

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

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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  
120 Moorgate  
EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

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-  
posure, Category 3 H335: May cause respiratory irritation.

#### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version 7.0      Revision Date: 13.11.2025      SDS Number: 9371322-00011      Date of last issue: 09.05.2025  
Date of first issue: 27.08.2021

Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H318 Causes serious eye damage. H335 May cause respiratory irritation. H361d Suspected of damaging the unborn child.
Precautionary statements	:	<b>Prevention:</b> P201 Obtain special instructions before use. P261 Avoid breathing dust. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  <b>Response:</b> 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.

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

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

For explanation of abbreviations see section 16.

### 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 advice immediately.<br>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.<br>Get medical attention.  |
| In case of skin contact    | : In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention immediately.  |
| If swallowed               | : If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |

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

- |       |  |
|-------|--|
| Risks | : Causes serious eye damage.<br>May cause respiratory irritation.<br>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 |
|------------------------------|---------------|

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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 products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
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 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.

## 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 protective 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.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 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.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

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.

### 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.<br>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.<br>Do not swallow.<br>Do not get in eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>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.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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.<br>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures,  |

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 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 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

dust of any kind	10 mg/m <sup>3</sup> Value type (Form of exposure): TWA (Inhalable) Basis: GB EH40
	4 mg/m <sup>3</sup> Value type (Form of exposure): TWA (Respirable fraction) Basis: GB EH40

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

#### Derived No Effect Level (DNEL)

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	1.4 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	0.4 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0.25 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	0.143 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0.143 mg/kg bw/day

#### Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Raltegravir	Fresh water	0.4 mg/l

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

	Marine water	0.4 mg/l
1,2-Benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt	Fresh water	10 mg/l
	Marine water	1 mg/l
	Fresh water sediment	2060 mg/kg dry weight (d.w.)
	Marine sediment	206 mg/kg dry weight (d.w.)
	Soil	407 mg/kg dry weight (d.w.)

### 8.2 Exposure controls

#### Engineering measures

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

#### Personal protective equipment

Eye/face protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	
Material	: Chemical-resistant gloves
Skin and body protection	: Work uniform or laboratory coat.
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143
Filter type	: Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

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.

### 9.2 Other information

Molecular weight	:	No data available
Particle size	:	No data available

## 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, handling or other means. Can react with strong oxidizing agents.
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### 10.4 Conditions to avoid



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

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 toxicological effects

Information on likely routes of exposure : Inhalation  
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.

#### 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.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

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### 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:**

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
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# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

	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
Target Organs	: Stomach
Species	: Mouse
NOAEL	: 50 mg/kg
LOAEL	: 500 mg/kg
Application Route	: Oral

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

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
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## SECTION 12: Ecological information

### 12.1 Toxicity

#### 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 microorganisms	: EC50 : > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

	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 toxicity)	: 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 (Chronic 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
Stability in water	: Hydrolysis: < 10 % (5 d)
	Method: OECD Test Guideline 111

### 12.3 Bioaccumulative potential

#### Components:

##### **Raltegravir:**

Partition coefficient: n-octanol/water	: log Pow: -0.328
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### 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.
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### 12.6 Other adverse effects

#### Product:

Endocrine disrupting poten-	: This substance/mixture does not contain components consid-
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# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

tial  
ered to have endocrine disrupting properties for environment  
according to UK REACH Article 57(f) at levels of 0.1% or  
higher.

### 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

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

#### 14.2 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
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# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

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 Transport in bulk according to Annex II of Marpol and the IBC Code

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	: Not applicable
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	: Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	: Not applicable
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	: Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	: Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	: Not applicable
Control of Major Accident Hazards Regulations 2015 (COMAH)	Not applicable

#### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

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

AICS	: not determined
CA. DSL	: not determined
IECSC	: not determined

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

### 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 eye 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  
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits  
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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 Harmonised 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 Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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 - Organisation 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; TSCA - Toxic Substances Control Act (United States); UN



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
7.0	13.11.2025	9371322-00011	Date of first issue: 27.08.2021

- United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### 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/>

### Classification of the mixture:

Eye Dam. 1	H318
Repr. 2	H361d
STOT SE 3	H335

### Classification procedure:

Calculation method
Calculation method
Calculation method

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

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.

GB / EN