

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.2	28.09.2024	9371336-00008	Date of first issue: 27.08.2021

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier Trade name	:	Raltegravir Pediatric Granules Formulation
1.2 Relevant identified uses of	of the s	ubstance or mixture and uses advised against
Use of the Sub- stance/Mixture		Pharmaceutical
Recommended restrictions on use	6 :	Not applicable
1.3 Details of the supplier of	the safe	ety data sheet
Company	:	MSD 120 Moorgate EC2M 6UR London, United Kingdom
Telephone	:	+44 (0) 2081548000
E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

### **1.4 Emergency telephone number**

1-908-423-6000

## **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

# Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Serious eye damage, Category 1 Reproductive toxicity, Category 2 Specific target organ toxicity - single exposure, Category 3 H318: Causes serious eye damage. H361d: Suspected of damaging the unborn child. H335: May cause respiratory irritation.

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms



UK REACH Regulations SI 2019/758



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Signa	al word	:	Danger	
Haza	ard statements	:	H318 H335 H361d	Causes serious eye damage. May cause respiratory irritation. Suspected of damaging the unborn child.
Prec	autionary statements	:	Prevention	:
			P201 P261 P280	Obtain special instructions before use. Avoid breathing dust. Wear protective gloves/ protective clothing/ eye protection/ face protection.
			Response:	
			P304 + P34	40 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
			P305 + P35	51 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rins- ing. Immediately call a POISON CENTER/ doctor.
			P308 + P31	I3 IF exposed or concerned: Get medical advice/ attention.

Hazardous components which must be listed on the label: Raltegravir

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Raltegravir	871038-72-1	Eye Dam. 1; H318 Repr. 2; H361d STOT SE 3; H335	>= 20 - < 30
Ammonium hydroxide	1336-21-6 215-647-6 007-001-01-2	Acute Tox. 4; H302 Skin Corr. 1B; H314 Eye Dam. 1; H318 Aquatic Acute 1; H400	>= 0.1 - < 0.25

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			Aquatic Chronic 2; H411 M-Factor (Acute aquatic toxicity): 1 specific concentra- tion limit STOT SE 3; H335 >= 5 %
Subst	ances with a workpla	ce exposure limit :	
Cellul	ose	9004-34-6 232-674-9	>= 20 - < 3

For explanation of abbreviations see section 16.

## **SECTION 4: First aid measures**

### 4.1 Description of 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.		
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).		
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		In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.		
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.		
4.2 Most important symptoms and effects, both acute and delayed				

Risks : Causes serious eye damage. May cause respiratory irritation.



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			Suspected of da	maging the unborn child.
			Contact with dus the skin.	t can cause mechanical irritation or drying of
4.3 Indica	tion of any immediate	mec	lical attention an	d special treatment needed
Treat	ment	:	Treat symptomation	tically and supportively.
SECTION	N 5: Firefighting mea	sure	25	
5.1 Exting	guishing media			
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide ( Dry chemical	
Unsu media	itable extinguishing a	:	None known.	
5.2 Specia	al hazards arising from	n the	substance or m	ixture
Spec fightir	ific hazards during fire- ng	:	concentrations, a potential dust ex	dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a plosion hazard. bustion products may be a hazard to health.
Haza ucts	rdous combustion prod-	:	Carbon oxides Nitrogen oxides Fluorine compou Metal oxides	
5.3 Advic	e for firefighters			
	ial protective equipment efighters	:		e, wear self-contained breathing apparatus. otective equipment.
Spec ods	ific extinguishing meth-	:	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. aged containers from fire area if it is safe to do

## 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment.
		Follow safe handling advice (see section 7) and personal pro-
		tective equipment recommendations (see section 8).

## **SAFETY DATA SHEET** According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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	nmental precautions nmental precautions	Retain and dispo If spillage enters	the environment. eakage or spillage if safe to do so. use of contaminated wash water. rivers or watercourses, inform the Environ- nergency telephone number 0800 807060).
6.3 Method	s and material for co	ntainment and clean	ing up
Method	ds for cleaning up	over the area to Add excess liquid Soak up with ine Avoid dispersal of with compressed Dust deposits sh es, as these may leased into the a Clean up remain bent. Local or national posal of this mate employed in the mine which regul Sections 13 and	th absorbents and place a damp covering minimise entry of the material into the air. d to allow the material to enter into solution. rt absorbent material. of dust in the air (i.e., clearing dust surfaces l air). ould not be allowed to accumulate on surfac- v form an explosive mixture if they are re- tmosphere in sufficient concentration. ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- lations are applicable. 15 of this SDS provide information regarding ational requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## **SECTION 7: Handling and storage**

## 7.1 Precautions for safe handling

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	: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	<ul> <li>Avoid breathing dust. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment 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 respira- tory irritants or sensitisers. Minimize dust generation and accumulation.</li> </ul>



