

Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1	26.09.2023	20375-00022	Date of first issue: 09.10.2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name

: Raltegravir Pediatric Formulation

Manufacturer or supplier's details							
Company name of supplier	:	MSD					
Address	:	126 E. Lincoln Avenue					
		Rahway, New Jersey U.S.A. 07065					
Telephone	:	908-740-4000					
Emergency telephone	:	1-908-423-6000					
E-mail address	:	EHSDATASTEWARD@msd.com					
Recommended use of the chemical and restrictions on use							

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Serious eye damage/eye irritation	:	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 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 victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.





Version 5.1	Revision Date: 26.09.2023	SDS Number: 20375-00022	Date of last issue: 20.03.2023 Date of first issue: 09.10.2014	
		water for seve and easy to do CENTER or do	+ P338 + P310 IF IN EYES: Rinse cautiously with tral minutes. Remove contact lenses, if present b. Continue rinsing. Immediately call a POISON octor/ physician. IF exposed or concerned: Get medical advice/	
		Storage: P405 Store loo	cked up.	
		Disposal:		
		P501 Dispose of contents/ container to an approved waste posal plant.		
•	, horarda			

Other hazards

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Raltegravir	871038-72-1	>= 20 -< 30

SECTION 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. Thoroughly clean shoes before reuse.
In case of eye contact	:	
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Causes serious eye damage. May cause respiratory irritation. Suspected of damaging the unborn child. Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection,



Versio 5.1	on	Revision Date: 26.09.2023	-	9S Number: 375-00022	Date of last issue: 20.03.2023 Date of first issue: 09.10.2014		
Notes to physician :		:	and use the recommended personal protective equipment when the potential for exposure exists (see section 8). Treat symptomatically and supportively.				
SECT	SECTION 5. FIRE-FIGHTING MEASURES						
S	Suitable extinguishing media		:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical			
	Jnsuita nedia	ble extinguishing	:	None known.			
S		hazards during fire	:	 Avoid generating dust; fine dust dispersed in air in suffice concentrations, and in the presence of an ignition source potential dust explosion hazard. Exposure to combustion products may be a hazard to here 			
	lazard icts	ous combustion prod-	 Carbon oxides Nitrogen oxides (Fluorine compour Chlorine compour Sulfur oxides Metal oxides 		ids		
	Specific ds	extinguishing meth-	:	cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe so.			
		protective equipment fighters	:	Evacuate area. In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.		
SECT	ION 6.	ACCIDENTAL RELE	ASE	EMEASURES			
tiv	ve equ	al precautions, protec- lipment and emer- procedures	:		ective equipment. ing advice (see section 7) and personal ent 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.
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Methods and materials for : containment and cleaning up	Surround spill with absorbents and place a damp covering over the area to minimize 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 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
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Version 5.1	Revision Date: 26.09.2023	SDS Number: 20375-00022	Date of last issue: 20.03.2023 Date of first issue: 09.10.2014
		disposal of th employed in t determine wh Sections 13 a	anal regulations may apply to releases and is material, as well as those materials and items he cleanup of releases. You will need to nich regulations are applicable. and 15 of this SDS provide information regarding or national requirements.
SECTION	7. HANDLING AND ST	ORAGE	
Tech	nical measures	causing an e Provide adeq	ity may accumulate and ignite suspended dust plosion. uate precautions, such as electrical grounding or inert atmospheres.
Loca	I/Total ventilation		entilation is unavailable, use with local exhaust
Advid	e on safe handling	: Avoid breathi Do not swalld Do not get in Avoid prolong Handle in acc practice, base assessment Keep contain Already sens to asthma, al should consu respiratory in Minimize dus Keep contain Keep away fr Take precaut Take care to environment.	w. eyes. ged or repeated contact with skin. cordance with good industrial hygiene and safety ed on the results of the workplace exposure er tightly closed. itized individuals, and those susceptible ergies, chronic or recurrent respiratory disease, It their physician regarding working with itants or sensitizers. t generation and accumulation. er closed when not in use. om heat and sources of ignition. ionary measures against static discharges. prevent spills, waste and minimize release to the
Hygie	ene measures	flushing syste place. When using o	o chemical is likely during typical use, provide eye ems and safety showers close to the working do not eat, drink or smoke. hinated clothing before re-use.
	litions for safe storage	: Keep in prop Store locked Keep tightly o Keep in a coo Store in acco	erly labeled containers. up. closed. ol, well-ventilated place. rdance with the particular national regulations.
iviate	rials to avoid	: Do not store Strong oxidiz	with the following product types: ing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
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	26.09.2023	20	375-00022	Date of fi	rst issue: 09.10.2014		
				exposure)	concentration		
Ralteç	gravir		871038-72-1	TWA	1000 µg/m3 (OEB 1)	Internal	
Engin	eering measures	:	Apply measur Ensure that du dust collectors designed in a work area (i.e	es to prevent oust-handling sy s, vessels, and manner to pre ., there is no le	re concentrations. dust explosions. ystems (such as exhau processing equipmen event the escape of dus eakage from the equipr available, use with loca	t) are st into the ment).	
Perso	onal protective equip	ment					
	ratory protection	:	exposure assessment demonstrates exposures outside recommended guidelines, use respiratory protection.			tside the	
	ter type protection	:	Particulates type				
Ma	aterial	:	: Chemical-resistant gloves				
Re	emarks	:	on the concertime is not det For special apresistance to a gloves with th	ntration specific termined for the oplications, we chemicals of the glove manuf	nds against chemicals c to place of work. Brea e product. Change glo recommend clarifying he aforementioned pro- acturer. Wash hands b rkday.	akthrough ves often! the tective	
Eye p	rotection	:	breaks and at the end of workday. Wear the following personal protective equipment: Chemical resistant goggles must be worn. If splashes are likely to occur, wear: Face-shield				
Skin a	and body protection	:	Select approp resistance dat potential. Skin contact r	ta and an asse	e clothing based on ch essment of the local ex ed by using impervious ots, etc).	posure	

