according to GB/T 16483 and GB/T 17519



# **Raltegravir Pediatric Granules Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
5.0	2024/09/28	20440-00025	Date of first issue: 2014/10/09

### **1. PRODUCT AND COMPANY IDENTIFICATION**

Product name	:	Raltegravir Pediatric Granules Formulation			
Manufacturer or supplier's details Company : MSD					
Company	•				
Address	:	199 Wenhai North Road HEDA, Hangzhou - Zhejiang Province - CHINA 310018			
Telephone	:	908-740-4000			
Emergency telephone number :		86-571-87268110			
E-mail address	:	EHSDATASTEWARD@msd.com			
Recommended use of the chemical and restrictions on use					
Recommended use : Restrictions on use :		Pharmaceutical Not applicable			

#### 2. HAZARDS IDENTIFICATION

#### **Emergency Overview**

Appearance Colour Odour	:	powder off-white odourless
Causes serious eye damage. N child. Harmful to aquatic life.	lay	cause respiratory irritation. Suspected of damaging the unborn
GHS Classification		
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		

according to GB/T 16483 and GB/T 17519



## **Raltegravir Pediatric Granules Formulation**

Hazard pictogr Signal word Hazard statem Precautionary	ients	H335 May o H361d Susp H402 Harmi	es serious eye damage. eause respiratory irritation. bected of damaging the unborn child. ful to aquatic life.
Hazard statem		: H318 Cause H335 May o H361d Susp H402 Harmi	cause respiratory irritation. Dected of damaging the unborn child. ful to aquatic life.
		H335 May o H361d Susp H402 Harmi	cause respiratory irritation. Dected of damaging the unborn child. ful to aquatic life.
Precautionary	statements	P201 Obtair	:
		and underst P261 Avoid P271 Use o P273 Avoid	breathing dust. nly outdoors or in a well-ventilated area. release to the environment. protective gloves/ protective clothing/ eye protec
		and keep co doctor if you P305 + P35 water for se and easy to CENTER/ d	0 + P312 IF INHALED: Remove person to fresh a omfortable for breathing. Call a POISON CENTER a feel unwell. 1 + P338 + P310 IF IN EYES: Rinse cautiously v veral minutes. Remove contact lenses, if present do. Continue rinsing. Immediately call a POISON octor. 3 IF exposed or concerned: Get medical advice/
		Storage:	laskadum
		P405 Store	iuckeu up.
		<b>Disposal:</b> P501 Dispo disposal pla	se of contents/ container to an approved waste nt.

#### Health hazards

Causes serious eye damage. Suspected of damaging the unborn child. May cause respiratory irritation.

#### **Environmental hazards**

Harmful to aquatic life.

#### Other hazards which do not result in classification

Contact with dust can cause mechanical irritation or drying of the skin.

according to GB/T 16483 and GB/T 17519



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May form explosive dust-air mixture during processing, handling or other means.

#### **3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

#### Components

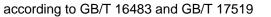
Chemical name	CAS-No.	Concentration (% w/w)
Raltegravir	871038-72-1	>= 20 -< 25
Cellulose	9004-34-6	>= 20 -< 30
Magnesium stearate	557-04-0	>= 1 -< 10
Ammonium hydroxide	1336-21-6	>= 0.1 -< 0.25

#### 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. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	
If swallowed	:	· · · · · · · · · · · · · · · · · · ·
Most important symptoms and effects, both acute and delayed	:	
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).
Notes to physician	:	Treat symptomatically and supportively.

### **5. FIREFIGHTING MEASURES**

Suitable extinguishing media	:	Water spray
0 0		Alcohol-resistant foam
		Carbon dioxide (CO2)
		Dry chemical





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Uns me	suitable extinguishing dia	:	None known.	
fighting concent potentia		concentrations, an potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. oustion products may be a hazard to health.	
Haz ucts	zardous combustion prod- s	:	Carbon oxides Nitrogen oxides (I Fluorine compour Metal oxides	
Spe ods	ecific extinguishing meth-	:	<ul> <li>Use extinguishing measures that are appropriate to local cumstances and the surrounding environment.</li> <li>Use water spray to cool unopened containers.</li> <li>Remove undamaged containers from fire area if it is safe so.</li> <li>Evacuate area.</li> </ul>	
	ecial protective equipment firefighters	:		e, wear self-contained breathing apparatus. rective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

