

according to the OSHA Hazard Communication Standard

# **Aprepitant Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 09/26/2023
10.2	01/24/2024	20618-00026	Date of first issue: 10/09/2014

### **SECTION 1. IDENTIFICATION**

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

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

### **SECTION 2. HAZARDS IDENTIFICATION**

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200) Combustible dust				
Specific target organ toxicity : - repeated exposure (Oral)	Category 2 (Prostate, Testis)			
GHS label elements Hazard pictograms :				
Signal Word :	Warning			
Hazard Statements :	If small particles are generated during further processing, han- dling or by other means, may form combustible dust concentra- tions in air. H373 May cause damage to organs (Prostate, Testis) through prolonged or repeated exposure if swallowed.			
Precautionary Statements :	<b>Prevention:</b> P260 Do not breathe dust.			
	<b>Response:</b> P314 Get medical attention if you feel unwell.			
	<b>Disposal:</b> P501 Dispose of contents and container to an approved waste disposal plant.			



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#### Other hazards

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin.

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

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Aprepitant	170729-80-3	37.1
Sucrose	57-50-1	37.1
Cellulose	9004-34-6	17

#### **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 medica advice.	
If inhaled	:	If inhaled, remove to fresh air. Get medical attention if symptoms occur.	
In case of skin contact	:	Wash with water and soap. Get medical attention if symptoms occur.	
In case of eye contact	:	If in eyes, rinse well with water. Get medical attention if irritation develops and persists.	
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.	
Most important symptoms and effects, both acute and	:	May cause damage to organs through prolonged or repeated exposure if swallowed.	
delayed		Contact with dust can cause mechanical irritation or drying of the skin.	
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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.	

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.



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	Hazardo ucts	ous combustion prod-	:	Carbon oxides Fluorine compoun Nitrogen oxides (N		
	Specific extinguishing meth- ods		:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so.		
	Special for fire-f	protective equipment fighters	:	Evacuate area. In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.		
SEC	TION 6.	ACCIDENTAL RELE	ASE	E MEASURES		
	tive equ	al precautions, protec- lipment and emer- procedures	:		ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).	
	Environ	mental precautions	:	<ul> <li>Avoid release to the environment.</li> <li>Prevent further leakage or spillage if safe to do so.</li> <li>Retain and dispose of contaminated wash water.</li> <li>Local authorities should be advised if significant spilla cannot be contained.</li> </ul>		
	Methods and materials for : containment and cleaning up		:	Sweep up or vacuum up spillage and collect in suitable container for disposal. 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 ar released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and iter employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regardi certain local or national requirements.		

## SECTION 7. HANDLING AND STORAGE

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation Advice on safe handling	:	Use only with adequate ventilation. Do not breathe dust. Do not swallow. Avoid contact with 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 assessment



ACGIH

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		Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharge Take care to prevent spills, waste and minimize releas environment.			
Conditions for safe storage		: Keep in properly labeled containers. Store in accordance with the particular national regulat			
Materials to avoid		: Do not store wi	Do not store with the following product types: Strong oxidizing agents		

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

inert or nuisance dust	50 Million particles per cubic foot Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3						
		15 mg/m³ Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3					
	5 mg/m³ Value type (Fo Basis: OSHA 2		: TWA (respirable fra	iction)			
	Value type (Fo	15 Million particles per cubic foot Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3					
Dust, nuisance dust and par- ticulates	10 mg/m³ Value type (Form of exposure): PEL (Total dust) Basis: CAL PEL						
	5 mg/m³ Value type (Fo Basis: CAL PE		: PEL (respirable dus	st fraction)			
Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis			
Aprepitant	170729-80-3	TWA	0.2 mg/m3 (OEB 2)	Internal			
Sucrose	57-50-1	TWA	10 mg/m <sup>3</sup>	ACGIH			
		TWA (Res- pirable)	5 mg/m <sup>3</sup>	NIOSH REL			
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL			
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1			
		TWÁ (respir- able fraction)	5 mg/m³	OSHA Z-1			
<b>A</b> II I	0001016						

