Commission Regulation (EU) 2020/878



Raltegravir Adult Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
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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 t	he 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	safe	ety 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 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





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		H335 H361d	May cause respiratory irritation. Suspected of damaging the unborn child.
Preca	autionary statements	: Prevention	:
		P201 P261 P280	Obtain special instructions before use. Avoid breathing dust. Wear protective gloves/ protective clothing/ eye protection/ face protection.
		Response:	
		P304 + P34	0 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
		P305 + P35	i1 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rins- ing. Immediately call a POISON CENTER/ doctor.
		P308 + P31	3 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

oomponomo			
Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Raltegravir	871038-72-1	Eye Dam. 1; H318	>= 30 - < 50
		Repr. 2; H361d	
		STOT SE 3; H335	

For explanation of abbreviations see section 16.



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SECTION 4: First aid measures

4.1 Description of first aid meas	ure	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	mer	dical attention and special treatment needed
Treatment	:	Treat symptomatically and supportively.
SECTION 5: Firefighting mean	sur	es
5.1 Extinguishing media		

Water spray

Suitable extinguishing media :

Alcohol-resistant foam



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				Carbon dioxide (C Dry chemical	002)
	Unsuitable extinguishing : media		None known.		
5.2 Sp	pecial	hazards arising from	the	substance or mi	xture
Specific hazards during fire- fighting		:	concentrations, a potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. pustion products may be a hazard to health.	
	Hazard ucts	ous combustion prod-	nbustion prod- : Carbon oxides Metal oxides Oxides of phosp Nitrogen oxides Fluorine compo		NOx)
5.3 Ao	dvice	for firefighters			
S	Special	protective equipment ighters	:		e, wear self-contained breathing apparatus. tective equipment.
	Specifi ods	c extinguishing meth-	:	cumstances and t Use water spray t	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. 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.
		Avoid dispersal of dust in the air (i.e., clearing dust surfaces

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



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		es, as these m leased into the Clean up rema bent. Local or nation posal of this m employed in th mine which reg Sections 13 an	ed air). should not be allowed to accumulate on surfac- ay form an explosive mixture if they are re- atmosphere in sufficient concentration. ining materials from spill with suitable absor- nal regulations may apply to releases and dis- aterial, as well as those materials and items e cleanup of releases. You will need to deter- gulations are applicable. Ind 15 of this SDS provide information regarding r 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 banding, or inert atmospheres.
Local/Total ventilation	and bonding, or inert atmospheres.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 storage, i	including any incompatibilities
- · · · · · · · -	

Requirements for storage : 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.

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

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Ad	vice on common storage	:	Do not store with Strong oxidizing a	the following product types: agents
•	cific end use(s) ecific use(s)	:	No data available	

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

dusts non-specific

Occupational Exposure Limits

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 of exposure)	Control parameters	Basis
Raltegravir	871038-72- 1	TWA	1000 µg/m3 (OEB 1)	Internal
Cellulose	9004-34-6	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL
Magnesium stea- rate	557-04-0	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL

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



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Remarks		: Choose gloves to protect hands against chemicals depending 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		resistance dat potential. Skin contact n	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		sure assessm ommended gu Equipment sh	cal exhaust ventilation is not available or expo- ent demonstrates exposures outside the rec- idelines, use respiratory protection. ould conform to I.S. EN 143		
Filter type		: Particulates ty	pe (P)		

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available

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	Decom	position temperature	:	No data available	e
	рН		:	No data available	e
	Viscos Vise	ity cosity, dynamic	:	No data availabl	e
	Vis	cosity, kinematic	:	No data available	e
	Flow ti	me	:	No data availabl	e
		ity(ies) ter solubility	:	No data availabl	e
		on coefficient: n- I/water	:	No data available	e
	Vapou	r pressure	:	No data available	e
	Densit	y	:	No data available	e
	Relativ	e vapour density	:	No data available	e
		e characteristics ticle size	:	No data availabl	e
9.2		nformation			
	Explos	ives	:	Not explosive	
	Oxidizi	ng properties	:	The substance of	r mixture is not classified as oxidizing.
	Self-ig	nition	:	No data availabl	e
	Evapo	ration rate	:	Not applicable	
	Molecu	ular weight	:	No data available	e