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. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment 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 surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfac- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Clean up remaining materials from spill with suitable absor- bent. 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 deter- mine which regulations are applicable.

according to GB/T 16483 and GB/T 17519



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			and 15 of this SDS provide information regarding or national requirements.
7. HANDL	ING AND STORAGE		
Hand	lling		
Tech	nical measures	causing an Provide ade	icity may accumulate and ignite suspended dust explosion. quate precautions, such as electrical grounding g, or inert atmospheres.
Local	/Total ventilation		ventilation is unavailable, use with local exhaust
Advice on safe handling		: Avoid breat Do not swal Do not get i Avoid prolon Handle in a practice, ba sessment Keep conta Already sen to asthma, a should cons tory irritants Minimize du Keep conta Keep away Take preca	low. n eyes. nged or repeated contact with skin. ccordance with good industrial hygiene and safety sed on the results of the workplace exposure as- ner tightly closed. sitised individuals, and those susceptible allergies, chronic or recurrent respiratory disease, sult their physician regarding working with respira- or sensitisers. Ist generation and accumulation. ner closed when not in use. from heat and sources of ignition. utionary measures against static discharges. o prevent spills, waste and minimize release to the
Avoid	lance of contact	: Oxidizing a	gents
Stora	-		
	litions for safe storage rials to avoid	Store locked Keep tightly Keep in a co Store in acc : Do not store	
Packa	aging material	: Unsuitable i	naterial: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

according to GB/T 16483 and GB/T 17519



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Raltegravir	871038-72-1	TWA	1000 µg/m3 (OEB 1)	Internal
Cellulose	9004-34-6	PC-TWA	10 mg/m3	CN OEL
		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
Ammonium hydroxide	1336-21-6	TŴA	25 ppm (Ammonia)	ACGIH
		STEL	35 ppm (Ammonia)	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	:	Particulates type
Eye/face protection	:	Wear the following personal protective equipment: Chemical resistant goggles must be worn. If splashes are likely to occur, wear: Face-shield
Skin and body protection	:	
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 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.

according to GB/T 16483 and GB/T 17519



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	Hygien	e measures	:	eye flushing syste ing place. When using do no	emical is likely during typical use, provide ems and safety showers close to the work- ot eat, drink or smoke. ed clothing before re-use.
9. P	HYSICA	AL AND CHEMICAL PI	ROP	ERTIES	
	Appear	ance	:	powder	
	Colour		:	off-white	
	Odour		:	odourless	
	Odour	Threshold	:	No data available	e
	рН		:	No data available	9
	Melting	point/freezing point	:	No data available	9
	Initial b range	oiling point and boiling	:	No data available	9
	Flash p	point	:	No data available	9
	Evapor	ation rate	:	No data available	9
	Flamm	ability (solid, gas)	:	May form explos dling or other me	ive dust-air mixture during processing, han- eans.
	Flamm	ability (liquids)	:	No data available	9
		explosion limit / Upper ability limit	:	No data available	9
		explosion limit / Lower ability limit	:	No data available	9
	Vapour	· pressure	:	No data available	e
	Relativ	e vapour density	:	No data available	9
	Relativ	e density	:	No data available	9
	Solubili Wat	ity(ies) er solubility	:	No data available	9
		n coefficient: n-	:	No data available	e
	octanol Auto-ig	//water inition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9

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Visco				
Vis	scosity, kinematic	:	No data available	9
Explo	sive properties	:	Not explosive	
Oxidiz	zing properties	:	The substance o	r mixture is not classified as oxidizing.
Molec	cular weight	:	No data available	e
	le characteristics le size	:	No data available	9
10. STABI	LITY AND REACTIVITY	/		
	ivity lical stability bility of hazardous reac-	:	Stable under nor May form explos dling or other me	ive dust-air mixture during processing, han-
Condi	tions to avoid	:	Heat, flames and	
	patible materials dous decomposition cts	:	Avoid dust forma Oxidizing agents No hazardous de	
11. TOXIC	OLOGICAL INFORMAT		1	
Expos	sure routes	:	Inhalation Skin contact Ingestion Eye contact	
Acute	e toxicity			
	assified based on availa	ble	information.	
<u>Produ</u> Acute	<u>uct:</u> oral toxicity	:	Acute toxicity esti Method: Calculati	mate: > 5,000 mg/kg on method
Comp	oonents:			
	gravir:			
Acute	oral toxicity	:	LD50 (Mouse, ma	ale and female): > 2,000 mg/kg
<b>Cellu</b> Acute	lose: oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg

