)-one	Fresh water	0.0158 mg/l
1,1-dioxide, sodium salt		
	Marine water	0.00158 mg/l
	Intermittent use/release	0.158 mg/l

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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### 8.2 Exposure controls

#### **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

Eye/face protection : Wear the following personal protective equipment:

Chemical resistant goggles must be worn. If splashes are likely to occur, wear:

Face-shield

Equipment should conform to I.S. EN 166

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.

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).

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to I.S. EN 143

Filter type : Particulates type (P)

### **SECTION 9: Physical and chemical properties**

# 9.1 Information on basic physical and chemical properties

Physical state : powder

Colour : yellow-orange

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling : No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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range

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

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Relative density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## **SECTION 10: Stability and reactivity**

### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

## 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## **SECTION 11: Toxicological information**

# 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**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

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Exposure time : 104 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 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

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.

### 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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

## **Aspiration toxicity**

Not classified based on available information.

### 11.2 Information on other hazards

# **Endocrine disrupting properties**

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

### **Experience with human exposure**

### **Components:**

Raltegravir:

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

irritation

### **SECTION 12: Ecological information**

### 12.1 Toxicity

## Components:

### Raltegravir:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 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

# 12.2 Persistence and degradability

#### **Components:**

Raltegravir:

Biodegradability Result: rapidly degradable

Biodegradation: 50 % Exposure time: 9 d

Method: OECD Test Guideline 302B

Hydrolysis: < 10 %(5 d) Stability in water

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Method: OECD Test Guideline 111

### 12.3 Bioaccumulative potential

# **Components:**

Raltegravir:

Partition coefficient: n-

octanol/water

: log Pow: -0.328

### 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

#### 12.6 Endocrine disrupting properties

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### 12.7 Other adverse effects

No data available

### **SECTION 13: Disposal considerations**

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

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.

## **SECTION 14: Transport information**

#### 14.1 UN number or ID number

**ADN** : Not regulated as a dangerous good

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

### **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, Not applicable

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High Not applicable

Concern for Authorisation (Article 59).

Regulation (EC) on substances that deplete the ozone Not applicable

layer

Regulation (EU) 2019/1021 on persistent organic pollu-Not applicable

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia-Not applicable

ment and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation Not applicable

(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

#### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations. where applicable.

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

**AICS** not determined

DSL not determined

**IECSC** not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information 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 H-Statements** 

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

H361d Suspected of damaging the unborn child.

Full text of other abbreviations

Eye Dam. Serious eye damage Repr. Reproductive toxicity

STOT SE Specific target organ toxicity - single exposure

IE OEL Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Raltegravir Pediatric Formulation

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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road: AIIC - Australian Inventory of Industrial Chemicals: ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### **Further information**

Sources of key data used to compile the Safety Data

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

Sheet cy, http://echa.europa.eu/

# Classification of the mixture: Classification procedure:

Eye Dam. 1H318Calculation methodRepr. 2H361dCalculation methodSTOT SE 3H335Calculation method

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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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