

Raltegravir Formulation

Vers 2.1	ion	Revision Date: 2023/09/30	-	S Number: 574-00018	Date of last issue: 2023/04/04 Date of first issue: 2016/06/06
1. PI	RODUC	T AND COMPANY IDI	ENT	IFICATION	
	Product	t name	:	Raltegravir Form	ulation
	Manufa	cturer or supplier's d	letai	ls	
	Compa	ny	:	MSD	
	Address	5	:	126 E. Lincoln Av Rahway, New Je	venue rsey U.S.A. 07065
	Telepho	one	:	908-740-4000	
	Emerge	ency telephone number	· :	1-908-423-6000	
	E-mail a	address	:	EHSDATASTEW	/ARD@msd.com
	Recom	mended use of the ch	nemi	ical and restriction	ons on use
		mended use ions on use	:	Pharmaceutical Not applicable	
	Restrict		•		
<u> </u>					
2. H	AZARD	S IDENTIFICATION			
		assification	:	Category 1	

Reproductive toxicity	:	Category 2
Specific target organ toxicity - single exposure	:	Category 3
GHS label elements		
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	:	Prevention:
		P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read



Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	741574-00018	Date of first issue: 2016/06/06

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Raltegravir	871038-72-1	>= 60 -<= 100
Cellulose	9004-34-6	>= 10 -< 30
Magnesium stearate	557-04-0	< 10

4. FIRST AID MEASURES

General advice	 In the case of accident or if you feel unwell, seek medical advice 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. Wash clothing before reuse.



In case of eye contact	_				
If swallowed Most important symptoms and effects, both acute and delayed Protection of first-aiders	 In case of contact, if for at least 15 minu If easy to do, remove Get medical attention If swallowed, DO N Get medical attention Rinse mouth thorout Causes serious eyee May cause respirate Suspected of dama Contact with dust contact with dust contact 	ve contact lens, if worn. on immediately. IOT induce vomiting. on. ughly with water. e damage.			
Notes to physician	 and use the recommended personal protective equipment when the potential for exposure exists (see section 8). Treat symptomatically and supportively. 				
FIREFIGHTING MEASURES					
Suitable extinguishing media Unsuitable extinguishing	 Water spray Alcohol-resistant fo Carbon dioxide (CC Dry chemical None known. 				
media Specific hazards during fire- fighting	concentrations, and potential dust explo	ust; fine dust dispersed in air in sufficient d in the presence of an ignition source is a psion hazard. ustion products may be a hazard to health.			
Hazardous combustion prod- ucts	: Carbon oxides Nitrogen oxides (No Fluorine compound Metal oxides				
Specific extinguishing meth- ods	cumstances and the Use water spray to	measures that are appropriate to local cir- e surrounding environment. cool unopened containers. ed containers from fire area if it is safe to d			
Special protective equipment for firefighters		wear self-contained breathing apparatus. ective equipment.			

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so.



Raltegravir Formulation

Version 2.1	Revision Date: 2023/09/30	SDS Number: 741574-00018	Date of last issue: 2023/04/04 Date of first issue: 2016/06/06	
			dispose of contaminated wash water. rities should be advised if significant spillages contained.	
	ods and materials for inment and 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 surface 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 dis posal 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 regardicertain local or national requirements. 		
7. HANDL	ING AND STORAGE			
Techr	nical measures	causing an Provide ade	ricity may accumulate and ignite suspended dust explosion. equate precautions, such as electrical grounding g, or inert atmospheres.	
Local	/Total ventilation		ventilation is unavailable, use with local exhaust	
Advic	e on safe handling	: Avoid breat Do not swa Do not get i Avoid prolo Handle in a practice, ba sessment Keep conta Already ser	llow.	

to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory 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.

