

Alvimopan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.2	28.09.2024	643699-00018	Date of first issue: 02.05.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name

: Alvimopan 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 of the chemical and restrictions on use

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards

Dust contact with the eyes can lead to mechanical irritation. 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)
Alvimopan	170098-38-1	>= 1 -< 5

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 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.



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	Most important symptoms and effects, both acute and delayed Protection of first-aiders Notes to physician		:	the skin. Dust contact with No special precau	can cause mechanical irritation or drying of the eyes can lead to mechanical irritation. tions are necessary for first aid responders. cally and supportively.
SEC	CTION 5	. FIRE-FIGHTING ME	ASL	IRES	
	Suitabl	e extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical	
	Unsuita media	able extinguishing	:	None known.	
	Specific fighting	c hazards during fire I	:	concentrations, ai potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. bustion products may be a hazard to health.
	Hazard ucts	lous combustion prod-	:	Carbon oxides	
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
		l protective equipment fighters	:	necessary.	ed breathing apparatus for firefighting if ective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : tive equipment and emer- gency procedures	Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions :	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for : containment and cleaning up	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 are



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		Local or nation disposal of thi employed in the determine white Sections 13 and	the atmosphere in sufficient concentration. The regulations may apply to releases and s material, as well as those materials and items the cleanup of releases. You will need to ch regulations are applicable. The 15 of this SDS provide information regarding r national requirements.
SECTION	7. HANDLING AND ST	ORAGE	
Tech	nnical measures	causing an ex Provide adequ	ty may accumulate and ignite suspended dust plosion. late precautions, such as electrical grounding or inert atmospheres.
	Il/Total ventilation ce on safe handling	 Use only with Do not breather Handle in according practice, base assessment Minimize dust Keep container Keep away from Take precaution 	adequate ventilation.
Hygi	ene measures	: If exposure to flushing system place. When using d	chemical is likely during typical use, provide eye ms and safety showers close to the working o not eat, drink or smoke. inated clothing before re-use.
Con	ditions for safe storage	: Keep in prope	rly labeled containers. dance with the particular national regulations.
Mate	erials to avoid		vith the following product types:

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Alvimopan	170098-38-1	TWA	10 µg/m³	Internal
		Wipe limit	100 µg/100 cm ²	Internal

Engineering measures : Ensure adequate ventilation, especially in confined areas. 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).



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P	Personal protective equipme	ent		
R	Respiratory protection Filter type Hand protection		exposure assessr	exhaust ventilation is not available or nent demonstrates exposures outside the idelines, use respiratory protection.
	Material	:	Chemical-resistar	nt gloves
	Remarks	:		repeated contact use protective gloves. re breaks and at the end of workday.
E	ye protection	:		g personal protective equipment:
S	kin and body protection	:		ashed after contact.
SECT	ION 9. PHYSICAL AND CHE	EMI		S
А	ppearance	:	powder	
C	Color	:	No data available	9
C	Ddor	:	No data available	9
С	Odor Threshold	:	No data available	9
р	Н	:	No data available	9
N	felting point/freezing point	:	No data available	9
	nitial boiling point and boiling ange	:	No data available	9
F	lash point	:	Not applicable	
E	vaporation rate	:	No data available	9
F	lammability (solid, gas)	:	May form explosi handling or other	ive dust-air mixture during processing, means.
F	lammability (liquids)	:	No data available	9
	Ipper explosion limit / Upper ammability limit	:	No data available	9
	ower explosion limit / Lower ammability limit	:	No data available	9
V	apor pressure	:	No data available	9
R	elative vapor density	:	No data available	9
D	Density	:	No data available	9



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	ıbility(ies) Vater solubility	:	No data available)
	ition coefficient: n- nol/water	:	No data available)
	bignition temperature	:	No data available	9
Dec	omposition temperature	:	No data available)
	osity /iscosity, dynamic	:	No data available	9
١	/iscosity, kinematic	:	No data available)
Exp	losive properties	:	Not explosive	
Oxic	lizing properties	:	The substance of	r mixture is not classified as oxidizing.
Mole	ecular weight	:	No data available	
	icle characteristics icle 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. 	Į,
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.	
Incompatible materials Hazardous decomposition products	Oxidizing agentsNo hazardous decomposition products are known.	