according to GB/T 16483 and GB/T 17519



ersion D	Revision Date: 2024/09/28		S Number: 40-00025	Date of last issue: 2024/04/06 Date of first issue: 2014/10/09
Acute	e inhalation toxicity	E	_C50 (Rat): > 5 Exposure time: Test atmospher	4 h
Acute	e dermal toxicity	: L	LD50 (Rabbit): :	> 2,000 mg/kg
Maqı	nesium stearate:			
	e oral toxicity	N A i	Assessment: Th city	,000 mg/kg Test Guideline 423 ne substance or mixture has no acute oral tox d on data from similar materials
Acute	e dermal toxicity		LD50 (Rabbit): : Remarks: Base	> 2,000 mg/kg d on data from similar materials
Amm	nonium hydroxide:			
Acute	e oral toxicity	: L	LD50 (Rat): 350	) mg/kg
Acute	e inhalation toxicity	: /	Assessment: Co	prrosive to the respiratory tract.
II	e inhalation toxicity corrosion/irritation	: /	Assessment: Co	prrosive to the respiratory tract.
 Skin				prrosive to the respiratory tract.
<b>Skin</b> Not c	corrosion/irritation			prrosive to the respiratory tract.
Skin Not c <u>Com</u>	corrosion/irritation			prrosive to the respiratory tract.
Skin Not c <u>Com</u>	corrosion/irritation classified based on ava ponents: egravir:	ailable in : F		
Skin Not o Com Ralte Spec Resu	corrosion/irritation classified based on ava ponents: gravir: cles llt	ailable in : F	iformation. Rabbit	
Skin Not o Com Ralte Spec Resu	corrosion/irritation classified based on ava ponents: egravir: cles ult	ailable in : F : N	nformation. Rabbit No skin irritatior	
Skin Not o Com Ralte Spec Resu Mage	corrosion/irritation classified based on ava ponents: egravir: cles ult nesium stearate: cles	ailable in : F : N : F	nformation. Rabbit No skin irritatior Rabbit	1
Skin Not o Com Ralte Spec Resu	corrosion/irritation classified based on ava ponents: egravir: sies ult nesium stearate: sies ult	ailable in : F : M : F : F	oformation. Rabbit No skin irritatior Rabbit No skin irritatior	1
Skin Not o Com Ralte Spec Resu Mage Spec Resu Resu	corrosion/irritation classified based on ava ponents: egravir: sies ult nesium stearate: sies ult	ailable in : F : M : F : F	oformation. Rabbit No skin irritatior Rabbit No skin irritatior	
Skin Not o Com Ralte Spec Resu Mage Spec Resu Resu	corrosion/irritation classified based on ava ponents: egravir: cles lit nesium stearate: cles lit arks	ailable in : F : T : F : F : F : F	nformation. Rabbit No skin irritatior Rabbit No skin irritatior Based on data f Rabbit	n irom similar materials
Skin Not o Com Ralte Spec Resu Resu Resu Rem Spec Resu	corrosion/irritation classified based on ava ponents: egravir: eies alt nesium stearate: cies arks nonium hydroxide: cies alt	ailable in : F : M : E : F : F : F : (	nformation. Rabbit No skin irritatior Rabbit No skin irritatior Based on data f Rabbit Corrosive after :	n From similar materials 3 minutes to 1 hour of exposure
Skin Not o Com Ralte Spec Resu Resu Resu Rem Spec Resu Rem	corrosion/irritation classified based on ava ponents: egravir: cles lit nesium stearate: cles lit arks nonium hydroxide: cles lit arks	ailable in : F : M : F : M : F : F : F : F : C : F : C	nformation. Rabbit No skin irritation Rabbit Based on data f Rabbit Corrosive after S	n irom similar materials
Skin Not o Com Ralte Spec Resu Resu Resu Rema Spec Resu Rema Spec Resu Rema	corrosion/irritation classified based on ava ponents: egravir: eies alt nesium stearate: cies arks nonium hydroxide: cies alt arks	ailable in : F : M : F : M : F : M : F : C : F : C : F : C : F : C : F : C : F : C : C : C : C : C : C : C : C	nformation. Rabbit No skin irritation Rabbit Based on data f Rabbit Corrosive after S	n From similar materials 3 minutes to 1 hour of exposure
Skin Not o Com Ralte Spec Resu Resu Resu Rema Spec Resu Rema Spec Resu Rema	corrosion/irritation classified based on ava ponents: egravir: cles lit nesium stearate: cles lit arks nonium hydroxide: cles lit arks	ailable in : F : M : F : M : F : M : F : C : F : C : F : C : F : C : F : C : F : C : C : C : C : C : C : C : C	nformation. Rabbit No skin irritation Rabbit Based on data f Rabbit Corrosive after S	n From similar materials 3 minutes to 1 hour of exposure
Skin Not o Com Ralte Spec Resu Resu Resu Rem Spec Resu Rem Spec Resu Rem Spec Resu Rem Spec Resu Rem	corrosion/irritation classified based on ava ponents: egravir: cies lit nesium stearate: cies lit arks nonium hydroxide: cies lit arks bus eye damage/eye ses serious eye damage	ailable in : F : M : F : M : F : M : F : C : F : C : F : C : F : C : F : C : F : C : C : C : C : C : C : C : C	nformation. Rabbit No skin irritation Rabbit Based on data f Rabbit Corrosive after S	n From similar materials 3 minutes to 1 hour of exposure

