

Raltegravir Adult Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371107-00008	Date of first issue: 27.08.2021

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

1.1	Product identifier Trade name	:	Raltegravir Adult Formulation
1.2	Relevant identified uses of th	ne s	ubstance 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	saf	ety 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

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 Reproductive toxicity, Category 2 Specific target organ toxicity - single exposure, Category 3 H318: Causes serious eye damage. H361d: Suspected of damaging the unborn child. 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)

Hazard pictograms



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



Raltegravir Adult Formulation

Version 4.3	Revision Date: 28.09.2024	-	DS Number: 371107-0000		Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
Signal word		:	Danger		
Hazard statements :		:	H318 H335 H361d	May o	es serious eye damage. cause respiratory irritation. ected of damaging the unborn child.
Preca	autionary statements	:	Prevention	:	
			P201 P261 P280	Avoid Wear	n special instructions before use. breathing dust. protective gloves/ protective clothing/ eye ction/ face protection.
			Response:		
			P304 + P34	air an	12 IF INHALED: Remove person to fresh d keep comfortable for breathing. Call a ON CENTER/ doctor if you feel unwell.
			P305 + P35	with v lense	38 + P310 IF IN EYES: Rinse cautiously vater for several minutes. Remove contact s, if present and easy to do. Continue rins- nmediately call a POISON CENTER/ doctor.
			P308 + P31		exposed or concerned: Get medical advice/

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	>= 30 - < 50
Substances with a workplace exposure limit :			
Cellulose	9004-34-6 232-674-9		>= 10 - < 20

For explanation of abbreviations see section 16.

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



Raltegravir Adult Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371107-00008	Date of first issue: 27.08.2021

SECTION 4: First aid measures

4.1 Description of first aid meas	sure	S
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	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
4.2 Most important symptoms a	nd e	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	me	dical attention and special treatment needed
Treatment	:	Treat symptomatically and supportively.
SECTION 5: Firefighting mea		05
SECTION 5. Thengining med	ISUI	65
5.1 Extinguishing media		

Sui	able extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
			Dry chemical

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



Raltegravir Adult Formulation

Versi 4.3	ion	Revision Date: 28.09.2024		OS Number: 71107-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
	Unsuita media	able extinguishing	:	None known.	
5.2 S	Special	hazards arising from	the	substance or mi	xture
Specific hazards during fire- fighting		:	Avoid generating concentrations, a potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a	
Hazardous combustion prod- ucts		:	Carbon oxides Metal oxides Oxides of phosph Nitrogen oxides (Fluorine compoun	NOx)	
5.3 A	dvice	for firefighters			
	Special for firef	l protective equipment ighters	:		e, wear self-contained breathing apparatus. tective equipment.
	Specific extinguishing meth- ods		:	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do

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. If spillage enters rivers or watercourses, inform the Environ- ment Agency (emergency telephone number 0800 807060).
6.3 Methods and material for co	ntaiı	nment 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. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

Dust deposits should not be allowed to accumulate on surfac-

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



Raltegravir Adult Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
4.3		9371107-00008	Date of first issue: 27.08.2021
		leased into the a Clean up remain bent. Local or nationa posal of this ma employed in the mine which regu Sections 13 and	ay form an explosive mixture if they are re- atmosphere in sufficient concentration. ning materials from spill with suitable absor- al regulations may apply to releases and dis- aterial, as well as those materials and items a cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding 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

	5
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 contaminated clothing before re-use.
7.2 Conditions for safe stora	age, 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:

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



Raltegravir Adult Formulation

Version 4.3	Revision Date: 28.09.2024	SDS Number: 9371107-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
		Strong oxidizing	g agents
7.3 Specific end use(s) Specific use(s)		: No data availab	le
SECTION	8: Exposure cont	rols/personal prote	ction

8.1 Control parameters

Occupational Exposure Limits

dust of any kind

10 mg/m3 Value type (Form of exposure): TWA (Inhalable) Basis: GB EH40

4 mg/m3 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/m3 (OEB 1)	Internal
Cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m3	GB EH40
		TWA (Respirable dust)	4 mg/m3	GB EH40
		STEL (inhalable dust)	20 mg/m3	GB EH40

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 BS EN 166
Hand protection		
Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending

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



Raltegravir Adult Formulation

Version 4.3	Revision Date: 28.09.2024	SDS Number: 9371107-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021			
		on the concentration and quantity of the hazardous sub- stance 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			priate protective clothing based on chemical re- a and an assessment of the local exposure poten-			
Respiratory protection		clothing (glo : If adequate I sure assessi ommended g	must be avoided by using impervious protective ves, aprons, boots, etc). ocal exhaust ventilation is not available or expo- ment demonstrates exposures outside the rec- guidelines, use respiratory protection. hould conform to BS EN 143			
Filter type : Particulates t						