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely rout Inhalation Skin contact Ingestion Eye contact	f exposure					
Acute toxicity Not classified based on ava	Acute toxicity Not classified based on available information.					
<u>Product:</u> Acute oral toxicity	Acute toxicity estima Method: Calculation					
Acute dermal toxicity	Acute toxicity estima	te: > 5,000 mg/kg				



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			Method: Calculati	on method
Comp	oonents:			
Alvim	iopan:			
Acute	oral toxicity	:	LD50 (Rat): > 500) mg/kg
			LD50 (Mouse): >	4,000 mg/kg
Acute	dermal toxicity	:	LD50 (Mouse): >	2,000 mg/kg
	toxicity (other routes of histration)	:	LD50 (Rat): > 20 Application Route Remarks: No sigr	
	corrosion/irritation assified based on availa	ble	information.	
Comp	oonents:			
Alvim	iopan:			
Specie Result	t us eye damage/eye irri			
Specia Resul Serio Not cl	t us eye damage/eye irri assified based on availa		Mild skin irritation	
Specie Result Serio Not cl <u>Comp</u>	t us eye damage/eye irri assified based on availa ponents:		Mild skin irritation	
Specie Result Serio Not cl <u>Comp</u>	t us eye damage/eye irri assified based on availa ponents: nopan:		Mild skin irritation	
Specie Result Serio Not cl <u>Comp</u>	t us eye damage/eye irri assified based on availa ponents: nopan: es		Mild skin irritation	
Specie Result Serio Not cl <u>Comp</u> Alvim Specie Result	t us eye damage/eye irri assified based on availa ponents: nopan: es	ble :	Mild skin irritation ion information. Rabbit Mild eye irritation	
Specie Result Serio Not cl Comp Alvim Specie Result Result Skin s	t us eye damage/eye irri assified based on availa ponents: nopan: es t	ble : : atic	Mild skin irritation ion information. Rabbit Mild eye irritation	
Specie Result Serio Not cl Comp Alvim Specie Result Result Skin s Not cl Respi	t us eye damage/eye irri assified based on availa <u>ponents:</u> nopan: es t iratory or skin sensitiza sensitization	ble : : ble	Mild skin irritation ion information. Rabbit Mild eye irritation on information.	
Specie Result Serio Not cl Comp Alvim Specie Result Result Skin s Not cl Not cl	t us eye damage/eye irri assified based on availa <u>conents:</u> aopan: es t iratory or skin sensitiza sensitization assified based on availa iratory sensitization	ble : : ble	Mild skin irritation ion information. Rabbit Mild eye irritation on information.	
Specie Result Serio Not cl Comp Alvim Specie Result Result Skin s Not cl Respi Not cl Not cl Comp	t us eye damage/eye irri assified based on availa <u>conents:</u> aopan: es t iratory or skin sensitiza sensitization assified based on availa iratory sensitization assified based on availa	ble : : ble	Mild skin irritation ion information. Rabbit Mild eye irritation on information.	
Specie Result Serio Not cl Comp Alvim Specie Result Result Skin s Not cl Respi Not cl Comp Alvim Test T	t us eye damage/eye irri assified based on availa <u>conents:</u> nopan: es t iratory or skin sensitiza sensitization assified based on availa iratory sensitization assified based on availa conents: nopan: Type	ble : atic ble :	Mild skin irritation ion information. Rabbit Mild eye irritation on information. information.	
Specie Result Serio Not cl Comp Alvim Specie Result Result Skin s Not cl Respi Not cl Comp Alvim Test T	t us eye damage/eye irri assified based on availa ponents: nopan: es t iratory or skin sensitiza sensitization assified based on availa iratory sensitization assified based on availa ponents: nopan: Type es of exposure	ble : atic ble :	Mild skin irritation ion information. Rabbit Mild eye irritation on information.	
Specie Result Serio Not cl Comp Alvim Specie Result Skin s Not cl Respi Not cl Comp Alvim Test T Route Result Comp	t us eye damage/eye irri assified based on availa ponents: nopan: es t iratory or skin sensitiza sensitization assified based on availa iratory sensitization assified based on availa ponents: nopan: Type es of exposure	ble : ble ble :	Mild skin irritation information. Rabbit Mild eye irritation Mild eye irritation on information. information. Maximization Tes Dermal negative	