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### Magnesium stearate:

Species Result Remarks	:	Rabbit
Result	:	No eye irritation
Remarks	:	Based on data from similar materials

#### Ammonium hydroxide:

Result	:	Irreversible effects on the eye
Remarks	:	Based on skin corrosivity.

#### 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

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ersion .0	Revision Date: 2024/09/28	SDS Number: 20440-00025	Date of last issue: 2024/04/06 Date of first issue: 2014/10/09
Geno	toxicity in vivo	Species: Mou Result: negat Test Type: Cl	ive nromosomal aberration D Test Guideline 475
		rtesur. negu	
<b>Cellu</b> Geno	<b>lose:</b> toxicity in vitro	: Test Type: Ba Result: negat	acterial reverse mutation assay (AMES) ive
		Test Type: In Result: negat	vitro mammalian cell gene mutation test ive
Geno	toxicity in vivo	cytogenetic a Species: Mou	use oute: Ingestion
II Magn	esium stearate:		
	toxicity in vitro	Result: negat	vitro mammalian cell gene mutation test ive sed on data from similar materials
		Method: OEC Result: negat	nromosome aberration test in vitro D Test Guideline 473 ive sed on data from similar materials
		Result: negat	acterial reverse mutation assay (AMES) ive sed on data from similar materials
II Amm	onium hydroxide:		
	toxicity in vitro	: Test Type: Ba Result: negat	acterial reverse mutation assay (AMES) ive
II Carci	nogenicity		
	lassified based on av ponents:	ailable information.	
	gravir:		
Speci	es sure time	: Mouse, male : 104 weeks : negative	and female

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### Cellulose:

Species Application Route Exposure time Result	:	Rat
Application Route	:	Ingestion
Exposure time	:	72 weeks
Result	:	negative

### **Reproductive toxicity**

Suspected of damaging the unborn child.

#### Components:

Raltegravir:	
Effects on fertility :	Test Type: Fertility/early embryonic development Species: Rat, male and female Application Route: Oral General Toxicity - Parent: NOAEL: 600 mg/kg body weight Result: negative
Effects on foetal develop- : ment	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
	Species: Rabbit General Toxicity Maternal: NOAEL: >= 1,000 mg/kg body weight Teratogenicity: NOAEL: >= 1,000 mg/kg body weight Result: negative
Reproductive toxicity - As- : sessment	Some evidence of adverse effects on development, based on animal experiments.
Cellulose:	
Effects on fertility :	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on foetal develop- : ment	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative
Magnesium stearate:	
Effects on fertility :	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test