Appearance	:	powder
Color	:	yellow-orange
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available



Raltegravir Pediatric Formulation

Ver 5.1	sion	Revision Date: 26.09.2023		S Number: 375-00022	Date of last issue: 20.03.2023 Date of first issue: 09.10.2014
	Flash p	oint	:	No data available	9
	Evapor	ation rate	:	No data available)
	Flamma	ability (solid, gas)	:	May form explosi handling or other	ve dust-air mixture during processing, means.
	Flamma	ability (liquids)	:	No data available)
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	No data available)
	Relative	e vapor density	:	No data available)
	Relative	e density	:	No data available)
	Solubili Wat	ty(ies) er solubility	:	No data available	9
	Partitio octanol	n coefficient: n-	:	No data available)
		nition temperature	:	No data available)
	Decom	position temperature	:	No data available)
	Viscosi Visc	ty cosity, kinematic	:	No data available	9
	Explosi	ve properties	:	Not explosive	
	Ovidi-i			The substance of	r mixture is not clossified as sydicized
		ng properties	•		r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	
	Particle	e size	:	No data available)

SECTION 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, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.



Version 5.1	Revision Date: 26.09.2023	SDS Number: 20375-00022	Date of last issue: 20.03.2023 Date of first issue: 09.10.2014
	npatible materials rdous decomposition acts	: Oxidizing a : No hazard	agents ous decomposition products are known.
SECTION	11. TOXICOLOGICAL	INFORMATION	
Infor i Inhala	mation on likely route	s of exposure	
Skin o Inges	contact		
	e toxicity lassified based on avai	able information.	
<u>Prode</u> Acute	uct: oral toxicity		ty estimate: > 5,000 mg/kg Iculation method
Com	oonents:		
	gravir: e oral toxicity	: LD50 (Mou	se, male and female): > 2,000 mg/kg
-	corrosion/irritation lassified based on avai	able information.	
	oonents:		
Ralte	gravir:		
Speci Resu		: Rabbit : No skin irrit	ation
	us eye damage/eye ir es serious eye damage		
<u>Com</u>	ponents:		
	gravir:		
Speci Resu		: Bovine corr : Severe irrita	
Resp	iratory or skin sensiti	zation	
-	sensitization lassified based on avai	able information.	
-	iratory sensitization lassified based on avai	able information.	
Com	oonents:		
Ralte Test⁻	gravir: Type	: Local lympl	n node assay (LLNA)
			/ 13