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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	itions to avoid			
Condi	tions to avoid		leat, flames void dust fo	
0.5 Incon	npatible materials			
Mater	ials to avoid	: (Dxidizing age	ents
0.6 Hazaı	dous decompositio	n produ	cts	
No ha	zardous decompositio	on produ	cts are know	n.
SECTION	11: Toxicological	inform	ation	
1 1 Inform	mation on hazard cla	sses as	defined in F	Regulation (EC) No 1272/2008
	nation on likely routes		halation	
expos	ure		kin contact	
			gestion ye contact	
Acute	toxicity	-	ye contact	
	assified based on ava	ilahle inf	ormation	
	onents:		ormation.	
	gravir:			male and female): $> 2,000 \text{ mg/kg}$
Acute	oral toxicity	. L		male and female): > 2,000 mg/kg
Skin o	corrosion/irritation			
Not cl	assified based on ava	ilable inf	ormation.	
<u>Comp</u>	oonents:			
Ralte	gravir:			
Speci	es	: R	abbit	
Resul	t	: N	o skin irritati	on
Serio	us eye damage/eye i	rritation		
	es serious eye damag			
Comp	onents:			
Ralte	gravir:			
Speci	-	: В	ovine cornea	
Resul		: S	evere irritatio	on
Respi	ratory or skin sensit	isation		
Skin	sensitisation			

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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	

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

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		Application R	city - Parent: NOAEL: 600 mg/kg body weight		
Effects on foetal develop- ment		Application R General Toxi Teratogenicit Symptoms: S	: 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		
		weight	city Maternal: NOAEL: >= 1,000 mg/kg body y: NOAEL: >= 1,000 mg/kg body weight		
Repro	oductive toxicity - As- nent	: Some eviden animal exper	ce of adverse effects on development, based on iments.		

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



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Expos Targe Speci NOAE LOAE Applic	EL cation Route sure time of Organs es EL EL cation Route	: 50 mg/kg : 500 mg/kg : Oral : 14 Weeks : Stomach : Rat : 50 mg/kg : 200 mg/kg : Oral	
Exposure time Target Organs		: 8 Weeks : 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 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.

Experience with human exposure

Components:

Raltegravir:

Ingestion

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

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	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l



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aqu	atic invertebrates		Exposure time: 4 Method: OECD	18 h Test Guideline 202
	Toxicity to algae/aquatic plants		Exposure time: 9	rchneriella subcapitata (green algae)): 66 mg/l 96 h Test Guideline 201
			mg/l Exposure time: 9	kirchneriella subcapitata (green algae)): 3.8 96 h Test Guideline 201
Tox	icity to microorganisms	:	Exposure time: 3 Test Type: Resp	3 ĥ
			NOEC : 1,000 m Exposure time: 3 Test Type: Resp Method: OECD	3 h
Tox icity	icity to fish (Chronic tox-)	:		33 d nales promelas (fathead minnow) Test Guideline 210
aqu	icity to daphnia and other atic invertebrates (Chron- oxicity)		NOEC: 9.5 mg/l Exposure time: 2 Species: Daphni Method: OECD	21 d a magna (Water flea) Test Guideline 211
12.2 Per	sistence and degradabil	lity		
<u>Co</u>	nponents:			
	tegravir: degradability	:	Result: rapidly d Biodegradation: Exposure time: S Method: OECD	50 %
Sta	bility in water	:	Hydrolysis: < 10 Method: OECD	%(5 d) Test Guideline 111
12.3 Bioaccumulative potential				
<u>Co</u>	Components:			
Par	tegravir: tition coefficient: n- anol/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.

12.6 Endocrine disrupting properties

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

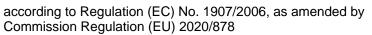
13.1 Waste treatment methods

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.
Contaminated packaging	 Do not dispose of waste into sewer. 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
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





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ADR		: Not regula	ted as a dangerous good			
RID		: Not regula	ted as a dangerous good			
IMDG		: Not regula	Not regulated as a dangerous good			
ΙΑΤΑ		: Not regula	ted as a dangerous good			
14.3 Trans	sport hazard class(es)					
ADN		: Not regula	ted as a dangerous good			
ADR		: Not regula	ted as a dangerous good			
RID		: Not regula	ted as a dangerous good			
IMDG		: Not regula	ted as a dangerous good			
ΙΑΤΑ		: Not regula	ted as a dangerous good			
14.4 Packi	ing group					
ADN		: Not regula	ted as a dangerous good			
ADR		: Not regula	ted as a dangerous good			
RID		: Not regula	ted as a dangerous good			
IMDG		: Not regula	ted as a dangerous good			
ΙΑΤΑ	(Cargo)	: Not regula	ted as a dangerous good			
ΙΑΤΑ	(Passenger)	: Not regula	ted as a dangerous good			
14.5 Environmental hazards Not regulated as a dangerous good						
•	14.6 Special precautions for user Not applicable					
1 4.7 Marit Rema	ime transport in bulk rks	•	IO instruments able 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, mixtures and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable



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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.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

ECTION 16: Other informati	on	
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 abbreviati	ons	
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)

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;



Raltegravir Adult Formulation

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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	:	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data Sheet		eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/

Classification of the mixt	ure:	Classification procedure:
Eye Dam. 1	H318	Calculation method
Repr. 2	H361d	Calculation method
STOT SE 3	H335	Calculation method

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IE / EN