TWA

10 mg/m<sup>3</sup>

9004-34-6

Cellulose



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				TWA (Res- pirable)	5 mg/m³	NIOSH REI
				TWA (total)	10 mg/m <sup>3</sup>	NIOSH RE
				TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
				TWA (respir- able fraction)	5 mg/m³	OSHA Z-1
Engir	neering measures	:	compound. All engineerin design and o	ng controls shoul	rols to minimize of d be implemented dance with GMP d the environmen	d by facility principles to
Perso	onal protective equip	ment				
	iratory protection	:	maintain vap concentration unknown, ap Follow OSHA use NIOSHA by air purifyir hazardous cl supplied resp release, expo	or exposures bell ns are above reco propriate respirat A respirator regul MSHA approved in ng respirators aga nemical is limited pirator if there is a posure levels are us where air purify	ntilation is recommended ow recommended ommended limits tory protection sh ations (29 CFR 1 respirators. Prote ainst exposure to . Use a positive p any potential for u unknown, or any o ing respirators ma	d limits. Where or are ould be worn. 910.134) and ection provided any pressure air uncontrolled other
	protection aterial	:	Chemical-res	sistant gloves		
Еуе р	protection	:	If the work er mists or aero Wear a faces	nvironment or act sols, wear the ap shield or other ful	shields or goggle ivity involves dus opropriate goggle I face protection i he face with dust	sty conditions, s. if there is a
	and body protection ne measures	:	Work uniform If exposure to eye flushing working place When using Wash contar The effective engineering appropriate of industrial hyg	systems and safe e. do not eat, drink ninated clothing b operation of a fa controls, proper p degowning and do	ly during typical u ety showers close or smoke. pefore re-use. acility should inclu- personal protectiv econtamination p medical surveilla	e to the ude review of re equipment, procedures,

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	colored



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# **Aprepitant Formulation**

Odor:odorlessOdor Threshold:No data availablepH:No data availableMelting point/freezing point:No data availableInitial boiling point and boiling:No data availableFlash point:No data available	
pH:No data availableMelting point/freezing point:No data availableInitial boiling point and boiling range:No data availableFlash point:No data available	
Melting point/freezing point : No data available Initial boiling point and boiling : No data available range Flash point : No data available	
Initial boiling point and boiling : No data available range Flash point : No data available	
range Flash point : No data available	
Evaporation rate : No data available	
Flammability (solid, gas) : May form explosive dust-air mixture during processing handling or other means.	],
Flammability (liquids) : No data available	
Upper explosion limit / Upper : No data available flammability limit	
Lower explosion limit / Lower : No data available flammability limit	
Vapor pressure : No data available	
Relative vapor density : No data available	
Relative density : No data available	
Density : No data available	
Solubility(ies) Water solubility : No data available	
Partition coefficient: n- : No data available octanol/water	
Autoignition temperature : No data available	
Decomposition temperature : No data available	
Viscosity Viscosity, kinematic : No data available	
Explosive properties : Not explosive	
Oxidizing properties : The substance or mixture is not classified as oxidizing	J.
Molecular weight : No data available	
Minimum ignition energy : < 3 mJ	



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Particle size		:	No data availabl	e
SECTION	N 10. STABILITY AND R	EAC	ΤΙVΙΤΥ	
Che Poss	Reactivity Chemical stability Possibility of hazardous reac- tions		Stable under nor May form explos handling or othe	ive dust-air mixture during processing,
Inco Haza	Conditions to avoid Incompatible materials Hazardous decomposition products		Heat, flames and Avoid dust forma Oxidizing agents No hazardous de	ation.

### SECTION 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

### Acute toxicity

Not classified based on available information.

#### **Components:**

### Aprepitant:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg
		LD50 (Mouse): > 2,000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): 800 - 2,000 mg/kg Application Route: Intraperitoneal
		LD50 (Mouse): > 2,000 mg/kg Application Route: Intraperitoneal
Sucrose:	:	LD50 (Rat): 29,700 mg/kg
Acute oral toxicity	•	LD30 (Rat). 29,700 mg/kg
Cellulose:		
Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist



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Acute	e dermal toxicity	: LD50 (Rabbi	it): > 2,000 mg/kg
-	corrosion/irritation	ailable information.	
<u>Com</u>	ponents:		
Apre	epitant:		
Spec Meth Resu	od	: Rabbit : Draize Test : No skin irrita	tion
	ous eye damage/eye classified based on av		
<u>Com</u>	ponents:		
Apre	epitant:		
Spec Resu		: Rabbit : No eye irritat	tion
Meth	od	: Draize Test	
Resp	piratory or skin sens	itization	
•	sensitization	ailable information.	
-	<b>biratory sensitization</b> classified based on av		
<u>Com</u>	ponents:		
Apre	pitant:		
Rem	arks	: No data avai	lable
	n cell mutagenicity classified based on av	ailable information.	
<u>Com</u>	ponents:		
Apre	epitant:		
Geno	otoxicity in vitro	: Test Type: A Result: nega	
			Chromosomal aberration Chinese hamster ovary cells tive
			Ikaline elution assay rat hepatocytes tive
		Test Type: ir	n vitro test



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			system: human lymphoblastoid cells lt: negative
Geno	toxicity in vivo	Spec Appli	Type: Micronucleus test ies: Mouse cation Route: Oral It: negative
Sucr	ose:		
	toxicity in vitro		Type: In vitro mammalian cell gene mutation test It: negative
Cellu	lose:		
Geno	toxicity in vitro		Type: Bacterial reverse mutation assay (AMES) It: negative
			Type: In vitro mammalian cell gene mutation test It: negative
Geno	toxicity in vivo	cytog Spec Appli	Type: Mammalian erythrocyte micronucleus test (in vivo enetic assay) ies: Mouse cation Route: Ingestion It: negative
Carci	inogenicity		
Not c	lassified based on ava	ailable inform	ation.
Com	ponents:		
Apre			
	pitant:		
Speci	ies		se, male
Speci Applie	ies cation Route	: Oral	
Speci Applie	ies cation Route sure time	: Oral : 106 v	se, male veeks 00 mg/kg body weight
Speci Applio Expos Dose Resu	ies cation Route sure time It	: Oral : 106 v : >=10 : positi	veeks 00 mg/kg body weight ve
Speci Applio Expos Dose	ies cation Route sure time It	: Oral : 106 v : >=10 : positi	veeks 00 mg/kg body weight
Speci Applio Expos Dose Resu	ies cation Route sure time It arks	: Oral : 106 v : >=10 : positi : The r	veeks 00 mg/kg body weight ve
Speci Applid Expose Dose Resu Rema Speci Applid	ies cation Route sure time It arks ies cation Route	: Oral : 106 v : >=10 : positi : The r : Mous : Oral	veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans. se, female
Speci Applic Expose Dose Resu Rema Speci Applic Expos	ies cation Route sure time It arks ies cation Route sure time	: Oral : 106 v : >=10 : positi : The r : Mous : Oral : 106 v	veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans. se, female veeks
Speci Applic Expose Resu Resu Rema Speci Applic Expose	ies cation Route sure time It arks ies cation Route sure time	: Oral : 106 v : >=10 : positi : The r : Mous : Oral : 106 v : >= 50	veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans. se, female veeks 00 mg/kg body weight
Speci Applic Expose Dose Resu Rema Speci Applic Expos	ies cation Route sure time It arks ies cation Route sure time It	: Oral : 106 v : >=10 : positi : The r : Mous : Oral : 106 v : >= 50 : positi	veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans. se, female veeks 00 mg/kg body weight
Speci Applid Expose Resu Rema Speci Applid Expose Resu Rema	ies cation Route sure time It arks ies cation Route sure time It arks	: Oral : 106 v : >=10 : positi : The r : Mous : Oral : 106 v : >= 50 : positi : The r	veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans. se, female veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans.
Speci Applid Expose Resu Rema Speci Applid Expose Resu Rema	ies cation Route sure time It arks ies cation Route sure time It arks	: Oral : 106 v : >=10 : positi : The r : Mous : Oral : 106 v : >= 50 : positi	veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans. se, female veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans.
Speci Applid Expose Resu Rema Speci Applid Expose Resu Rema Speci Applid Expose	ies cation Route sure time It arks ies cation Route sure time It arks ies cation Route sure time	: Oral : 106 v : >=10 : positi : The r : Mous : Oral : 106 v : >= 50 : positi : The r : Mous : Oral : Oral : Oral : oral : 106 v	veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans. se, female veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans. se
Speci Applie Expose Resu Rema Speci Applie Expose Resu Rema Speci Applie Expose Dose	ies cation Route sure time It arks ies cation Route sure time It arks ies cation Route sure time	: Oral : 106 v : >=10 : positi : The r : Mous : Oral : 106 v : >= 50 : positi : The r : Mous : Oral : Oral : Oral : 105 v : 2000	veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans. se, female veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans. se veeks mg/kg body weight
Speci Applid Expose Resu Rema Speci Applid Expose Resu Rema Speci Applid Expose	ies cation Route sure time It arks ies cation Route sure time It arks ies cation Route sure time It	: Oral : 106 v : >=10 : positi : The r : Mous : Oral : 106 v : >= 50 : positi : The r : Mous : Oral : Oral : Oral : 2000 : positi	veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans. se, female veeks 00 mg/kg body weight ve nechanism or mode of action is not relevant in humans. se veeks mg/kg body weight