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



Version	Revision Date: 2023/09/30	SDS Number:	Date of last issue: 2023/04/04
2.1		741574-00018	Date of first issue: 2016/06/06

	Store in accordance with the particular national regulations.
Materials to avoid	: Do not store with the following product types:
	Strong oxidizing agents

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	NAB	10 mg/m3	ID OEL
		TWA	10 mg/m3	ACGIH
Magnesium stearate	557-04-0	NAB	10 mg/m3	ID OEL
			fied as carcinogenic t materials as carcinog	
	mans or anima		nateriale as carolinog	
		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 determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the	



Raltegravir Formulation

Versi 2.1	ion	Revision Date: 2023/09/30	-	S Number: 574-00018	Date of last issue: 2023/04/04 Date of first issue: 2016/06/06
Ş	Skin an	otection nd body protection e measures	:	end of workday. Wear the following Chemical resistan If splashes are lik Face-shield Select appropriate resistance data an potential. Skin contact must clothing (gloves, a If exposure to che eye flushing syste ing place.	er. Wash hands before breaks and at the g personal protective equipment: it goggles must be worn. ely to occur, wear: e protective clothing based on chemical and an assessment of the local exposure t be avoided by using impervious protective aprons, boots, etc). emical is likely during typical use, provide ems and safety showers close to the work- ot eat, drink or smoke.
				Wash contaminat	ed clothing before re-use.
9. PH	IYSICA	AL AND CHEMICAL PI	ROP	ERTIES	
/	Appear	ance	:	powder	
(Colour		:	No data available	9
(Odour		:	No data available	9
(Odour ⁻	Threshold	:	No data available	9
F	pН		:	No data available	9
I	Melting	point/freezing point	:	No data available	9
	Initial b range	oiling point and boiling	:	No data available	2
I	Flash p	oint	:	Not applicable	
I	Evapor	ation rate	:	No data available	9
I	Flamma	ability (solid, gas)	:	May form explosi dling or other me	ive dust-air mixture during processing, han- ans.
I	Flamma	ability (liquids)	:	No data available	9

No data available

No data available

Upper explosion limit / Upper : No data available

Lower explosion limit / Lower : No data available flammability limit

:

:

flammability limit

Vapour pressure

Relative vapour density



Raltegravir Formulation

Version 2.1	Revision Date: 2023/09/30		Number: 74-00018	Date of last issue: 2023/04/04 Date of first issue: 2016/06/06
Dens	ity	: 1	No data available	9
	bility(ies) /ater solubility	: 1	No data available	9
	tion coefficient: n- nol/water	: 1	No data available	2
	-ignition temperature	: 1	No data available	9
Decc	mposition temperature	: 1	No data available	9
Visco Vi	osity iscosity, kinematic	: 1	No data available	
Explo	osive properties	: 1	Not explosive	
Oxidi	zing properties	: 1	The substance o	r mixture is not classified as oxidizing.
Mole	cular weight	: 1	No data available	9
Parti	cle size	: 1	No data available	9

10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions		Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials Hazardous decomposition products	:	Oxidizing agents

11. TOXICOLOGICAL INFORMATION

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Ingestion
		Eye contact

Acute toxicity

Not classified based on available information.

Components:

Raltegravir:

Acute oral toxicity

: LD50 (Mouse, male and female): > 2,000 mg/kg



sion	Revision Date: 2023/09/30		DS Number: 1574-00018	Date of last issue: 2023/04/04 Date of first issue: 2016/06/06
Cellu	lose:			
Acute	e oral toxicity	:	LD50 (Rat): > 5	000 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 5 Exposure time: Test atmospher	4 h
Acute	e dermal toxicity	:	LD50 (Rabbit): :	> 2,000 mg/kg
Magn	nesium stearate:			
-	e oral toxicity	:	Assessment: Th icity	000 mg/kg Test Guideline 423 le substance or mixture has no acute oral t d on data from similar materials
Acute	e dermal toxicity	:	LD50 (Rabbit): :	> 2,000 mg/kg d on data from similar materials
Skin	corrosion/irritation	ailable		o on data nom similar materials
Skin Not cl Comp		ailable		o on data nom similar materials
Skin Not cl Comp	corrosion/irritation lassified based on ava ponents: gravir: ies	ailable :		
Skin Not cl Comp Ralte Speci Resul	corrosion/irritation lassified based on ava ponents: gravir: ies		information. Rabbit	
Skin Not cl Comp Ralte Speci Resul	corrosion/irritation lassified based on ava ponents: gravir: ies lt mesium stearate:		information. Rabbit	
Skin Not cl Comp Ralte Speci Resul	corrosion/irritation lassified based on ava <u>ponents:</u> gravir: ies lt nesium stearate: ies lt		information. Rabbit No skin irritation Rabbit No skin irritation	
Skin Not cl Com Ralte Speci Resul Speci Resul Rema	corrosion/irritation lassified based on ava ponents: gravir: ies lt nesium stearate: ies lt arks	::	information. Rabbit No skin irritation Rabbit No skin irritation Based on data f	
Skin o Not cl Comp Ralte Speci Resul Resul Rema Serio	corrosion/irritation lassified based on ava <u>ponents:</u> gravir: ies lt nesium stearate: ies lt	: : : irritati	information. Rabbit No skin irritation Rabbit No skin irritation Based on data f	
Skin Not cl Comp Ralte Speci Resul Resul Rema Secio Causo	corrosion/irritation lassified based on ava ponents: gravir: ies lt nesium stearate: ies lt arks	: : : irritati	information. Rabbit No skin irritation Rabbit No skin irritation Based on data f	
Skin o Not cl Comp Ralte Speci Resul Rema Speci Resul Rema Serio Causo Causo	corrosion/irritation lassified based on ava ponents: gravir: ies lt nesium stearate: ies lt arks ous eye damage/eye es serious eye damage	: : : irritati	information. Rabbit No skin irritation Rabbit No skin irritation Based on data f	
Skin Not cl Comp Ralte Speci Resul Resul Rema Secio Causo Causo	corrosion/irritation lassified based on ava ponents: gravir: ies lt nesium stearate: ies lt arks ous eye damage/eye es serious eye damage ponents: gravir: ies	: : : irritati	information. Rabbit No skin irritation Rabbit No skin irritation Based on data f	rom similar materials
Skin (Not cl Comp Ralte Speci Resul Rema Secio Causo Causo Causo Resul Rema	corrosion/irritation lassified based on ava ponents: gravir: ies lt nesium stearate: ies lt arks ous eye damage/eye es serious eye damage ponents: gravir: ies	: : : irritati	information. Rabbit No skin irritation Rabbit No skin irritation Based on data f on Bovine cornea	rom similar materials
Skin (Not cl Comp Ralte Speci Resul Rema Secio Causo Causo Causo Resul Rema	corrosion/irritation lassified based on ava ponents: gravir: ies lt nesium stearate: ies lt arks us eye damage/eye es serious eye damage ponents: gravir: ies lt ass bus eye damage/eye es serious eye damage ponents: ies	: : : irritati	information. Rabbit No skin irritation Rabbit No skin irritation Based on data f on Bovine cornea	rom similar materials



Raltegravir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	741574-00018	Date of first issue: 2016/06/06

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

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



rsion	Revision Date: 2023/09/30	SDS Number: 741574-00018	Date of last issue: 2023/04/04 Date of first issue: 2016/06/06
		Test Type: I Result: nega	n vitro mammalian cell gene mutation test ative
Genot	oxicity in vivo	cytogenetic Species: Mo	use Route: Ingestion
Magn	esium stearate:		
-	oxicity in vitro	Result: nega	n vitro mammalian cell gene mutation test ative ased on data from similar materials
		Method: OE Result: nega	Chromosome aberration test in vitro CD Test Guideline 473 ative ased on data from similar materials
		Result: nega	Bacterial reverse mutation assay (AMES) ative ased on data from similar materials
Not cla	nogenicity assified based on av	ailable information.	
<u>Comp</u>	oonents:		
	gravir:		
Specie	es sure time	: Mouse, male : 104 weeks	e and female
Result		: negative	
Cellul	ose:		
Specie		: Rat	
	ation Route	: Ingestion : 72 weeks	
Result		: negative	
	oductive toxicity	e unborn child.	
<u>Comp</u>	oonents:		
Ralte	gravir:		
	s on fertility	Species: Ra Application	Fertility/early embryonic development t, male and female Route: Oral ricity - Parent: NOAEL: 600 mg/kg body weight



