according to the Globally Harmonized System



### **Raltegravir Formulation**

Versior 4.0	n Revision Date: 28.09.2024		S Number: 3567-00018	Date of last issue: 30.09.2023 Date of first issue: 06.06.2016
1. PRC	DUCT AND COMPANY ID	ENT	IFICATION	
Pr	Product name		Raltegravir Form	ulation
Ma	anufacturer or supplier's d	leta	ils	
Co	ompany	:	MSD	
Ac	ldress	:	Briahnager - Off Wagholi - Pune -	Pune Nagar Road India  412 207
Τe	lephone	:	+1-908-740-4000	)
Er	nergency telephone number	•	+1-908-423-6000	)
E-	mail address	:	EHSDATASTEW	/ARD@msd.com
Re	ecommended use of the ch ecommended use estrictions on use	<b>nem</b> י	ical and restriction Pharmaceutical Not applicable	ons on use

### 2. HAZARDS IDENTIFICATION

### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification Acute toxicity (Oral)	:	Category 5
Serious eye damage/eye irri- tation	:	Category 1
Reproductive toxicity	:	Category 2
Specific target organ toxicity - single exposure	:	Category 3
Short-term (acute) aquatic hazard	:	Category 3
GHS label elements Hazard pictograms	:	
Signal word	:	Danger

according to the Globally Harmonized System



### **Raltegravir Formulation**

		Date of first issue: 06.06.2016
d statements	H318 Causes H335 May cau H361d Suspec	narmful if swallowed. serious eye damage. se respiratory irritation. ted of damaging the unborn child. to aquatic life.
utionary statements	P261 Avoid bre P264+P265 W touch eyes. P271 Use only P273 Avoid rel P280 Wear pro	ash hands thoroughly after handling. Do not outdoors or with adequate ventilation. ease to the environment. otective gloves/ protective clothing/ eye protec-
	P304 + P340 + and keep comf unwell. P305 + P354 + with water for s sent and easy	F SWALLOWED: Get medical help. - P319 IF INHALED: Remove person to fresh air fortable for breathing. Get medical help if you feel - P338 + P317 IF IN EYES: Immediately rinse several minutes. Remove contact lenses, if pre- to do. Continue rinsing. Get medical help. ed or concerned, get medical advice.
	<b>Storage:</b> P405 Store loc	ked up.
	<b>Disposal:</b> P501 Dispose disposal plant.	of contents/ container to an approved waste
	utionary statements	H318 Causes s H335 May cause H361d Suspect H402 Harmful f P203 Obtain, r P261 Avoid bre P264+P265 W touch eyes. P271 Use only P273 Avoid rel P280 Wear pro- tion/ face prote <b>Response:</b> P301 + P317 II P304 + P340 + and keep comf unwell. P305 + P354 + with water for s sent and easy P318 IF expose <b>Storage:</b> P405 Store loc <b>Disposal:</b> P501 Dispose

### 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

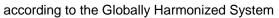
Chemical name	CAS-No.	Concentration (% w/w)
Raltegravir	871038-72-1	>= 50 - < 70
Cellulose	9004-34-6	>= 10 - < 20
Magnesium stearate	557-04-0	>= 1 - < 5