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Effects on foetal develop- ment		/ M F F S / T S F	Result: negative Remarks: Base Fest Type: Emb Species: Rat Application Rou Result: negative	D Test Guideline 422 /e ed on data from similar materials lbryo-foetal development ute: Ingestion		
May o	F - single exposure cause respiratory irritat ponents:	ion.				
Expo Targe	<b>gravir:</b> sure routes et Organs ssment	: F	nhalation Respiratory Tra Iay cause resp	ct piratory irritation.		
	<b>onium hydroxide:</b> ssment arks			biratory irritation. nal or regional regulation.		
Not c	F - repeated exposure lassified based on ava ated dose toxicity		formation.			
Com	ponents:					
Speci NOAI Applie	EL cation Route sure time	: 9 : 0 : 3	Dog 90 mg/kg Dral 871 d /omiting			
Expo	ΞL	: 3 : 1 : 0 : 1	Rat 80 mg/kg 20 mg/kg Dral 89 d Stomach			

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Expo	cation Route sure time et Organs	: Oral : 14 Weeks : Stomach				
NOA LOAE Appli Expo	Species NOAEL LOAEL Application Route Exposure time Target Organs					
Cellu	llose:					
NOA Appli	Species NOAEL Application Route Exposure time		Rat >= 9,000 mg/kg Ingestion 90 Days			
Magr	nesium stearate:					
	EL cation Route sure time	: Rat : > 100 mg/kg : Ingestion : 90 Days : Based on data	a from similar materials			
Aspi	ration toxicity					
•	lassified based on ava	ailable information.				
Expe	rience with human e	xposure				
Com	ponents:					
Ralte	e <b>gravir:</b> stion	: Symptoms: Na irritation	ausea, Diarrhoea, Headache, Fever, Rash, Skin			
12. ECOL	OGICAL INFORMATI	ON				
Foot	ovicity					
	oxicity					
	ponents:					
	<b>gravir:</b> ity to fish	Exposure time	nales promelas (fathead minnow)): > 100 mg/l e: 96 h D Test Guideline 203			

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 100 mg/l Exposure time: 96 h

Method: OECD Test Guideline 203

according to GB/T 16483 and GB/T 17519



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п				
	y to daphnia and other c invertebrates	:	Exposure time:	a magna (Water flea)): > 100 mg/l 48 h 9 Test Guideline 202
Toxicity plants	y to algae/aquatic	:	Exposure time:	kirchneriella subcapitata (green algae)): 66 m 96 h 9 Test Guideline 201
			mg/l Exposure time:	okirchneriella subcapitata (green algae)): 3.8 96 h 9 Test Guideline 201
Toxicity icity)	y to fish (Chronic tox-	:	Exposure time:	nales promelas (fathead minnow)): 9.3 mg/l 33 d 9 Test Guideline 210
	y to daphnia and other c invertebrates (Chron- ity)	:	Exposure time:	a magna (Water flea)): 9.5 mg/l 21 d 9 Test Guideline 211
Toxicity	y to microorganisms	:		
Cellulo	ose:			
Toxicity	y to fish	:	Exposure time:	latipes (Japanese medaka)): > 100 mg/l 48 h ed on data from similar materials
Magne	esium stearate:			
	y to fish	:	Exposure time: Method: DIN 3	
	y to daphnia and other invertebrates	:	Exposure time: Test substance Method: Direct Remarks: Base	magna (Water flea)): > 1 mg/l 47 h e: Water Accommodated Fraction ive 67/548/EEC, Annex V, C.2. ed on data from similar materials he limit of solubility

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	Toxicity to algae/aquatic plants		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
Toxici	ty to microorganisms	:	Exposure time: 16 Test substance: V	nas putida): > 100 mg/l 5 h Vater Accommodated Fraction on data from similar materials
Ammo	onium hydroxide:			
	ty to fish	:	Exposure time: 96	hus mykiss (rainbow trout)): 0.89 mg/l ን h leutralised product
	ty to daphnia and other c invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (Water flea)): 101 mg/l 3 h
	tor (Acute aquatic tox-	:	1	
icity) Toxici <sup>:</sup> icity)	ty to fish (Chronic tox-	:	Exposure time: 73	chus mykiss (rainbow trout)): 0.0135 mg/l 3 d Ieutralised product
	ty to daphnia and other c invertebrates (Chron- city)	:	Exposure time: 21	nagna (Water flea)): 0.961 mg/l l d on data from similar materials
Persis	stence and degradabili	ty		
Comp	onents:			
Ralteg	gravir:			
Biode	gradability	:	Result: rapidly de Biodegradation: 5 Exposure time: 9 Method: OECD To	50 %
Stabili	ty in water	:	Hydrolysis: < 10 % Method: OECD To	

