Version



Date of last issue: 04.04.2023

Raltegravir Formulation

Revision Date:

Version 3.1	Revision Date: 30.09.2023	-	S Number: 581-00017	Date of last issue: 04.04.2023 Date of first issue: 06.06.2016
Section '	1: Identification			
Prod	luct name	:	Raltegravir For	mulation
Man	ufacturer or supplier's d	etai	ls	
Com	ipany	:	MSD	
Addı	ress	:	33 Whakatiki S Upper Hutt - Ne	treet - Private Bag 908 ew Zealand
Tele	phone	:	0800 800 543	
Eme	rgency telephone number	:	0800 764 766 (CHEMCALL)	0800 POISON) 0800 243 622 (080
E-ma	ail address	:	EHSDATASTE	WARD@msd.com
Rec	ommended use of the ch	nem	ical and restrict	tions on use
	ommended use trictions on use	:	Pharmaceutica Not applicable	
Section 2	2: Hazard identification			
GHS	Classification			
	ous eye damage/eye irri-	:	Category 1	
Repi	roductive toxicity	:	Category 2	
	cific target organ toxicity - le exposure	:	Category 3	
GHS	abel elements			
Haza	ard pictograms	:		
Sign	al word	:	Danger	v v
Haza	ard statements	:	H335 May caus	serious eye damage. se respiratory irritation. ted of damaging the unborn child.
Prec	autionary statements	:	Prevention:	pecial instructions before use.
			1 201 000011 36	

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P202 Do not handle until all safety precautions have been read and understood.

P261 Avoid breathing dust.

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

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.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Raltegravir	871038-72-1	>= 50 -< 70
Cellulose	9004-34-6	>= 10 -< 20
Magnesium stearate	557-04-0	>= 1 -< 10

Section 4: 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.
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.



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				Wash clothing be	fore reuse.
	In case of eye contact		:	Thoroughly clean In case of contact for at least 15 mir If easy to do, rem	shoes before reuse. t, immediately flush eyes with plenty of water nutes. ove contact lens, if worn.
	If swall	owed	:	 Get medical attention immediately. If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. 	
		nportant symptoms ects, both acute and d	:	Causes serious e May cause respire Suspected of dan Contact with dust	ye damage.
	Protect	tion of first-aiders	:	and use the recor	ers should pay attention to self-protection, nmended personal protective equipment Il for exposure exists (see section 8).
	Notes	to physician	:		cally and supportively.
Sec	tion 5:	Fire-fighting measure	S		
	Suitabl	e extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical	
	Unsuita media	able extinguishing	:	None known.	
	Specifi fighting	c hazards during fire-)	:	concentrations, and 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.
	Hazaro ucts	dous combustion prod-	:	Carbon oxides Nitrogen oxides (I Fluorine compour Metal oxides	
	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
_		l protective equipment fighters	:	In the event of fire	e, wear self-contained breathing apparatus. tective equipment.
Sec	tion 6:	Accidental release me	eas	ures	
	tive eq	al precautions, protec- uipment and emer- procedures	:	Follow safe handl	tective equipment. ing advice (see section 7) and personal pro- t recommendations (see section 8).
	Enviro	nmental precautions	:	Avoid release to t	he environment.



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		Retain and dis	r leakage or spillage if safe to do so. pose of contaminated wash water. es should be advised if significant spillages rained.
Methods and materials for containment and cleaning up		over the area t Add excess liq Soak up with ir Avoid dispersa with compress Dust deposits 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 ar certain local or	with absorbents and place a damp covering o minimise entry of the material into the air. uid to allow the material to enter into solution. hert absorbent material. I of dust in the air (i.e., clearing dust surfaces ed air). should not be allowed to accumulate on surface 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. In 15 of this SDS provide information regarding in national requirements.
Section 7	: Handling and storage		
Tech	nical measures	: Static electricit causing an exp	y may accumulate and ignite suspended dust

	causing an explosion.
	Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	 If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	: Avoid breathing dust. Do not swallow. Do not get in eyes.
	Avoid prolonged or repeated contact with skin.
	Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
	Keep container tightly closed.
	Already 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.