### 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





Versior 4.0	Revision Date: 28.09.2024		S Number: 3567-00018	Date of last issue: 30.09.2023 Date of first issue: 06.06.2016
	If inhaled In case of skin contact In case of eye contact		of water.	ention. act, immediately flush skin with soap and plenty ninated clothing and shoes.
In			Wash clothing Thoroughly clear In case of conta for at least 15 r	before reuse. an shoes before reuse. act, immediately flush eyes with plenty of water
Mo	swallowed ost important symptoms d effects, both acute and layed	:	Get medical att If swallowed, D Get medical att Rinse mouth th May be harmfu Causes serious May cause resp	ention immediately. O NOT induce vomiting. ention. oroughly with water. I if swallowed.
	otection of first-aiders otes to physician	<ul> <li>Contact with dust can cause mechanical irritati the skin.</li> <li>First Aid responders should pay attention to se and use the recommended personal protective when the potential for exposure exists (see sec</li> <li>Treat symptomatically and supportively.</li> </ul>		ast can cause mechanical irritation or drying of nders should pay attention to self-protection, commended personal protective equipment itial for exposure exists (see section 8).
	FIGHTING MEASURES			
Su	itable extinguishing media	:	Water spray Alcohol-resista Carbon dioxide Dry chemical	
	suitable extinguishing edia	:	None known.	
	ecific hazards during fire- hting	:	concentrations potential dust e	ng dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a xplosion hazard. mbustion products may be a hazard to health.
Ha uc	zardous combustion prod- ts	:	Carbon oxides Nitrogen oxides Fluorine compo Metal oxides	
Sp od	ecific extinguishing meth- s	:	cumstances an Use water spra	ng measures that are appropriate to local cir- d the surrounding environment. y to cool unopened containers. naged containers from fire area if it is safe to do
Sp	ecial protective equipment	:	In the event of	fire, wear self-contained breathing apparatus.

according to the Globally Harmonized System



### Raltegravir Formulation

Version 4.0	Revision Date: 28.09.2024		DS Number: 3567-00018	Date of last issue: 30.09.2023 Date of first issue: 06.06.2016	
for firefighters			Use personal pro	tective equipment.	
6. ACCIE	6. ACCIDENTAL RELEASE MEASURES				
tive	conal precautions, protec- equipment and emer- cy procedures	:	Follow safe handl	tective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).	
Envi	ronmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages	
Methods and materials for containment and cleaning up Add excess Soak up w Avoid disp with comp Dust depo es, as the leased into Clean up to bent. Local or n posal of th employed mine whice Sections 2		over the area to n Add excess liquid Soak up with iner Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the att Clean up remainin bent. Local or national posal of this mate employed in the of mine which regula Sections 13 and	h absorbents and place a damp covering ninimise entry of the material into the air. to allow the material to enter into solution. t absorbent material. If dust in the air (i.e., clearing dust surfaces air). build not be allowed to accumulate on surfac- form an explosive mixture if they are re- mosphere in sufficient concentration. Ing materials from spill with suitable absor- regulations may apply to releases and dis- trial, as well as those materials and items cleanup of releases. You will need to deter- ations are applicable. Its of this SDS provide information regarding tional requirements.		
7. HAND	LING AND STORAGE				
Tech	nnical measures	:	causing an explos	precautions, such as electrical grounding	
Loca	al/Total ventilation	:		ation is unavailable, use with local exhaust	

Advice on safe handling :

handling : Avoid breathing dust. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin.

ventilation.

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 respiratory irritants or sensitisers.



according to the Globally Harmonized System

# **Raltegravir Formulation**

Version 4.0	Revision Date: 28.09.2024	SDS Number: 743567-00018	Date of last issue: 30.09.2023 Date of first issue: 06.06.2016
Conc	ditions for safe storage	Keep containe Keep away fro Take precautic Take care to p environment.	generation and accumulation. r closed when not in use. m heat and sources of ignition. onary measures against static discharges. revent spills, waste and minimize release to the
Mate	rials to avoid	Keep tightly clo Keep in a cool Store in accord	bsed. , well-ventilated place. dance with the particular national regulations. ith the following product types:

### 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	TWA	10 mg/m3	ACGIH	
Magnesium stearate	557-04-0	TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH	
		TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH	

### Components with workplace control parameters

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 equipment	nt	
	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type
Hand protection	•	
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



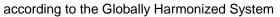
according to the Globally Harmonized System

# **Raltegravir Formulation**

Version 4.0	Revision Date: 28.09.2024	SDS Number: 743567-00018	Date of last issue: 30.09.2023 Date of first issue: 06.06.2016		
Eye protection		<ul> <li>determined for the product. Change gloves often! For sp applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with t glove manufacturer. Wash hands before breaks and at the end of workday.</li> <li>Wear the following personal protective equipment: Chemical resistant goggles must be worn. If splashes are likely to occur, wear:</li> </ul>			
Skin	and body protection	sistance data a tial. Skin contact m	riate protective clothing based on chemical re- and an assessment of the local exposure poten- nust be avoided by using impervious protective es, aprons, boots, etc).		
Hygie	ene measures	: If exposure to flushing syster place. When using do	chemical is likely during typical use, provide eye ns and safety showers close to the working o not eat, drink or smoke. nated clothing before re-use.		

