



Version 5.2	Revision Date: 06.04.2024		S Number: 350-00023	Date of last issue: 26.09.2023 Date of first issue: 09.10.2014
	1: IDENTIFICATION		Poltogravir Do	diatric Formulation
FIUU		•	Railegravii Pe	
Manu	ufacturer or supplier's	deta	ils	
Com	pany	:	MSD	
Address		:		evel 1/26 Talavera Rd rk NSW, Australia 2113
Telep	phone	:	1 800 033 461	
Emergency telephone number :		er :	Poisons Inform	nation Centre: Phone 13 11 26
E-ma	E-mail address		EHSDATASTE	EWARD@msd.com
Reco	ommended use of the c	hem	ical and restric	ctions on use
Reco	mmended use	:	Pharmaceutica	al
Restr	rictions on use	:	Not applicable	
ECTION	2. HAZARDS IDENTIF	ICAT	ION	
GHS	Classification			
Serio	ous eye damage/eye irri-	:	Category 1	

Serious eye damage/eye irri- tation	:	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	:	<b>Prevention:</b> P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood.



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P261 Avoid breathing dust.P271 Use only outdoors or in a well-ventilated area.P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Response:

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

### Storage:

P405 Store locked up.

#### Disposal:

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

### Other hazards which do not result in classification

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

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

## Components

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

### **SECTION 4. FIRST AID MEASURES**

General advice	<ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medical advice.</li> </ul>
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	<ul> <li>In case of contact, immediately flush skin with soap and plenty of water.</li> <li>Remove contaminated clothing and shoes.</li> <li>Get medical attention.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul>
In case of eye contact	<ul> <li>In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.</li> <li>If easy to do, remove contact lens, if worn.</li> </ul>



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N	If swallowed Most important symptoms and effects, both acute and		:	Get medical atten Rinse mouth thor Causes serious e	NOT induce vomiting. tion. oughly with water. ye damage.		
d	lelayed		May cause respiratory irritation. Suspected of damaging the unborn child. Contact with dust can cause mechanical irritat the skin.		naging the unborn child. can cause mechanical irritation or drying of ers should pay attention to self-protection,		
N	lotes to	o physician	:	and use the recommended personal protective equipment when the potential for exposure exists (see section 8). Treat symptomatically and supportively.			
SECT	'ION 5.	FIREFIGHTING MEA	SU	RES			
S	Suitable	extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical			
	Unsuitable extinguishing media		:	None known.			
	Specific ighting	hazards during fire-	<ul> <li>Avoid generating dust; fine dust dispersed in air concentrations, and in the presence of an ignitio potential dust explosion hazard.</li> <li>Exposure to combustion products may be a haza</li> </ul>		nd in the presence of an ignition source is a losion hazard.		
	lazardo icts	ous combustion prod-	:	<ul> <li>Carbon oxides         <ul> <li>Nitrogen oxides (NOx)</li> <li>Fluorine compounds</li> <li>Chlorine compounds</li> <li>Sulphur oxides</li> <li>Metal oxides</li> </ul> </li> </ul>			
	Specific ods	extinguishing meth-	<ul> <li>Use extinguishing measures that are appropriate to le 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 so.</li> </ul>		he surrounding environment. o cool unopened containers.		
	Special or firefi	protective equipment ghters	Evacuate area.				
SECT	ION 6.	ACCIDENTAL RELE	ASI	E MEASURES			
tiv	Personal precautions, protec- tive equipment and emer- gency procedures		:	Follow safe handl	ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).		
E	Environmental precautions		:		he environment. akage or spillage if safe to do so. se of contaminated wash water.		

Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages



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0.2		ds and materials for iment and cleaning up	:	cannot be contain Surround spill with 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 in posal of this mate employed in the of mine which regula Sections 13 and 1	hed. h absorbents and place a damp covering hinimise entry of the material into the air. to allow the material to enter into solution. t absorbent material. f 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. 15 of this SDS provide information regarding
				centain local of ha	tional requirements.