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	<b>Cellulo</b> Species Applica Exposu Result	s tion Ro	ute	: :	Rat Ingestion 72 weeks negative				
l	IARC			No ingredient of this product present at levels greater than or equal to 0.1% identified as probable, possible or confirmed human carcinogen by IARC.					
	OSHA		No componer on OSHA's lis	nt at levels greater than or equal to 0.1% is ens.					
	NTP					at levels greater than or equal to 0.1% is carcinogen by NTP.			
	-		<b>toxicity</b> based on availa	ble	information.				
	Compo	onents:							
	<b>Aprepi</b> t Effects		lity	:	Test Type: Fertilit Species: Rat, mal Fertility: NOAEL: Result: No effects	e and female 2,000 mg/kg body weight			
	Effects	on feta	l development	:	Result: No effects Test Type: Develo Species: Rabbit Application Route Developmental To	: Oral oxicity: NOAEL: 2,000 mg/kg body weight on fetal development. opment			
	<b>Cellulo</b> Effects		lity	:	Test Type: One-g Species: Rat Application Route Result: negative	eneration reproduction toxicity study : Ingestion			
	Effects	on feta	l development	:	Test Type: Fertilit Species: Rat Application Route Result: negative	y/early embryonic development : Ingestion			

## STOT-single exposure

Not classified based on available information.

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		ns (Prostate, Testis)	through prolonged or repeated exposure if swal-
<u>Com</u>	ponents:		
Apre	pitant:		
	et Organs ssment	<ul> <li>Prostate, Tes</li> <li>May cause da exposure.</li> </ul>	tis amage to organs through prolonged or repeated
Repe	eated dose toxicity		
<u>Com</u>	ponents:		
Apre	pitant:		
Expo		: Dog : >= 50 mg/kg : Oral : 39 Weeks : Prostate, Tes	tis
Expo		: Rat : 125 mg/kg : Oral : 27 Weeks : Liver, Thyroid	
	EL cation Route sure time	: Monkey : 0.240 mg/kg : Intravenous : 7 d : No significant	adverse effects were reported
Expo		: Rat, female : 125 mg/kg : Oral : 106 Weeks : Kidney	
Cellu	Ilose:		
		: Rat : >= 9,000 mg/ : Ingestion : 90 Days	kg
Aspi	ration toxicity		

Not classified based on available information.





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Expe	rience with human exp	osu	ire						
<u>Comp</u>	oonents:								
Aprepitant: Ingestion			: Symptoms: Headache, Fatigue, hiccups, constipation, anorex- ia, liver function change, Rash, Nausea, Diarrhea, hypoten- sion						
CTION	12. ECOLOGICAL INFO	ORN	IATION						
Ecoto	oxicity								
<u>Comp</u>	oonents:								
	pitant:								
Toxici	ity to fish	:	Exposure time: 96 Method: OECD Te						
	ity to daphnia and other ic invertebrates	:	Exposure time: 48 Method: OECD Te						
Toxici plants	ty to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD To						
			0.184 mg/l Exposure time: 72 Method: OECD To						
Toxici icity)	ty to fish (Chronic tox-	:	NOEC (Pimephale Exposure time: 32 Method: OECD Te						
	ity to daphnia and other ic invertebrates (Chron- city)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te						
Toxici	ty to microorganisms	:	EC50: > 100 mg/l Exposure time: 3 Test Type: Respir Method: OECD To Remarks: No toxio	ation inhibition					