	Revision Date: 26.09.2023		9S Number: 375-00022	Date of last issue: 20.03.2023 Date of first issue: 09.10.2014
Spec Resu		:	Mouse negative	
	n cell mutagenicity lassified based on availa	ble	information.	
Com	ponents:			
Ralte	gravir:			
Geno	otoxicity in vitro	:	Test Type: revers Result: negative	e mutation assay
			Test Type: Alkalir Test system: rat h Result: negative	
				nosomal aberration est Guideline 473
Geno	otoxicity in vivo	:	Test Type: In vivo Species: Mouse Result: negative	o micronucleus test
				nosomal aberration est Guideline 475
Carci	inogenicity			
	lassified based on availa	ble	information.	
Com	ponents:			
Ralte	gravir:			
Nanc	0		Maura mala and	
Spec		:	Mouse, male and	female
Spec	sure time	:	104 weeks negative	female
Speci Expo Resu	sure time It	:	104 weeks	female
Speci Expo Resu Repr	sure time It oductive toxicity	:	104 weeks negative	female
Speci Expo Resu Repr Susp	sure time It oductive toxicity ected of damaging the u	nbo	104 weeks negative	female
Speci Expo Resu Resu Susp <u>Com</u>	sure time It oductive toxicity ected of damaging the u ponents:	nbo	104 weeks negative	female
Speci Expo Resu Repr Susp <u>Com</u>	sure time It oductive toxicity ected of damaging the u ponents: gravir:	nbo	104 weeks negative rn child.	
Speci Expo Resu Repr Susp <u>Com</u>	sure time It oductive toxicity ected of damaging the u ponents:	nbo	104 weeks negative rn child. Test Type: Fertilit Species: Rat, ma Application Route	y/early embryonic development le and female



		Symptoms: Skele Result: positive	tal malformations.
		weight Teratogenicity: N	Maternal: NOAEL: >= 1,000 mg/kg body OAEL: >= 1,000 mg/kg body weight
		Result: negative	
ductive toxicity - As- ent	:		f adverse effects on development, based on tts.
single exposure			
	on.		
onents:			
ravir:			
s of exposure Organs sment		Respiratory Tract	
repeated exposure			
	lable	information.	
ted dose toxicity			
<u>onents:</u>			
ravir:			
S	:	Dog	
	:	90 mg/kg	
	÷		
	:	Vomiting	
		Pot	
-			
ation Route	:	Oral	
	:		
Organs		Stomach	
S	:	Mouse	
L	:	50 mg/kg	
- tian Dauta	:		
	÷		
Organs	:	Stomach	
19		Rat	
	•		
-	:	200 mg/kg	
ation Route	:	Oral	
ure time		8 Weeks	
	ent single exposure ause respiratory irritation onents: pravir: s of exposure Organs sment repeated exposure assified based on avainted dose toxicity onents: pravir: ass L ation Route ure time Organs s L ation Route ure time Organs s L ation Route ure time Organs s L ation Route ure time Organs s L ation Route ure time Organs s L ation Route ure time Organs s L	ent single exposure ause respiratory irritation. onents: pravir: s of exposure Organs sment repeated exposure assified based on available ted dose toxicity onents: pravir: s L ation Route ure time oms s L ation Route ure time Organs s L ation Route ure time Organs s L ation Route ure time Organs s L ation Route ure time Organs s L ation Route ure time organs s L ation Route ation Route ation Route ation Route ation Route ation Route ation Route s L ation Route ation	Species: Rabbit General Toxicity I weight Teratogenicity: Ne Result: negative ductive toxicity - As- ent Single exposure ause respiratory irritation. onents: yravir: s of exposure inhalation Organs Respiratory Tract sment Nay cause respiratory Tract may cause respiratory Tract sment Nay cause respiratory Tract sment Nay cause respiratory Tract sment Nay cause respiratory repeated exposure respected exposure respected exposure still dose toxicity onents: yravir: s Dog L 90 mg/kg ation Route Oral ure time 371 d oms Vomiting s Rat L 30 mg/kg ation Route Oral ure time 189 d Organs Stomach s Mouse L 50 mg/kg ation Route Oral ure time 14 Weeks Organs Stomach s Stomach