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	:	powder No data available No data available No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	No data available
range Flash point	:	No data available
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
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
Density	:	No data available
Solubility(ies)		

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



Raltegravir Adult Formulation

Versio 4.3	n Revision Date: 28.09.2024	SDS Number:Date of last issue: 06.04.20249371107-00008Date of first issue: 27.08.2021	
Water solubility Partition coefficient: n- octanol/water Auto-ignition temperature		 No data available No data available No data available 	
D	ecomposition temperature	: No data available	
Viscosity Viscosity, dynamic		: No data available	
	Viscosity, kinematic	: No data available	
Flow time		: No data available	
Explosive properties		: Not explosive	
O	xidizing properties	: The substance or mixture is not classified as oxidizing.	
9.2 Other information Flammability (liquids)		: No data available	
М	olecular weight	: No data available	
Pa	article size	: No data available	
Se	elf-ignition	: No data available	

SECTION 10: Stability and reactivity

10.1 Reactivity Not classified as a reactivity haza	rd.
10.2 Chemical stability Stable under normal conditions.	
10.3 Possibility of hazardous reaction	ons
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

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



Raltegravir Adult Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371107-00008	Date of first issue: 27.08.2021

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

exposure	:	Inhalation Skin contact Ingestion Eye contact
Acute toxicity Not classified based on availa	ıble	information.
Components:		
Raltegravir:		
Acute oral toxicity	:	LD50 (Mouse, male and female): > 2,000 mg/kg
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
Skin corrosion/irritation Not classified based on availa Components:	ble	information.
Raltegravir:		
Raltegravir: Species Result	:	Rabbit No skin irritation
Species	itati	No skin irritation
Species Result Serious eye damage/eye irri	itati	No skin irritation
Species Result Serious eye damage/eye irri Causes serious eye damage.	itati	No skin irritation
Species Result Serious eye damage/eye irri Causes serious eye damage. <u>Components:</u>	itati	No skin irritation

Not classified based on available information.

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



Raltegravir Adult Formulation

Version 4.3	Revision Date: 28.09.2024	SDS Number: 9371107-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021	
Resp	iratory sensitisation	1		
Not classified based on available information.				
<u>Com</u>	ponents:			

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
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 Application Route: Ingestion Result: negative

Carcinogenicity

Not classified based on available information.

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



Raltegravir Adult Formulation

Version 4.3	Revision Date: 28.09.2024	SDS Numbe 9371107-00	
<u>Com</u>	ponents:		
Spec	sure time	: Mouse, r : 104 wee : negative	
Cellu	llose:		
	cation Route sure time	: Rat : Ingestior : 72 week : negative	S
-	oductive toxicity ected of damaging the	e unborn child.	
<u>Com</u>	ponents:		
	e gravir: ts on fertility	Species: Applicati	e: Fertility/early embryonic development Rat, male and female on Route: Oral Toxicity - Parent: NOAEL: 600 mg/kg body weight legative
Effec ment	ts on foetal develop-	General Teratoge	on Route: Oral Toxicity Maternal: NOAEL: >= 600 mg/kg body weight enicity: LOAEL F1: 300 mg/kg body weight ns: Skeletal malformations
		weight	Toxicity Maternal: NOAEL: >= 1,000 mg/kg body enicity: NOAEL: >= 1,000 mg/kg body weight
Repr sessi	oductive toxicity - As- ment		ridence of adverse effects on development, based on xperiments.
Cellu	llose:		
Effec	ts on fertility	Species:	on Route: Ingestion
Effec ment	ts on foetal develop-	Species:	on Route: Ingestion

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



Raltegravir Adult Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371107-00008	Date of first issue: 27.08.2021

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 NOAEL Application Route Exposure time Symptoms	:	Dog 90 mg/kg Oral 371 d Vomiting
Species NOAEL LOAEL Application Route Exposure time Target Organs	:	Rat 30 mg/kg 120 mg/kg Oral 189 d Stomach
Species NOAEL LOAEL Application Route Exposure time Target Organs	:	Mouse 50 mg/kg 500 mg/kg Oral 14 Weeks Stomach
Species NOAEL LOAEL Application Route Exposure time Target Organs	:	Rat 50 mg/kg 200 mg/kg Oral 8 Weeks Stomach
Cellulose: Species NOAEL Application Route Exposure time	:	Rat >= 9,000 mg/kg Ingestion 90 Days