sion	Revision Date: 2023/09/30	SDS Number: 741574-00018	Date of last issue: 2023/04/04 Date of first issue: 2016/06/06
		Result: negati	ve
Effect: ment	s on foetal develop-	Teratogenicity	sity Maternal: NOAEL: >= 600 mg/kg body weig /: LOAEL F1: 300 mg/kg body weight keletal malformations
		weight	tity Maternal: NOAEL: >= 1,000 mg/kg body /: NOAEL: >= 1,000 mg/kg body weight
Repro sessm	oductive toxicity - As- nent	: Some evidence animal experi	ce of adverse effects on development, based or ments.
Cellul	lose:		
Effect	s on fertility	Species: Rat	ne-generation reproduction toxicity study oute: Ingestion
Effect: ment	s on foetal develop-	Species: Rat	ertility/early embryonic development oute: Ingestion ive
Magn	esium stearate:		
-	s 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 we sed on data from similar materials
Effecta ment	s on foetal develop-	Species: Rat Application Re Result: negation	nbryo-foetal development oute: Ingestion ive sed on data from similar materials
	- single exposure ause respiratory irritati	on.	
<u>Comp</u>	oonents:		
Ralte	gravir:		
	sure routes	: Inhalation	



ersion I	Revision Date: 2023/09/30	SDS Number: 741574-00018	
Targe	et Organs	: Respirato	v Tract
	ssment		e respiratory irritation.
STOT	- repeated exposu	e	
Not cl	assified based on av	ailable information	
Repe	ated dose toxicity		
Com	oonents:		
	gravir:		
Speci		: Dog	
NOAE		: 90 mg/kg : Oral	
	cation Route sure time	: 371 d	
Symp		: Vomiting	
		-	
Speci		: Rat	
NOAE		: 30 mg/kg	
LOAE		: 120 mg/kg	1
	cation Route	: Oral : 189 d	
	sure time et Organs	: Stomach	
rarge	t organs	. Otomach	
Speci		: Mouse	
NOAE		: 50 mg/kg	
LOAE		: 500 mg/kg)
	cation Route	: Oral	
	sure time et Organs	: 14 Weeks : Stomach	
Targe	et Organs	. Stomach	
Speci	es	: Rat	
NOAE		: 50 mg/kg	
LOAE		: 200 mg/kg	1
	cation Route	: Oral	
	sure time	: 8 Weeks	
rarge	et Organs	: Stomach	
Cellu	lose:		
Speci	es	: Rat	
NOAE		: >= 9,000 r	ng/kg
	cation Route	: Ingestion	
Expos	sure time	: 90 Days	
Magn	esium stearate:		
Speci	es	: Rat	
NOAE		: > 100 mg/	kg
	cation Route	: Ingestion	
	sure time	: 90 Days	data for a static
Rema	arks	: Based on	data from similar materials



ersion Revision Date: 1 2023/09/30		SDS Number: 741574-00018		Date of last issue: 2023/04/04 Date of first issue: 2016/06/06				
-	ation toxicity assified based on availa	ble	information.					
-	rience with human exp	osı	ire					
	oonents:							
Raltegravir: Ingestion			: Symptoms: Nausea, Diarrhoea, Headache, Fever, Rash, Ski irritation					
. ECOLO	OGICAL INFORMATION	N						
Ecoto	oxicity							
<u>Comp</u>	oonents:							
	gravir:							
Toxici	ity to fish	:	Exposure time: 9	s promelas (fathead minnow)): > 100 mg/l 5 h est Guideline 203				
			mg/l Exposure time: 9	n variegatus (sheepshead minnow)): > 100 6 h est Guideline 203				
	ty to daphnia and other ic invertebrates	:	Exposure time: 4	nagna (Water flea)): > 100 mg/l 3 h est Guideline 202				
Toxici plants	ty to algae/aquatic	:	Exposure time: 9	chneriella subcapitata (green algae)): 66 m 5 h est Guideline 201				
			NOEC (Pseudoki mg/l Exposure time: 90 Method: OECD T					
Toxici icity)	ty to fish (Chronic tox-	:	Exposure time: 3	es promelas (fathead minnow)): 9.3 mg/l 3 d est Guideline 210				
	ity to daphnia and other ic invertebrates (Chron- city)	:	NOEC (Daphnia Exposure time: 2 Method: OECD T					
Toxici	ty to microorganisms	:	EC50: > 1,000 m Exposure time: 3 Test Type: Respi Method: OECD T	ĥ				