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	itions for safe storage	Wash contamina : Keep in properly Store locked up. Keep tightly clos Keep in a cool, w Store in accorda	vell-ventilated place. nce with the particular national regulations. hthe following product types:

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Raltegravir	871038-72-1	TWA	1000 µg/m3 (OEB 1)	Internal
Cellulose	9004-34-6	WES-TWA	10 mg/m3	NZ OEL
		TWA	10 mg/m3	ACGIH
Magnesium stearate	557-04-0	WES-TWA	10 mg/m3	NZ OEL
		TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH

Engineering measures	:	Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are de- signed 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 equipme	ent	
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type Hand protection	:	Particulates type
Material	:	Chemical-resistant gloves
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



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	Eye protection :		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. Wear the following personal protective equipment: Chemical resistant goggles must be worn. If splashes are likely to occur, wear: Face-shield Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).		
Section 9): Physical and chemica	al pr	operties		
Арре	earance	:	powder		
Colo	ur	:	No data available	9	
Odou	ır	:	No data available	e	
Odou	ur Threshold	:	No data available	e	
pН		:	No data available	e	
Melti	ng point/freezing point	:	No data available	e	
Initia	I boiling point and boiling		No data availabl		

Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, 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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Density	:	No data available



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W Partit octan	pility(ies) ater solubility ion coefficient: n- iol/water ignition temperature	: No	data available data available data available	9
	Decomposition temperature		No data available	
	Viscosity Viscosity, kinematic		data available	9
Explo	Explosive properties		explosive	
Oxidi	zing properties	: The	e substance o	r mixture is not classified as oxidizing.
Moleo	Molecular weight		No data available	
Partic	cle size	: No	data available	2
Section 1	0: Stability and reactiv	itv		
Reac	-	-	classified as	a reactivity hazard.

Reactivity Chemical stability Possibility of hazardous reac-	:	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han-
tions		dling or other means.
		Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials		
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes	: Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Raltegravir:

Cellulose:



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Acute	oral toxicity	: LD50 (Rat): >	5,000 mg/kg
Acute	inhalation toxicity	: LC50 (Rat): > Exposure time Test atmosph	
Acute	e dermal toxicity	: LD50 (Rabbit): > 2,000 mg/kg
Magn	esium stearate:		
Acute	oral toxicity	Assessment: icity	2,000 mg/kg D Test Guideline 423 The substance or mixture has no acute oral t sed on data from similar materials
Acute	e dermal toxicity	: LD50 (Rabbit Remarks: Bas): > 2,000 mg/kg sed on data from similar materials
Not cl	corrosion/irritation lassified based on ava	ailable information.	
Not cl		ailable information.	
Not cl	lassified based on ava ponents: gravir: es	ailable information. : Rabbit : No skin irritati	on
Not cl Comp Ralte Speci Resul	lassified based on ava ponents: gravir: es	: Rabbit	on
Not cl Comp Ralte Speci Resul	lassified based on ava <u>conents:</u> gravir: es It mesium stearate:	: Rabbit	on
Not cl Comp Ralte Speci Resul	lassified based on ava <u>ponents:</u> gravir: es It mesium stearate: es	: Rabbit : No skin irritat	
Not cl Comp Ralte Speci Resul Magn Speci	lassified based on ava <u>conents:</u> gravir: es It es es t	: Rabbit : No skin irritati : Rabbit : No skin irritati	
Not cl Comp Ralte Speci Resul Resul Resul Rema	lassified based on ava <u>conents:</u> gravir: es It es t arks us eye damage/eye	: Rabbit : No skin irritati : Rabbit : No skin irritati : Based on dat irritation	on
Not cl Comp Ralte Speci Resul Speci Resul Rema Serio Causo	lassified based on ava <u>conents:</u> gravir: es It es It arks us eye damage/eye es serious eye damage	: Rabbit : No skin irritati : Rabbit : No skin irritati : Based on dat irritation	on
Not cl Comp Ralte Speci Resul Resul Resul Resul Rema Serio Causo Causo	lassified based on ava <u>conents:</u> gravir: es It es It arks us eye damage/eye es serious eye damage <u>conents:</u>	: Rabbit : No skin irritati : Rabbit : No skin irritati : Based on dat irritation	on
Not cl Comp Ralte Speci Resul Resul Resul Rema Serio Cause Comp Ralte	lassified based on ava <u>conents:</u> gravir: es It es t us eye damage/eye es serious eye damage <u>conents:</u> gravir:	: Rabbit : No skin irritati : Rabbit : No skin irritati : Based on dat irritation ge.	on a from similar materials
Not cl Comp Ralte Speci Resul Resul Resul Resul Rema Serio Causo Causo	lassified based on ava <u>conents:</u> gravir: es It es t arks us eye damage/eye es serious eye damage <u>conents:</u> gravir: es	: Rabbit : No skin irritati : Rabbit : No skin irritati : Based on dat irritation	on a from similar materials a
Not cl Comp Ralte Speci Resul Speci Resul Rema Serio Cause Cause Cause Resul	lassified based on ava <u>conents:</u> gravir: es It es t arks us eye damage/eye es serious eye damage <u>conents:</u> gravir: es	: Rabbit : No skin irritati : Rabbit : No skin irritati : Based on dat irritation ge. : Bovine corne	on a from similar materials a
Not cl Comp Ralte Speci Resul Speci Resul Rema Serio Cause Cause Cause Resul	lassified based on ava <u>conents:</u> gravir: es t es t es t us eye damage/eye es serious eye damage <u>conents:</u> gravir: es t es t es t es t es t es t es t es t es es es es es es es es es es	: Rabbit : No skin irritati : Rabbit : No skin irritati : Based on dat irritation ge. : Bovine corne	on a from similar materials a
Not cl Comp Ralte Speci Resul Resul Rema Serio Cause Comp Ralte Speci Resul Magn	lassified based on ava <u>conents:</u> gravir: es It es It arks us eye damage/eye es serious eye damage <u>conents:</u> gravir: es It es It es It es It	 Rabbit No skin irritati Rabbit No skin irritati Based on dat irritation je. Bovine cornet Severe irritati Severe irritati No eye irritati 	on a from similar materials a on



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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

Magnesium stearate:

Test Type :	Maximisation Test
Exposure routes :	Skin contact
Species :	Guinea pig
Method :	OECD Test Guideline 406
Result :	negative
Remarks :	Based on data from similar materials

Chronic toxicity

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:



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Geno	toxicity in vitro		Test Type: Bac Result: negativ	cterial reverse mutation assay (AMES) e
			Test Type: In v Result: negativ	itro mammalian cell gene mutation test e
Geno	toxicity in vivo		Test Type: Mar cytogenetic ass Species: Mous Application Roo Result: negativ	ute: Ingestion
Magn	esium stearate:			
Geno	toxicity in vitro		Result: negativ	itro mammalian cell gene mutation test e ed on data from similar materials
			Method: OECD Result: negativ	omosome aberration test in vitro) Test Guideline 473 e ed on data from similar materials
			Result: negativ	eterial reverse mutation assay (AMES) e ed on data from similar materials
	nogenicity assified based on av	ailahle i	nformation	
Comp	oonents:			
	oonents: gravir:			
	gravir:	:	Mouse, male a	nd female
Ralte Speci	gravir: es sure time	:	Mouse, male a 104 weeks negative	nd female
Ralte Speci Expos	gravir: es sure time t	:	104 weeks	nd female
Ralte Speci Expos Resul	gravir: es sure time t lose:	:	104 weeks	nd female
Ralte Speci Expos Resul Cellu Speci Applic	gravir: es sure time t t lose: es cation Route	:	104 weeks negative Rat Ingestion	nd female
Ralte Speci Expos Resul Cellul Speci Applic	gravir: es sure time t t lose: es cation Route sure time	:	104 weeks negative Rat	nd female
Raite Speci Expos Resul Speci Applic Expos Resul	gravir: es sure time t lose: es cation Route sure time t bductive toxicity		104 weeks negative Rat Ingestion 72 weeks negative	nd female
Raite Speci Expos Resul Speci Applic Expos Resul	gravir: es sure time t lose: es cation Route sure time		104 weeks negative Rat Ingestion 72 weeks negative	nd female
Raite Speci Expos Resul Speci Applic Expos Resul Resul	gravir: es sure time t lose: es cation Route sure time t bductive toxicity		104 weeks negative Rat Ingestion 72 weeks negative	nd female
Raite Speci Expos Resul Speci Applic Expos Resul Resul Suspe <u>Comp</u>	gravir: es sure time t lose: es cation Route sure time t bductive toxicity ected of damaging th		104 weeks negative Rat Ingestion 72 weeks negative	nd female