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Hygiene measures :		<ul> <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 environment.</li> <li>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.</li> </ul>			
7.2 Condit	ions for safe storage,	inc	luding any incom	patibilities	
Requirements for storage areas and containers		:	tightly closed. Ke	labelled containers. Store locked up. Keep ep in a cool, well-ventilated place. Store in the particular national regulations.	
Advice	on common storage	:	Do not store with Strong oxidizing a	the following product types: agents	
-	<b>c end use(s)</b> ic use(s)	:	No data available		

## **SECTION 8: Exposure controls/personal protection**

## 8.1 Control parameters

Occupational Exposure Limits	
dust of any kind	10 mg/m3 Value type (Form of exposure): TWA (Inhalable) Basis: GB EH40

4 mg/m3 Value type (Form of exposure): TWA (Respirable fraction) Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Raltegravir	871038-72- 1	TWA	1000 µg/m3 (OEB 1)	Internal
Cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m3	GB EH40
		TWA (Respirable dust)	4 mg/m3	GB EH40
		STEL (inhalable dust)	20 mg/m3	GB EH40

### Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Ammonium hydroxide	Fresh water	0.001 mg/l
	Freshwater - intermittent	0.008 mg/l
	Marine water	0.001 mg/l

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		Soil	0.022 mg/kg dry weight (d.w.)

### 8.2 Exposure controls

### **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 designed 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

Eye/face protection	:	Wear the following personal protective equipment: Chemical resistant goggles must be worn. If splashes are likely to occur, wear: Face-shield Equipment should conform to BS EN 166
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.
Skin and body protection	:	Select appropriate protective clothing based on chemical re- sistance data and an assessment of the local exposure poten- tial. Skin contact must be avoided by using impervious protective
Respiratory protection	:	clothing (gloves, aprons, boots, etc). If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to BS EN 143
Filter type	:	Particulates type (P)

## **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	::	powder off-white odourless No data available
рН	:	No data available
Melting point/freezing point	:	No data available

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	range	oiling point and boiling	:	No data available	
	Flash p	point	:	No data available	2
	Evapor	ation rate	:	No data available	9
	Flammability (solid, gas)		:	May form explosi dling or other me	ive dust-air mixture during processing, han- eans.
		explosion limit / Upper bility limit	:	No data available	9
		explosion limit / Lower bility limit	:	No data available	9
	Vapour	pressure	:	No data available	9
	Relativ	e vapour density	:	No data available	9
	Relativ	e density	:	No data available	9
	Partitio octanol	er solubility n coefficient: n-	:	No data available No data available No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	No data available	9
	Explosi	ve properties	:	Not explosive	
	Oxidizing properties		:	The substance o	r mixture is not classified as oxidizing.
9.2	Other ir	formation			
	Flamm	ability (liquids)	:	No data available	9
	Molecu	lar weight	:	No data available	e
	Particle	e size	:	No data available	e

## **SECTION 10: Stability and reactivity**

## 10.1 Reactivity

Not classified as a reactivity hazard.



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		<b>cal stability</b> under normal conditior	ns.			
10.3	Possib	oility of hazardous re	acti	ons		
<b>10.3 Possibility of hazardous reactions</b> Hazardous reactions       : May form explosive dust-air mixture during processi dling or other means.         Can react with strong oxidizing agents.						
10.4	Condit	ions to avoid				
	Conditi	ons to avoid	:	Heat, flames and Avoid dust forma		
10.5	Incom	patible materials				
		lls to avoid	:	Oxidizing agents		
10.6	Hazaro	lous decomposition	nro	ducts		
		ardous decomposition	-			
		11: Toxicological ir				
0L0			1101	mation		
11.1	Inform	ation on toxicologica	al ef	fects		
	Informa exposu	ation on likely routes of re	f :	Inhalation Skin contact Ingestion Eye contact		
		<b>toxicity</b> ssified based on availa	able	information.		
	Compo	onents:				
	Ralteg	ravir:				
	Acute c	oral toxicity	:	LD50 (Mouse, ma	ale and female): > 2,000 mg/kg	
	Ammo	nium hydroxide:				
		oral toxicity	:	LD50 (Rat): 350 r	ng/kg	
	Acute i	nhalation toxicity	:	Assessment: Cor	rosive to the respiratory tract.	
	Cellulo	se:				
		oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg	
	Acute i	nhalation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 Test atmosphere:	h	
	Acute c	lermal toxicity	:	LD50 (Rabbit): >	2,000 mg/kg	