# SECTION 7. HANDLING AND STORAGE

Technical measures	<ul> <li>Static electricity may accumulate and ignite suspended dust causing an explosion.</li> <li>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</li> </ul>	
Local/Total ventilation	<ul> <li>If sufficient ventilation is unavailable, use with local exhaust ventilation.</li> </ul>	
Advice on safe handling	<ul> <li>Avoid breathing dust.</li> <li>Do not swallow.</li> <li>Do not get in eyes.</li> <li>Avoid prolonged or repeated contact with skin.</li> <li>Handle in accordance with good industrial hygiene and safe practice, based on the results of the workplace exposure as sessment</li> <li>Keep container tightly closed.</li> <li>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.</li> <li>Minimize dust generation and accumulation.</li> <li>Keep container closed when not in use.</li> <li>Keep away from heat and sources of ignition.</li> <li>Take precautionary measures against static discharges.</li> <li>Take care to prevent spills, waste and minimize release to the spirate of the spira</li></ul>	- ə, a-
Hygiene measures	<ul> <li>environment.</li> <li>If exposure to chemical is likely during typical use, provide e flushing systems and safety showers close to the working place.</li> <li>When using do not eat, drink or smoke.</li> <li>Wash contaminated clothing before re-use.</li> </ul>	



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	itions for safe storage rials to avoid	Store locked u Keep tightly cl Keep in a cool Store in accord	osed. , well-ventilated place. dance with the particular national regulations. <i>v</i> ith the following product types:

# SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Components with workplace control parameters

Components with workplace control parameters						
Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis		
Raltegravir	871038-72-1	TŴA	1000 µg/m3 (OEB 1)	Internal		
Engineering measures	Apply meas Ensure that dust collecto signed in a work area (i	ors, vessels, and   manner to preven .e., there is no lea		t) are de- nto the nent).		
Personal protective equipme	ent					
Respiratory protection Filter type Hand protection	sure assess ommended	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type				
Material	: Chemical-re	Chemical-resistant gloves				
Remarks	on the conc stance and determined applications chemicals o glove manuf	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 and of workdow.				
Eye protection	: Wear the fol Chemical re If splashes a	end of workday. Wear the following personal protective equipment: Chemical resistant goggles must be worn. If splashes are likely to occur, wear: Face-shield Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.				
Skin and body protection	: Select appro resistance d					



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Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

ECTION 9. PHYSICAL AND CHEMICAL PROPERTIES					
Appearance	:	powder			
Colour	:	yellow-orange			
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	:	No data available			
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			
Relative density	:	No data available			
Solubility(ies) Water solubility	:	No data available			
Partition coefficient: n- octanol/water	:	No data available			
Auto-ignition temperature	:	No data available			
Decomposition temperature	:	No data available			
Viscosity Viscosity, kinematic	:	No data available			

# SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES



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Explo	sive properties	:	Not explosive			
Oxidiz	zing properties	:	The substance	or mixture is not classified as oxidizing.		
Molec	cular weight	:	No data availab	le		
	le characteristics le size	:	No data availab	le		
ECTION	10. STABILITY AND R	EAC	TIVITY			
	tivity nical stability bility of hazardous reac-		Stable under no May form explo- dling or other m	sive dust-air mixture during processing, han		
Condi	itions to avoid	:	Heat, flames an			
Incompatible materials Hazardous decomposition products		:	<ul><li>Avoid dust formation.</li><li>Oxidizing agents</li><li>No hazardous decomposition products are known.</li></ul>			
CTION	11. TOXICOLOGICAL	INFO	ORMATION			
Expos	sure routes	:	Inhalation Skin contact Ingestion Eye contact			
	e toxicity					
	lassified based on availa	able	information.			
	<u>oonents:</u>					
	gravir: oral toxicity	:	LD50 (Mouse, m	ale and female): > 2,000 mg/kg		
	corrosion/irritation lassified based on availa	able	information.			
<u>Com</u>	oonents:					
Ralte	gravir:					
Speci Resul		:	Rabbit No skin irritation			
Seria	us eye damage/eye irr	itati	on			
	es serious eye damage.					



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### **Components:**

# Raltegravir:

Species	:	Bovine cornea
Result	:	Severe irritation

## 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

### **Chronic toxicity**

#### Germ cell mutagenicity

Not classified based on available information.

#### Components:

#### Raltegravir:

Genotoxicity in vitro :	Test Type: reverse mutation assay Result: negative
	Test Type: Alkaline elution assay Test system: rat hepatocytes Result: negative
	Test Type: Chromosomal aberration Method: OECD Test Guideline 473 Result: negative
Genotoxicity in vivo :	Test Type: In vivo micronucleus test Species: Mouse Result: negative
	Test Type: Chromosomal aberration Method: OECD Test Guideline 475 Result: negative

## Carcinogenicity

Not classified based on available information.