#### Cellulose:





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Toxic	Toxicity to fish		Exposure time: 4	ipes (Japanese medaka)): > 100 mg/l 3 h on data from similar materials
Persi	stence and degradabi	lity		
<u>Com</u>	ponents:			
	pitant:			
Biode	egradability	:	Result: not rapidl Biodegradation: Exposure time: 6 Method: OECD T	50 %
Cellu	lose:			
Biode	egradability	:	Result: Readily b	odegradable.
Bioa	ccumulative potential			
Com	ponents:			
Apre	pitant:			
Bioac	ccumulation	:	Bioconcentration	s macrochirus (Bluegill sunfish) factor (BCF): 50.1 est Guideline 305
	ion coefficient: n- ol/water	:	log Pow: 4.75	
Sucr	ose:			
	ion coefficient: n- Iol/water	:	Pow: < 1	
Mobi	lity in soil			
<u>Com</u>	ponents:			
Distri	<b>pitant:</b> bution among environ- al compartments	:	log Koc: 3.10	
	r adverse effects ata available			

## SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods		
Waste from residues	:	Dispose of in accordance with local regulations.
		Do not dispose of waste into sewer.
Contaminated packaging	:	
		handling site for recycling or disposal.
		If not otherwise specified: Dispose of as unused product.





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

### **International Regulations**

UNRTDG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Aprepitant)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes
IATA-DGR		
UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Aprepitant)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passen- ger aircraft)	:	956
Environmentally hazardous	:	yes
IMDG-Code		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Aprepitant)
Class		9
Packing group	:	
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes
	•	,

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

Not applicable for product as supplied.

## **Domestic regulation**

:	UN 3077
:	Environmentally hazardous substance, solid, n.o.s. (Aprepitant)
:	9
:	
:	CLASS 9
:	171
:	yes(Aprepitant)
:	Above applies only to containers over 119 gallons or 450 liters.
	Shipment by ground under DOT is non-regulated; however it
	: : : : : : : : : : : : : : : : : : : :



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may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

#### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### **SECTION 15. REGULATORY INFORMATION**

#### **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

#### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards	:	Combustible dust Specific target organ toxicity (single or repeated exposure)
SARA 313	:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### **US State Regulations**

Pennsylvania Right To Knov	V		
Sucrose Aprepitant Cellulose Hydroxypropyl cellu	lose	57-50-1 170729-80-3 9004-34-6 9004-64-2	
California Permissible Exposure Limits for Chemical Contaminants			
Sucrose Cellulose		57-50-1 9004-34-6	
The ingredients of this product are reported in the following inventories:			
AICS	: not determined		
DSL	: not determined		
IECSC	: not determined		

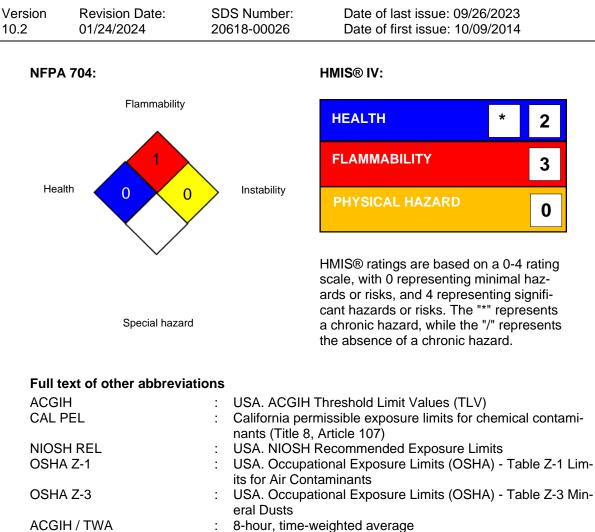
#### **SECTION 16. OTHER INFORMATION**

Further information



according to the OSHA Hazard Communication Standard

# **Aprepitant Formulation**



ACGIH / TWA	:	8-hour, time-weighted average
CAL PEL / PEL	:	Permissible exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour
		workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average

OSHA Z-1 / TWA:8-hour time weighted averageOSHA Z-3 / TWA:8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Pre-



according to the OSHA Hazard Communication Standard

# Aprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/26/2023
10.2	01/24/2024	20618-00026	Date of first issue: 10/09/2014

vention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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

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

Revision Date : 01/24/2024

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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