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-	corrosion/irritation	lable	information	
_	lassified based on ava	allable	mormation.	
-	<u>oonents:</u>			
	gravir:		Dabbit	
Speci Resul		:	Rabbit No skin irritation	
Amm	onium hydroxide:			
Speci Resul		:	Rabbit	minutes to 1 hour of expensive
Rema		:		minutes to 1 hour of exposure al or regional regulation.
	<b>us eye damage/eye</b> i es serious eye damag		on	
<u>Com</u>	oonents:			
Ralte	gravir:			
Speci	es	:	Bovine cornea	
Resul	lt	:	Severe irritation	
Amm	onium hydroxide:			
Resu		:	Irreversible effec	•
Rema	arks	:	Based on skin co	prrosivity.
Resp	iratory or skin sensi	tisatio	n	
•••••	<b>sensitisation</b> lassified based on ava	ailable	information.	
Resp	iratory sensitisation			
Not cl	assified based on ava	ailable	information.	
<u>Com</u>	oonents:			
Ralte	gravir:			
Test T		:	Local lymph node	e assay (LLNA)
Speci Resul		:	Mouse negative	
	cell mutagenicity		information.	
	assified based on ava	aiiadie	iniormation.	
Com	<u>ponents:</u>			

## Raltegravir:

Genotoxicity in vitro

: Test Type: reverse mutation assay Result: negative



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			kaline elution assay rat hepatocytes ive
			nromosomal aberration D Test Guideline 473 ive
Geno	toxicity in vivo	: Test Type: In Species: Mou Result: negat	
			nromosomal aberration D Test Guideline 475 ive
Amm	onium hydroxide:		
	toxicity in vitro	: Test Type: Ba Result: negat	acterial reverse mutation assay (AMES) ive
Cellu	lose:		
	toxicity in vitro	: Test Type: Ba Result: negat	acterial reverse mutation assay (AMES)
		Test Type: In Result: negat	vitro mammalian cell gene mutation test ive
Geno	toxicity in vivo	cytogenetic a Species: Mou	se oute: Ingestion
	i <b>nogenicity</b> lassified based on ava	ilable information.	
Com	ponents:		
Ralte	gravir:		
Spec	ies	: Mouse, male	and female
Expo Resu	sure time It	: 104 weeks : negative	
Cellu	lose:		
Spec		: Rat	
	cation Route sure time	: Ingestion : 72 weeks	
Resu		: negative	

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-	oductive toxicity ected of damaging the	unbo	rn child.	
<u>Com</u>	ponents:			
Ralte	egravir:			
Effec	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
Repr sessi	oductive toxicity - As- ment	:	Some evidence c animal experimer	f adverse effects on development, based on nts.
Cellu	llose:			
Effec	ts on fertility	:	Test Type: One-g Species: Rat Application Route Result: negative	eneration reproduction toxicity study
Effec ment	ts on foetal develop-	:	Test Type: Fertilit Species: Rat Application Route Result: negative	y/early embryonic development
	<b>T - single exposure</b> cause respiratory irritati	on.		
Com	ponents:			
Expo Targe	e <b>gravir:</b> Isure routes et Organs ssment	::	Inhalation Respiratory Tract May cause respir	

## STOT - repeated exposure

Not classified based on available information.

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Repe	ated dose toxicity		
<u>Comp</u>	oonents:		
Ralte	gravir:		
Speci	es	: Dog	
NOAE		: 90 mg/kg	
Applic	cation Route	: Oral	
	sure time	: 371 d	
Symp	toms	: Vomiting	
Speci		: Rat	
NOAE		: 30 mg/kg	
LOAE	EL	: 120 mg/kg	
	cation Route	: Oral	
	sure time	: 189 d	
Targe	et Organs	: Stomach	
Speci		: Mouse	
NOAE		: 50 mg/kg	
LOAE		: 500 mg/kg	
	cation Route	: Oral	
	sure time	: 14 Weeks	
Targe	et Organs	: Stomach	
Speci		: Rat	
NOAE		: 50 mg/kg	
LOAE		: 200 mg/kg	
	cation Route	: Oral	
	sure time	: 8 Weeks	
Targe	et Organs	: Stomach	
Cellu	lose:		
Speci		: Rat	
NOAE		: >= 9,000 mg/l	(Q
	cation Route	: Ingestion	ъ.
	sure time	: 90 Days	
-	ation toxicity		
	assified based on ava		
Expe	rience with human e	exposure	
<u>Comp</u>	oonents:		
Ralte	gravir:		
Inges	tion	: Symptoms: N irritation	ausea, Diarrhoea, Headache, Fever, Rash, S

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## **SECTION 12: Ecological information**

12.1 Toxicity		
Components:		
Raltegravir:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
		LC50 (Cyprinodon variegatus (sheepshead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 66 mg/l Exposure time: 96 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 3.8 mg/l Exposure time: 96 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC50 : > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
		NOEC : 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic tox- icity)	:	NOEC: 9.3 mg/l Exposure time: 33 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 9.5 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
Ammonium hydroxide:		
Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 0.89 mg/l Exposure time: 96 h