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	No data available
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



SDS Number:



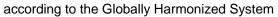
Date of last issue: 30.09.2023

# **Raltegravir Formulation**

Revision Date:

Version

4.0	28.09.2024		3567-00018	Date of first issue: 06.06.2016
Dens	sity	:	No data available	9
	bility(ies) /ater solubility	:	No data available	9
	tion coefficient: n-	:	No data available	9
	nol/water -ignition temperature	:	No data available	9
Deco	omposition temperature	:	No data available	9
Visco V	osity iscosity, kinematic	:	No data available	9
Explo	osive properties	:	Not explosive	
Oxid	izing properties	:	The substance o	r mixture is not classified as oxidizing.
Mole	cular weight	:	No data available	9
	cle characteristics cle size	:	No data available	9
10. STAB		(		
Cher	ctivity mical stability sibility of hazardous reac-	::	Stable under nor May form explos dling or other me	ive dust-air mixture during processing, han-
Cond	ditions to avoid	:	Heat, flames and	
	mpatible materials ardous decomposition ucts	:	Avoid dust forma Oxidizing agents No hazardous de	
11. TOXI		ΓΙΟΙ	N	
Infor expo	mation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact	
	t <b>e toxicity</b> be harmful if swallowed.			
Prod	luct:			
Acut	e oral toxicity	:	Acute toxicity esti Method: Calculati	mate: 4,026 mg/kg on method