rsion	Revision Date: 26.09.2023		S Number: 375-00022	Date of last issue: 20.03.2023 Date of first issue: 09.10.2014			
Targe	et Organs	:	Stomach				
-	a tion toxicity lassified based on availa	ble	information.				
Expe	rience with human exp	osu	re				
<u>Comp</u>	oonents:						
Ralte Inges	gravir: tion	: Symptoms: Nausea, Diarrhea, Headache, Fever, Rash, Skin irritation					
CTION	12. ECOLOGICAL INFO	ORN	IATION				
Ecoto	oxicity						
	oonents:						
	gravir:						
	ity to fish	:	LC50 (Pimephale Exposure time: 96 Method: OECD T				
			LC50 (Cyprinodor mg/l Exposure time: 96 Method: OECD T				
	ity to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD T				
Toxici plants	ity to algae/aquatic	:	EC50 (Pseudokin Exposure time: 96 Method: OECD T				
			NOEC (Pseudoki mg/l Exposure time: 96 Method: OECD T				
Toxici icity)	ity to fish (Chronic tox-	:	NOEC (Pimephal Exposure time: 33 Method: OECD T				
	ity to daphnia and other ic invertebrates (Chron- icity)		NOEC (Daphnia i Exposure time: 2 ⁻⁷ Method: OECD T				
Toxici	ity to microorganisms	:	EC50: > 1,000 m Exposure time: 3 Test Type: Respin Method: OECD T	h ration inhibition			



Versio 5.1	on	Revision Date: 26.09.2023		9S Number: 375-00022	Date of last issue: 20.03.2023 Date of first issue: 09.10.2014
				NOEC: 1,000 mg/ Exposure time: 3 Test Type: Respir Method: OECD T	h ration inhibition
P	Persist	ence and degradabil	ity		
<u>c</u>	Compo	nents:			
R	Raltegr	avir:			
В	Biodegr	adability	:	Result: rapidly de Biodegradation: 4 Exposure time: 9 Method: OECD T	50 %
S	Stability	in water	:	Hydrolysis: < 10 % Method: OECD T	%(5 d) est Guideline 111
В	Bioacc	umulative potential			
<u>c</u>	Compo	nents:			
P	Raltegr Partitior	n coefficient: n-	:	log Pow: -0.328	
Μ	lobility	y in soil			
Ν	lo data	available			
-		dverse effects available			
SECT	ION 13	3. DISPOSAL CONSI	DER	ATIONS	
D	Dispos	al 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 handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 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





Version 5.1	Revision Date: 26.09.2023	SDS Number: 20375-00022	Date of last issue: 20.03.2023 Date of first issue: 09.10.2014
	sport in bulk accordi pplicable for product a	-	RPOL 73/78 and the IBC Code
	estic regulation		
	-002-SCT egulated as a dangero	ous good	
-	ial precautions for u pplicable	ser	
SECTION	15. REGULATORY I	NFORMATION	
Safet mixtu		nmental regulations/	legislation specific for the substance or
esser	ral Law for the control ntial chemical products icing capsules, tablets	2	rs, : Not applicable
The i	ngredients of this pr	oduct are reported in	n the following inventories:

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

SECTION 16. OTHER INFORMATION

Revision Date	:	26.09.2023
Date format	:	dd.mm.yyyy

Full text of other abbreviations

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 Develop-



Raltegravir Pediatric Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1	26.09.2023	20375-00022	Date of first issue: 09.10.2014

ment; 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

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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