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			Test substance:	Neutralised product
	y to daphnia and other c invertebrates	:	EC50 (Daphnia n Exposure time: 4	nagna (Water flea)): 101 mg/l 8 h
M-Fact icity)	tor (Acute aquatic tox-	:	1	
Toxicit icity)	y to fish (Chronic tox-	:		
	y to daphnia and other c invertebrates (Chron- ity)	:		
<b>Cellui</b> Toxicit	<b>ose:</b> y to fish	:	Exposure time: 4	tipes (Japanese medaka)): > 100 mg/l 8 h on data from similar materials
12.2 Persis	tence and degradabil	ity		
Comp	onents:			
Ralteg Biodeg	<b>ravir:</b> Jradability	:	Result: rapidly de Biodegradation: Exposure time: 9 Method: OECD T	50 %
Stabilit	y in water	:	Hydrolysis: < 10 Method: OECD T	%(5 d) Test Guideline 111
<b>Cellulo</b> Biodeg	<b>ose:</b> Iradability	:	Result: Readily b	iodegradable.
12.3 Bioac	cumulative potential			
Comp	onents:			
<b>Ralteg</b> Partitic octano	n coefficient: n-	:	log Pow: -0.328	
<b>12.4 Mobili</b> No dat	<b>ty in soil</b> a available			

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#### 12.5 Results of PBT and vPvB assessment

Product	

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## 12.6 Other adverse effects

Product:

Flouuci.		
Endocrine disrupting poten-	:	This substance/mixture does not contain components consid-
tial		ered to have endocrine disrupting properties for environment
		according to UK REACH Article 57(f).

## **SECTION 13: Disposal considerations**

### 13.1 Waste treatment methods

Product	<ul> <li>Dispose of in accordance with local regulations.</li> <li>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.</li> <li>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.</li> <li>Do not dispose of waste into sewer.</li> </ul>
Contaminated packaging	<ul> <li>Empty containers should be taken to an approved waste han- dling site for recycling or disposal.</li> <li>If not otherwise specified: Dispose of as unused product.</li> </ul>

## **SECTION 14: Transport information**

## 14.1 UN number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good
ADN ADR	:	Not regulated as a dangerous good Not regulated as a dangerous good
	::	5 5 5
ADR	: : :	Not regulated as a dangerous good
ADR RID		Not regulated as a dangerous good Not regulated as a dangerous good

14.3 Transport hazard class(es)



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A	ADN .	: Not regulated as a dangerous good	
A	ADR	: Not regulated as a dangerous good	
F	RID	: Not regulated as a dangerous good	
I	MDG	: Not regulated as a dangerous good	
L	ΑΤΑ	: Not regulated as a dangerous good	
14.4 F	Packing group		
A	ADN .	: Not regulated as a dangerous good	
A	ADR	: Not regulated as a dangerous good	
F	RID	: Not regulated as a dangerous good	
I	MDG	: Not regulated as a dangerous good	
L	ATA (Cargo)	: Not regulated as a dangerous good	
L	ATA (Passenger)	: Not regulated as a dangerous good	
14.5 E	Environmental hazards		

Not regulated as a dangerous good

#### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks

# : Not applicable for product as supplied.

## **SECTION 15: Regulatory information**

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Not applicable
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Brit-	:	Not applicable
ain)		
Regulation (EC) on substances that deplete the ozone	:	Not applicable
layer UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable
GB Export and import of hazardous chemicals - Prior	:	Not applicable
Informed Consent (PIC) Regulation		
Control of Major Accident Hazards Regulations 2015 (CC	IVIA	NH)
Not applicable		

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements



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relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

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

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

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other inform	nation	
Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
Full text of H-Statement	S	
H302	:	Harmful if swallowed.
H314	:	Causes severe skin burns and eye damage.
H318	:	Causes serious eye damage.
H335	:	May cause respiratory irritation.
H361d	:	Suspected of damaging the unborn child.
H400	:	Very toxic to aquatic life.
H411	:	Toxic to aquatic life with long lasting effects.
Full text of other abbrev	viations	
Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Dam.	:	Serious eye damage
Repr.	:	Reproductive toxicity
Skin Corr.	:	Skin corrosion
STOT SE	:	Specific target organ toxicity - single exposure
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	:	Short-term exposure limit (15-minute reference period)
Waterways; ADR - Agre	ement o	cerning the International Carriage of Dangerous Goods by Inland concerning the International Carriage of Dangerous Goods by of Industrial Chemicals; ASTM - American Society for the Test-

Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Miand Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 - Interna-



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tional 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

### Further information

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

Classification of the mixtur	Classification procedure:	
Eye Dam. 1	H318	Calculation method
Repr. 2	H361d	Calculation method
STOT SE 3	H335	Calculation method

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.

GB / EN