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		Application Ro General Toxic Result: negati	ity - Parent: NOAEL: 600 mg/kg body weight
Effe mer	ects on foetal develop- nt	Teratogenicity	<pre>sity Maternal: NOAEL: >= 600 mg/kg body weight c: LOAEL F1: 300 mg/kg body weight keletal malformations</pre>
		weight	tity Maternal: NOAEL: >= 1,000 mg/kg body /: NOAEL: >= 1,000 mg/kg body weight
	productive toxicity - As- sment	: Some evidend animal experi	ce of adverse effects on development, based on ments.
Cel	lulose:		
Effe	ects on fertility	Species: Rat	ne-generation reproduction toxicity study oute: Ingestion ve
Effe mer	ects on foetal develop- nt	Species: Rat	rtility/early embryonic development oute: Ingestion ve
Ма	gnesium stearate:		
Effe	ects on fertility	reproduction/o Species: Rat Application Ro Method: OEC Result: negati	ombined repeated dose toxicity study with the developmental toxicity screening test oute: Ingestion D Test Guideline 422 ve sed on data from similar materials
Effe mer	ects on foetal develop- nt	Species: Rat Application Re Result: negati	nbryo-foetal development oute: Ingestion ve sed on data from similar materials

STOT - single exposure

May cause respiratory irritation.



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Raite Expo Targe	ponents: egravir: osure routes et Organs ssment	: Inhalation : Respiratory Tr : May cause res	act spiratory irritation.
Not c	T - repeated exposure classified based on avai eated dose toxicity		
<u>Com</u>	ponents:		
Spec NOA Appli Expo Symp	EL cation Route osure time otoms	: Dog : 90 mg/kg : Oral : 371 d : Vomiting	
Expo	EL	: Rat : 30 mg/kg : 120 mg/kg : Oral : 189 d : Stomach	
Expo	EL	: Mouse : 50 mg/kg : 500 mg/kg : Oral : 14 Weeks : Stomach	
Expo	EL	: Rat : 50 mg/kg : 200 mg/kg : Oral : 8 Weeks : Stomach	
Spec NOA Appli		: Rat : >= 9,000 mg/k : Ingestion : 90 Days	۶g

Magnesium stearate:

Species	:	Rat
NOAEL	:	> 100 mg/kg



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	cation Route sure time arks	:	Ingestion 90 Days Based on data	from similar materials
	ration toxicity lassified based on availa	bla	information	
	rience with human exp			
<u>Com</u>	ponents:			
Ralte Inges	egravir: stion	:	Symptoms: Na irritation	ausea, Diarrhoea, Headache, Fever, Rash, Sk
ection 1	2: Ecological informati	on		
Ecot	oxicity			
<u>Com</u>	ponents:			
	e gravir: bity to fish	:	Exposure time	ales promelas (fathead minnow)): > 100 mg/l : 96 h D Test Guideline 203
			mg/l Exposure time	don variegatus (sheepshead minnow)): > 100 : 96 h D Test Guideline 203
	tity to daphnia and other tic invertebrates	:	Exposure time	a magna (Water flea)): > 100 mg/l : 48 h D Test Guideline 202
Toxic plant	sity to algae/aquatic s	:	Exposure time	okirchneriella subcapitata (green algae)): 66 m : 96 h D Test Guideline 201
			mg/l Exposure time	okirchneriella subcapitata (green algae)): 3.8 : 96 h D Test Guideline 201
Toxic icity)	to fish (Chronic tox-	:	Exposure time	hales promelas (fathead minnow)): 9.3 mg/l : 33 d D Test Guideline 210
	tity to daphnia and other tic invertebrates (Chron- cicity)		Exposure time	ia magna (Water flea)): 9.5 mg/l : 21 d D Test Guideline 211



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Toxic	ity to microorganisms	:	EC50: > 1,000 mg Exposure time: 3 Test Type: Respin Method: OECD T	ĥ
			NOEC: 1,000 mg, Exposure time: 3 Test Type: Respin Method: OECD T	h
	llose:			
Toxic	ity to fish	:	Exposure time: 48	ipes (Japanese medaka)): > 100 mg/l 3 h on data from similar materials
Magr	nesium stearate:			
Toxic	ity to fish	:	Exposure time: 48 Method: DIN 384	
	ity to daphnia and other tic invertebrates	:	Exposure time: 4 Test substance: V Method: Directive	Vater Accommodated Fraction 67/548/EEC, Annex V, C.2. on data from similar materials
Toxic plants	ity to algae/aquatic s	:	mg/l Exposure time: 72 Test substance: V Method: OECD T	Vater Accommodated Fraction est Guideline 201 on data from similar materials
			mg/l Exposure time: 72 Test substance: V Method: OECD T	Vater Accommodated Fraction
Toxic	ity to microorganisms	:	Exposure time: 10 Test substance: V	onas putida): > 100 mg/l 5 h Vater Accommodated Fraction on data from similar materials



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Persi	istence and degrada	bility		
Com	ponents:			
Ralte	gravir:			
	egradability	:	Result: rapidly Biodegradation Exposure time: Method: OECD	n: 50 %
Stabi	lity in water	:	Hydrolysis: < 1 Method: OECD	0 %(5 d)) Test Guideline 111
Cellu	llose:			
Biode	egradability	:	Result: Readily	v biodegradable.
Magr	nesium stearate:			
Biode	egradability	:		degradable ed on data from similar materials
Bioa	ccumulative potentia	l		
Com	ponents:			
Partit	e gravir: ion coefficient: n- iol/water	:	log Pow: -0.328	8
Partit	nesium stearate: ion coefficient: n- iol/water	:	log Pow: > 4	
	lity in soil ata available			
	r adverse effects ata available			

Section 13: Disposal considerations

Disposal methods		
Waste from residues	:	Do not dispose of waste into sewer.
		Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal.
		If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations



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C Code
3

National Regulations

NZS 5433		
UN number	: Not applicable	
Proper shipping name	: Not applicable	
Class	: Not applicable	
Subsidiary risk	: Not applicable	
Packing group	: Not applicable	
Labels	: Not applicable	
Hazchem Code	: Not applicable	

Special precautions for user

Not applicable

Section 15: Regulatory information

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

HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard



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HSW Controls

Certified handler certificate not required. Tracking hazardous substance not required. Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

Section 16: Other information

Revision Date	:	30.09.2023
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/
Date format	:	dd.mm.yyyy
Full text of other abbreviation	ns	
ACGIH NZ OEL	:	USA. ACGIH Threshold Limit Values (TLV) New Zealand. Workplace Exposure Standards for Atmospher- ic Contaminants
ACGIH / TWA NZ OEL / WES-TWA	:	8-hour, time-weighted average Workplace Exposure Standard - Time Weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New



Raltegravir Formulation

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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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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