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



Raltegravir Adult Formulation

Version 4.3	Revision Date: 28.09.2024		OS Number: 71107-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021				
	piration toxicity t classified based on availa	ble	information.					
Ex	perience with human exp	osu	ire					
<u>Co</u>	mponents:							
	Raltegravir: Ingestion		: Symptoms: Nausea, Diarrhoea, Headache, Fever, Rash, Skin irritation					
SECTION	ON 12: Ecological infor	ma	tion					
12.1 To	xicity							
<u>Co</u>	mponents:							
	Itegravir: xicity to fish	:	LC50 (Pimephales Exposure time: 96 Method: OECD Te					
			LC50 (Cyprinodor mg/l Exposure time: 96 Method: OECD Te					
	xicity to daphnia and other uatic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te					
To: pla	xicity to algae/aquatic nts	:	EC50 (Pseudokiro Exposure time: 96 Method: OECD Te					
			NOEC (Pseudokir mg/l Exposure time: 96 Method: OECD Te					
To	xicity to microorganisms	:	EC50 : > 1,000 m Exposure time: 3 Test Type: Respir Method: OECD Te	n ation inhibition				
			NOEC : 1,000 mg Exposure time: 3 Test Type: Respir Method: OECD Te	n ation inhibition				
To: icit	xicity to fish (Chronic tox- y)	:	NOEC: 9.3 mg/l Exposure time: 33 Species: Pimepha	d les promelas (fathead minnow)				



Raltegravir Adult Formulation

Version 4.3	Revision Date: 28.09.2024		DS Number: 71107-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021		
			Method: OECD T	est Guideline 210		
	ty to daphnia and other ic invertebrates (Chron- city)	:	NOEC: 9.5 mg/l Exposure time: 2 Species: Daphnia Method: OECD T	n magna (Water flea)		
Cellu	lose:					
Toxici	Toxicity to fish		LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials			
12.2 Persi	stence and degradabil	ity				
<u>Comp</u>	oonents:					
	gravir: gradability		Result: rapidly de	aradabla		
Biode	gradability	•	Biodegradation: 8 Exposure time: 9	50 %		
Stabil	ity in water	:	Hydrolysis: < 10 9 Method: OECD T			
Cellu Biode	l ose: gradability	:	Result: Readily bi	odegradable.		
12.3 Bioad	cumulative potential					
<u>Comp</u>	oonents:					
Partiti	gravir: on coefficient: n- ol/water	:	log Pow: -0.328			
12.4 Mobi No da	l ity in soil ta available					
12.5 Resu	Its of PBT and vPvB as	se	ssment			
<u>Produ</u> Asses	<u>uct:</u> ssment	:	to be either persis	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of		
12.6 Other	adverse effects					
<u>Produ</u> Endoc	<u>uct:</u> crine disrupting poten-	:	This substance/m	ixture does not contain components consid-		
			14 / 18			



Raltegravir Adult Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
4.3		9371107-00008	Date of first issue: 27.08.2021
tial			docrine disrupting properties for environment K REACH Article 57(f).

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
ΙΑΤΑ	:	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
ΙΑΤΑ	:	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
ΙΑΤΑ	:	Not regulated as a dangerous good
14.4 Packing group		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good



Raltegravir Adult Formulation

Version 4.3	Revision Date: 28.09.2024		DS Number: 371107-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
RID IMDG IATA	i (Cargo)	:	Not regulated as	a dangerous good a dangerous good a dangerous good
IATA (Passenger)		:	Not regulated as	a dangerous good
14.5 Environmental hazards Not regulated as a dangerous go			od	
14.6 Special precautions for user Not applicable		ser		

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

Remarks	: Not applicable for product as supplied.
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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 Brit-	:	Not applicable
ain) Regulation (EC) on substances that deplete the ozone laver	:	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 (CC Not applicable	MA	λH)

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.

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.

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



Raltegravir Adult Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371107-00008	Date of first issue: 27.08.2021

Full text of H-Statements

H318 H335 H361d	: : :	Causes serious eye damage. May cause respiratory irritation. 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)			
GB EH40 / STEL	:	Short-term exposure limit (15-minute 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; 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; 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

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:

Classification procedure:



Raltegravir Adult Formulation

Version 4.3	Revision Date: 28.09.2024	SDS Number: 9371107-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021	
Eye D	am. 1	H318	Calculation method	
Repr.	2	H361d	Calculation method	
STOT	SE 3	H335	Calculation method	

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