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<u>Com</u>	ponents:			
Spec	sure time	:	Mouse, male and 104 weeks negative	female
-	oductive toxicity ected of damaging the	unbor	n child.	
Com	ponents:			
	egravir: ts on fertility	:	Species: Rat, ma Application Route	
Effec ment	ts on foetal develop-	:	Teratogenicity: L	e: Oral Maternal: NOAEL: >= 600 mg/kg body weight DAEL F1: 300 mg/kg body weight etal malformations
			weight	Maternal: NOAEL: >= 1,000 mg/kg body OAEL: >= 1,000 mg/kg body weight
Repro sessr	oductive toxicity - As- ment	:	Some evidence o animal experimer	f adverse effects on development, based on nts.
May	F - single exposure cause respiratory irritat ponents:	ion.		
	egravir:			
Expo Targe	sure routes et Organs ssment	:	Inhalation Respiratory Tract May cause respir	

### STOT - repeated exposure

Not classified based on available information.



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# Repeated dose toxicity

Components:		
Raltegravir: Species NOAEL Application Route Exposure time Symptoms		Dog 90 mg/kg Oral 371 d Vomiting
Species NOAEL LOAEL Application Route Exposure time Target Organs	: : : : : : : : : : : : : : : : : : : :	Rat 30 mg/kg 120 mg/kg Oral 189 d Stomach
Species NOAEL LOAEL Application Route Exposure time Target Organs		Mouse 50 mg/kg 500 mg/kg Oral 14 Weeks Stomach
Species NOAEL LOAEL Application Route Exposure time Target Organs	:	Rat 50 mg/kg 200 mg/kg Oral 8 Weeks Stomach

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### **Components:**

# Raltegravir:

Ingestion

: Symptoms: Nausea, Diarrhoea, Headache, Fever, Rash, Skin irritation

### **SECTION 12. ECOLOGICAL INFORMATION**

### Ecotoxicity

#### Components:

### Raltegravir:

Toxicity to fish

: LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h



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			Method: OECD T	est Guideline 203
			LC50 (Cyprinodor mg/l Exposure time: 96 Method: OECD T	
	city to daphnia and other tic invertebrates	:	EC50 (Daphnia m Exposure time: 4ł Method: OECD T	
Toxic plants	city to algae/aquatic s	:	EC50 (Pseudokire Exposure time: 96 Method: OECD T	
			NOEC (Pseudoki mg/l Exposure time: 96 Method: OECD T	
Toxic icity)	city to fish (Chronic tox-	•	NOEC (Pimephal Exposure time: 33 Method: OECD T	
	city to daphnia and other tic invertebrates (Chron- cicity)	:	NOEC (Daphnia i Exposure time: 2 Method: OECD T	
Toxic	sity to microorganisms	:	EC50: > 1,000 mg Exposure time: 3 Test Type: Respin Method: OECD T	h ration inhibition
			NOEC: 1,000 mg, Exposure time: 3 Test Type: Respin Method: OECD T	h
Pers	istence and degradabil	ity		
<u>Com</u>	ponents:			
	e <b>gravir:</b> egradability	:	Result: rapidly de Biodegradation: Exposure time: 9 Method: OECD T	50 %
Stabi	ility in water	:	Hydrolysis: < 10 9 Method: OECD T	



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Bioa	ccumulative potentia	ıl		
<u>Com</u>	ponents:			
Partit	egravir: tion coefficient: n- nol/water	: log Pow: -0.32	28	
	i <b>lity in soil</b> ata available			
	<b>r adverse effects</b> ata available			
SECTION	13. DISPOSAL CON	SIDERATIONS		
Disp	osal methods			
\A/	. (	Design	end and the second	

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

### **SECTION 14. TRANSPORT INFORMATION**

### International Regulations

#### 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
IATA-DGR UN/ID No. Proper shipping name Class Subsidiary risk Packing group Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft)		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
IMDG-Code UN number Proper shipping name Class Subsidiary risk	: : : : : : : : : : : : : : : : : : : :	Not applicable Not applicable Not applicable Not applicable



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Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

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

Not applicable for product as supplied.

## National Regulations

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

## Special precautions for user

Not applicable

# SECTION 15. REGULATORY INFORMATION

Safety, health and environm ture	nen	tal regulations/legislatio	on s	specific for the substance or mix-
Therapeutic Goods (Poisons Standard) Instrument	:	Schedule 6 (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)		
Prohibition/Licensing Require	mei	nts :	a re g th	There is no applicable prohibition, uthorisation and restricted use equirements, including for carcino- ens referred to in Schedule 10 of the model WHS Act and Regula- ons.
The components of this product are reported in the following inventories:				
AICS	:	not determined		
DSL	:	not determined		
IECSC	:	not determined		

# SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information		
Revision Date Sources of key data used to compile the Safety Data Sheet	-	06.04.2024 Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/



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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 Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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