ersion 1	Revision Date: 2023/09/30		OS Number: 1574-00018	Date of last issue: 2023/04/04 Date of first issue: 2016/06/06
Cellul	ose:			
Toxicit	y to fish	:	Exposure time: 4	atipes (Japanese medaka)): > 100 mg/l 48 h d on data from similar materials
Magne	esium stearate:			
Toxicit	y to fish	:	Exposure time: 4 Method: DIN 38	
	y to daphnia and other c invertebrates	:	Exposure time: Test substance: Method: Directiv Remarks: Based	magna (Water flea)): > 1 mg/l 47 h Water Accommodated Fraction ve 67/548/EEC, Annex V, C.2. d on data from similar materials e limit of solubility
Toxicit plants	y to algae/aquatic	:	mg/l Exposure time: Test substance: Method: OECD Remarks: Based	rchneriella subcapitata (green algae)): > 1 72 h Water Accommodated Fraction Test Guideline 201 d on data from similar materials e limit of solubility
			mg/l Exposure time: Test substance: Method: OECD	okirchneriella subcapitata (green algae)): : 72 h Water Accommodated Fraction Test Guideline 201 d on data from similar materials
Toxicit	y to microorganisms	:	Exposure time: Test substance:	nonas putida): > 100 mg/l 16 h Water Accommodated Fraction d on data from similar materials
Persis	tence and degradabil	ity		
Comp	onents:			
Ralteg Biodeg	ravir: gradability	:	Result: rapidly d Biodegradation: Exposure time: 9	50 %



Version 2.1	Revision Date: 2023/09/30		DS Number: 1574-00018	Date of last issue: 2023/04/04 Date of first issue: 2016/06/06		
			Method: OECD 7	Fest Guideline 302B		
Stat	ility in water	:		%(5 d) Fest Guideline 111		
Cell	ulose:					
Bioc	legradability	:	Result: Readily b	iodegradable.		
Мас	nesium stearate:					
-	legradability	:	Result: Not biodegradable Remarks: Based on data from similar materials			
Bioa	accumulative potential					
<u>Con</u>	nponents:					
Part	egravir: ition coefficient: n- nol/water	:	log Pow: -0.328			
	nesium stearate:					
	ition coefficient: n- nol/water	:	log Pow: > 4			
	b ility in soil data available					
Oth	er adverse effects					
No d	data available					
13. DISP	OSAL CONSIDERATIO	NS				
Dis	oosal methods					
-	ste from residues	:		f waste into sewer.		
Con	taminated packaging	:	Empty containers dling site for recy	cordance with local regulations. s should be taken to an approved waste han- cling or disposal. specified: Dispose of as unused product.		
14. TRAI	NSPORT INFORMATIO	N				
Inte	rnational Regulations					
UN Prop Clas Sub	sidiary risk king group		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable			



Raltegravir Formulation

Version 2.1	Revision Date: 2023/09/30	 DS Number: 1574-00018	Date of last issue: 2023/04/04 Date of first issue: 2016/06/06
UN/I Prop Clas Subs Pacl Labe Pacl aircr Pacl	sidiary risk king group els king instruction (cargo	 Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	
UN r Prop Clas Subs Pack Labe EmS	sidiary risk king group	 Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials



Raltegravir Formulation

Versio 2.1	on	Revision Date: 2023/09/30		DS Number: 1574-00018	Date of last issue: 2023/04/04 Date of first issue: 2016/06/06			
c T	Type of hazardous materials subject to distribution and : Not applicable control, Annex I Type of hazardous materials subject to distribution and : Not applicable control, Annex II							
The components of this product are reported in the following inventories: AICS : not determined								
[DSL		:	not determined				
I	IECSC			not determined				
16. O	THER	INFORMATION						
F	Revisio	n Date	:	2023/09/30				
e c	Further information Sources of key data used to compile the Safety Data Sheet		:	Internal technical data, data from raw material SDSs, OEC eChem Portal search results and European Chemicals Age cy, http://echa.europa.eu/				
[Date format		:	yyyy/mm/dd				
A	Full tex ACGIH ID OEL		ons : :	USA. ACGIH Thr	eshold Limit Values (TLV) ational Exposure Limits			
	ACGIH ID OEL	/ TWA . / NAB	:	8-hour, time-weig Long term exposi				

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

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	741574-00018	Date of first issue: 2016/06/06

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.

ID / EN