ersion )	Revision Date: 28.09.2024	SDS Number: 743567-00018	Date of last issue: 30.09.2023 Date of first issue: 06.06.2016
Com	oonents:		
-	gravir:		
	e oral toxicity	: LD50 (Mouse	e, male and female): > 2,000 mg/kg
Cellu	lose:		
Acute	oral toxicity	: LD50 (Rat): >	> 5,000 mg/kg
Acute	inhalation toxicity	: LC50 (Rat): > Exposure tim Test atmosph	
Acute	e dermal toxicity	: LD50 (Rabbit	t): > 2,000 mg/kg
Magn	esium stearate:		
	oral toxicity	Assessment: icity	> 2,000 mg/kg CD Test Guideline 423 The substance or mixture has no acute oral tox sed on data from similar materials
Acute	e dermal toxicity		t): > 2,000 mg/kg sed on data from similar materials
<b>Skin</b> Not cl	corrosion/irritation lassified based on ava	Remarks: Ba	
Skin o Not cl <u>Com</u>	corrosion/irritation lassified based on ava ponents:	Remarks: Ba	
Skin o Not cl <u>Com</u>	corrosion/irritation lassified based on ava ponents: gravir: les	Remarks: Ba	sed on data from similar materials
Skin Not cl Com Ralte Speci Resul	corrosion/irritation lassified based on ava <u>ponents:</u> gravir: les lt	Remarks: Ba ailable information. : Rabbit	sed on data from similar materials
Skin Not cl Com Ralte Speci Resul	corrosion/irritation lassified based on ava <u>ponents:</u> gravir: les lt <b>besium stearate</b> :	Remarks: Ba ailable information. : Rabbit	sed on data from similar materials
Skin ( Not cl <u>Comp</u> Ralte Speci Resul Speci Resul	corrosion/irritation lassified based on ava <u>ponents:</u> gravir: les lt <b>esum stearate:</b> les lt	Remarks: Ba ailable information. : Rabbit : No skin irritat : Rabbit : No skin irritat	ised on data from similar materials
Skin Not cl Comp Ralte Speci Resul Speci Resul Resul Rema	corrosion/irritation lassified based on ava <u>conents:</u> gravir: les lt <b>nesium stearate:</b> les lt arks	Remarks: Ba ailable information. : Rabbit : No skin irritat : Rabbit : No skin irritat : Based on dat	sed on data from similar materials
Skin ( Not cl Com Ralte Speci Resul Speci Resul Resul Rema	corrosion/irritation lassified based on ava <u>ponents:</u> gravir: les lt <b>esum stearate:</b> les lt	Remarks: Ba ailable information. : Rabbit : No skin irritat : Rabbit : No skin irritat : Based on dat irritation	ised on data from similar materials
Skin ( Not cl Comp Ralte Speci Resul Speci Resul Rema Serio Causo	corrosion/irritation lassified based on ava <u>ponents:</u> gravir: les lt <b>essium stearate:</b> les lt arks	Remarks: Ba ailable information. : Rabbit : No skin irritat : Rabbit : No skin irritat : Based on dat irritation	ised on data from similar materials
Skin ( Not cl Comp Ralte Speci Resul Resul Rema Serio Causo <u>Comp</u>	corrosion/irritation lassified based on ava <u>ponents:</u> gravir: les lt <b>nesium stearate:</b> les lt arks <b>us eye damage/eye</b> es serious eye damage ponents:	Remarks: Ba ailable information. : Rabbit : No skin irritat : Rabbit : No skin irritat : Based on dat irritation	ised on data from similar materials
Skin ( Not cl Comp Ralte Speci Resul Resul Rema Serio Causo <u>Comp</u>	corrosion/irritation lassified based on ava <u>ponents:</u> gravir: les lt <b>nesium stearate:</b> les lt <b>nesium stearate:</b> les lt arks <b>us eye damage/eye</b> es serious eye damage <u>ponents:</u> gravir: les	Remarks: Ba ailable information. : Rabbit : No skin irritat : Rabbit : No skin irritat : Based on dat irritation	tion ta from similar materials
Skin ( Not cl Comp Ralte Speci Resul Resul Rema Serio Cause Cause Cause Ralte Speci Resul	corrosion/irritation lassified based on ava ponents: gravir: les lt mesium stearate: les lt arks us eye damage/eye es serious eye damage ponents: gravir: les lt	Remarks: Ba ailable information. : Rabbit : No skin irritat : Based on dat irritation ge. : Bovine corne	tion ta from similar materials
Skin ( Not cl Comp Ralte Speci Resul Resul Rema Serio Cause Cause Cause Ralte Speci Resul	corrosion/irritation lassified based on avaination ponents: gravir: les lt nesium stearate: les lt arks us eye damage/eye es serious eye damage ponents: gravir: les lt assit mesium stearate:	Remarks: Ba ailable information. : Rabbit : No skin irritat : Based on dat irritation ge. : Bovine corne	tion ta from similar materials
Skin o Not cl Comp Ralte Speci Resul Resul Rema Serio Cause Comp Ralte Speci Resul	corrosion/irritation lassified based on avaination ponents: gravir: les lt mesium stearate: les lt arks us eye damage/eye es serious eye damage ponents: gravir: les lt mesium stearate: les lt	Remarks: Ba ailable information. : Rabbit : No skin irritat : Rabbit : No skin irritat : Based on dat irritation ge. : Bovine corne : Severe irritat : Rabbit : No eye irritat	ised on data from similar materials tion ta from similar materials

according to the Globally Harmonized System



### **Raltegravir Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	28.09.2024	743567-00018	Date of first issue: 06.06.2016

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

### Respiratory sensitisation

Not classified based on available information.

### Components:

#### Raltegravir:

Test Type Species Result	:	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
Test Type Exposure routes Species Method Result 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