according to GB/T 16483 and GB/T 17519



# **Raltegravir Pediatric Granules Formulation**

ersion 0	Revision Date: 2024/09/28	SDS Number: 20440-00025	Date of last issue: 2024/04/06 Date of first issue: 2014/10/09		
II					
Cellu	lose.				
	egradability	: Result: Rea	dily biodegradable.		
Magn	esium stearate:				
Biodegradability			: Result: Not biodegradable Remarks: Based on data from similar materials		
Bioad	ccumulative potentia	I			
Com	oonents:				
Ralte	gravir:				
Partit	ion coefficient: n- ol/water	: log Pow: -0.	: log Pow: -0.328		
Magn	esium stearate:				
	ion coefficient: n- ol/water	: log Pow: > 4	ŀ		
Mobi	lity in soil				
No da	ata available				
Othe	r adverse effects				
No data available					

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.

### 14. TRANSPORT INFORMATION

### International Regulations

UNRTDG UN number Proper shipping name Class Subsidiary risk Packing group Labels Environmentally hazardous	: : : : : : : : : : : : : : : : : : : :	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable no
<b>IATA-DGR</b> UN/ID No.	:	Not applicable

according to GB/T 16483 and GB/T 17519



## **Raltegravir Pediatric Granules Formulation**

Version 5.0	Revision Date: 2024/09/28	SDS Number: 20440-00025		Date of last issue: 2024/04/06 Date of first issue: 2014/10/09
Class Subsic Packir Labels Packir aircraf Packir	ng instruction (cargo t) ng instruction (passen-	: Not app : Not app : Not app : Not app : Not app : Not app : Not app	licable licable licable licable licable	
IMDG- UN nu Proper Class Subsic Packir Labels EmS C	ger aircraft) IMDG-Code UN number Proper shipping name		licable licable licable licable licable licable licable	
Not applicable for product a			of MARP	OL 73/78 and the IBC Code
Natior	al Regulations			
UN nu Proper Class Subsid	<sup>r</sup> shipping name liary risk Ig group	Not app Not app Not app Not app Not app	licable licable licable licable	

### Special precautions for user

Not applicable

Marine pollutant

Labels

### **15. REGULATORY INFORMATION**

### National regulatory information Law on the Prevention and Control of Occupational Diseases

: no

: Not applicable

### **Regulations on Safety Management of Hazardous Chemicals**

Catalogue of Hazardous Chemicals	:	This product is not listed in the cata- logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de- termination.
Identification of Major Hazard Installations for Hazardo	ous C	chemicals (GB : Not listed

according to GB/T 16483 and GB/T 17519



Versior 5.0	n Revision Date: 2024/09/28		OS Number: 1440-00025	Date of last issue: 2024/04/06 Date of first issue: 2014/10/09			
Hazardous Chemicals for Priority Management under : Not listed SAWS							
	egulations on Labour Prot atalogue of Highly Toxic Ch	where Toxic Substances are Used : Not listed					
Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals							
China Severely Restricted Toxic Chemicals for Import : Not listed and Export							
II Regulation on the Administration of Precursor Chemicals Catalogue and Classification of Precursor Chemicals : Not listed							
Ya	angtze River Protection La	aw					
Tł	nis product does not contain	an	y dangerous chemi	cals prohibited for inland river transport.			
Tł	ne components of this pro	dud	ct are reported in t	he following inventories:			
	cs	:	not determined	-			
D	SL	:	not determined				
IE	CSC	:	not determined				
16. OTHER INFORMATION							
Re	evision Date	:	2024/09/28				
Fu	urther information						
CC	ources of key data used to mpile the Safety Data neet	:		data, data from raw material SDSs, OECD rch results and European Chemicals Agen- opa.eu/			
Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.							
Da	ate format	:	yyyy/mm/dd				
Fu	Full text of other abbreviations						
	CGIH N OEL	:	Occupational exp	shold Limit Values (TLV) osure limits for hazardous agents in the ical hazardous agents.			
A	CGIH / TWA CGIH / STEL N OEL / PC-TWA	:	8-hour, time-weig Short-term exposi Permissible conce				



## Raltegravir Pediatric Granules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
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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 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

#### Disclaimer

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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