according to the Globally Harmonized System

Version 4.0	Revision Date: 28.09.2024		S Number: 3567-00018	Date of last issue: 30.09.2023 Date of first issue: 06.06.2016			
			Test Type: In Result: negati	vitro mammalian cell gene mutation test ve			
Geno	toxicity in vivo	:	: Test Type: Mammalian erythrocyte micronucleus test (in cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative				
Magr	nesium stearate:						
	toxicity in vitro	:	Result: negati	vitro mammalian cell gene mutation test ve sed on data from similar materials			
			Method: OEC Result: negati	romosome aberration test in vitro D Test Guideline 473 ve sed on data from similar materials			
			Test Type: Ba Result: negati	cterial reverse mutation assay (AMES)			
	inogenicity						
	lassified based on ava	ilable	information.				
Com	ponents:						
	gravir:						
Spec Expo	ies sure time	:	Mouse, male a 104 weeks	and female			
Resu	lt	:	negative				
Collu	lose:						
Spec		:	Rat				
Appli	cation Route	:	Ingestion				
Expo Resu	sure time It	:	72 weeks negative				
, tood			noganio				
-	oductive toxicity ected of damaging the	unbo	rn child.				
Com	ponents:						
Ralte	gravir:						
	ts on fertility	:	Species: Rat, Application Ro	ity - Parent: NOAEL: 600 mg/kg body weight			
Effect	to on footal days lan		Species: Rat				
	ts on foetal develop-	·	opecies. Nat				

according to the Globally Harmonized System



ersion .0	Revision Date: 28.09.2024	SDS Number: 743567-00018	Date of last issue: 30.09.2023 Date of first issue: 06.06.2016
ment		Teratogenic	<pre>kicity Maternal: NOAEL: &gt;= 600 mg/kg body weight ity: LOAEL F1: 300 mg/kg body weight Skeletal malformations</pre>
		weight	xicity Maternal: NOAEL: >= 1,000 mg/kg body ity: NOAEL: >= 1,000 mg/kg body weight
Repro sessm	ductive toxicity - As- nent	: Some evide animal expe	nce of adverse effects on development, based on riments.
Cellul	ose:		
Effect	s on fertility	Species: Ra	Route: Ingestion
Effect ment	s on foetal develop-	Species: Ra	Route: Ingestion
II Magn	esium stearate:		
	s on fertility	reproductior Species: Ra Application Method: OE Result: nega	Route: Ingestion CD Test Guideline 422
Effect: ment	s on foetal develop-	Species: Ra Application Result: nega	Route: Ingestion
	- single exposure ause respiratory irritati	on.	
	oonents:		
	gravir:		
Expos Targe	sure routes t Organs sment	: Inhalation : Respiratory : May cause i	Tract respiratory irritation.

according to the Globally Harmonized System



# **Raltegravir Formulation**

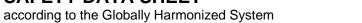
Version 4.0	Revision Date: 28.09.2024	SDS Number: 743567-00018	Date of last issue: 30.09.2023 Date of first issue: 06.06.2016
	<b>- repeated exposur</b> lassified based on ava		
	ated dose toxicity		
<u>Com</u>	oonents:		
Ralte	gravir:		
	EL cation Route sure time	: Dog : 90 mg/kg : Oral : 371 d : Vomiting	
Expo	ΞL	: Rat : 30 mg/kg : 120 mg/kg : Oral : 189 d : Stomach	
Expo	ΞL	: Mouse : 50 mg/kg : 500 mg/kg : Oral : 14 Weeks : Stomach	
Expo	ΞL	: Rat : 50 mg/kg : 200 mg/kg : Oral : 8 Weeks : Stomach	
Cellu	lose:		
		: Rat : >= 9,000 mg/ : Ingestion : 90 Days	kg
Magn	esium stearate:		
Speci NOAE Applic Expos Rema	EL cation Route sure time	: Rat : > 100 mg/kg : Ingestion : 90 Days : Based on dat	a from similar materials

### Not classified based on available information.

according to the Globally Harmonized System



ersion D	Revision Date: 28.09.2024		OS Number: 3567-00018	Date of last issue: 30.09.2023 Date of first issue: 06.06.2016
Expe	rience with human exp	osı	ire	
<u>Comp</u>	ponents:			
Ralte	gravir:			
Inges	tion	:	Symptoms: Na irritation	usea, Diarrhoea, Headache, Fever, Rash, Sl
ECOL	OGICAL INFORMATION	N		
Ecoto	oxicity			
<u>Com</u>	ponents:			
Ralte	gravir:			
Toxic	ity to fish	:	Exposure time	ales promelas (fathead minnow)): > 100 mg/l : 96 h ) Test Guideline 203
			mg/l Exposure time	don variegatus (sheepshead minnow)): > 100 : 96 h D Test Guideline 203
	ity to daphnia and other ic invertebrates	:	Exposure time	a magna (Water flea)): > 100 mg/l : 48 h ) Test Guideline 202
Toxic plants	ity to algae/aquatic	:	mg/l Exposure time	okirchneriella subcapitata (green algae)): 66 : 96 h D Test Guideline 201
			mg/l Exposure time	lokirchneriella subcapitata (green algae)): 3.8 : 96 h ) Test Guideline 201
Toxic	ity to microorganisms	:		
Toxici icity)	ity to fish (Chronic tox-	:		
Toxic	ity to daphnia and other	:	NOEC: 9.5 mg	/I



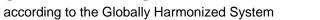


# Raltegravir Formulation

Version 4.0	Revision Date: 28.09.2024		98 Number: 3567-00018	Date of last issue: 30.09.2023 Date of first issue: 06.06.2016	
	tic invertebrates (Chron- cicity)		Exposure time: 21 Species: Daphnia Method: OECD Te	magna (Water flea)	
	llose:				
Toxic	city to fish	:	Exposure time: 48	ipes (Japanese medaka)): > 100 mg/l 3 h on data from similar materials	
Magi	nesium stearate:				
Τοχία	city to fish	:	LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l Exposure time: 48 h Method: DIN 38412 Remarks: Based on data from similar materials		
	city to daphnia and other tic invertebrates	:	Exposure time: 47 Test substance: V Method: Directive	Vater Accommodated Fraction 67/548/EEC, Annex V, C.2. on data from similar materials	
Toxic plant	city to algae/aquatic s	:	mg/l Exposure time: 72 Test substance: V Method: OECD To	Vater Accommodated Fraction est Guideline 201 on data from similar materials	
			mg/l Exposure time: 72 Test substance: V Method: OECD To	Vater Accommodated Fraction	
Toxic	city to microorganisms	:	Exposure time: 16 Test substance: V	nas putida): > 100 mg/l 5 h Vater Accommodated Fraction on data from similar materials	
Pers	istence and degradabili	ity			
<u>Com</u>	ponents:				
	e <b>gravir:</b> egradability	:	Result: rapidly de Biodegradation: 4	50 %	

Method: OECD Test Guideline 302B

Exposure time: 9 d





### **Raltegravir Formulation**

ersion )	Revision Date: 28.09.2024		OS Number: 3567-00018	Date of last issue: 30.09.2023 Date of first issue: 06.06.2016
Stabi	lity in water	:	Hydrolysis: < 1 Method: OECD	0 %(5 d) • Test Guideline 111
Cellu	lose:			
Biode	egradability	:	Result: Readily	biodegradable.
Magr	nesium stearate:			
Biode	egradability	:	Result: Not bio Remarks: Base	degradable ed on data from similar materials
Bioa	ccumulative potentia	I		
Com	ponents:			
Ralte	gravir:			
	ion coefficient: n- ol/water	:	log Pow: -0.328	3
Magr	esium stearate:			
Partit	ion coefficient: n- ol/water	:	log Pow: > 4	
Mobi	lity in soil			
	ata available			
Othe	r adverse effects			
No da	ata available			

lations.
approved waste han-
unused product.

### **14. TRANSPORT INFORMATION**

### **International Regulations**

UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

### IMDG-Code

Not regulated as a dangerous good

according to the Globally Harmonized System



### **Raltegravir Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	28.09.2024	743567-00018	Date of first issue: 06.06.2016

#### Transport in bulk according to IMO instruments

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

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

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

#### 16. OTHER INFORMATION

Revision Date	:	28.09.2024
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 Agen- cy, http://echa.europa.eu/

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

	Date format	:	dd.mm.yyyy			
Full text of other abbreviations						
	ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)			
	ACGIH / TWA	:	8-hour, 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 Svstem; 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;

according to the Globally Harmonized System



### Raltegravir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	28.09.2024	743567-00018	Date of first issue: 06.06.2016

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 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.

IN / EN