Alvimopan:



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Genoto	xicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: Chromosome aberration test in vitro Result: negative
		Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells Result: negative
Genoto	xicity in vivo	: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Mouse Application Route: Oral Result: negative
	ogenicity ssified based on av	ailable information.
	onents:	
Alvimo	pan:	
	tion Route ire time	: Rat : Oral : 2 Years : 500 mg/kg body weight : negative
Exposu LOAEL Result	tion Route ire time Organs	 Mouse Oral 2 Years 4,000 mg/kg body weight positive Bone, Skin Benign and malignant tumor(s) Adverse effects were observed in females only. These is no evidence that these findings are relevant to humans.
-	Juctive toxicity ssified based on av	ailable information.
	onents:	
Alvimo	pan:	
	on fertility	 Test Type: Fertility/early embryonic development Species: Rat Application Route: Intravenous injection Fertility: NOAEL: 5 mg/kg body weight Result: No effects on fertility.
		Test Type: Fertility/early embryonic development Species: Rat Application Route: Oral



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			rtility: NOAEL: sult: No effect	200 mg/kg body weight s on fertility.
		Sp Ap Fe	ecies: Rabbit plication Route	15 mg/kg body weight
Effect	s on fetal development	Sp Ap	ecies: Rat plication Route	yo-fetal development e: Oral oxicity: NOAEL: 100 mg/kg body weight
		Sp Ap De	ecies: Rat plication Route	oxicity: LOAEL: 200 mg/kg body weight
		Sp Ap De	ecies: Rat plication Route velopmental T	yo-fetal development e: Intravenous injection oxicity: NOAEL: 10 mg/kg body weight cant adverse effects were reported
		Sp Ap De	ecies: Rabbit plication Route velopmental T	yo-fetal development e: Intravenous injection oxicity: NOAEL: 15 mg/kg body weight cant adverse effects were reported
	-single exposure assified based on availa	ble info	rmation.	
STOT	-repeated exposure assified based on availa			
	ated dose toxicity		inidion.	
Comp	oonents:			
Speci NOAE Applic	EL cation Route sure time	: 10 : Or : 13	Weeks	verse effects were reported
	EL cation Route sure time	: Or : 39	00 mg/kg al Weeks	verse effects were reported



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Exp		::	Rat 500 mg/kg Oral 1 y No significant adv	verse effects were reported
Exp		:	Dog 2 mg/kg Intravenous 1 Months No significant adv	verse effects were reported
Not	iration toxicity classified based on availa erience with human exp			
-	nponents:			
	mopan: estion	:	Symptoms: stoma Nausea, Vomiting	ach discomfort, Gastrointestinal disturbance, J, Abdominal pain
Alvi	nponents: mopan: icity to fish	:	Exposure time: 96	
	city to daphnia and other atic invertebrates	:	Method: OECD To Remarks: No toxi EC50 (Daphnia m Exposure time: 48 Method: OECD To	est Guideline 203 city at the limit of solubility. nagna (Water flea)): > 17 mg/l 3 h est Guideline 202
Toxi plan	city to algae/aquatic ts	:	EC50 (Scenedesi Exposure time: 72 Method: OECD T	
			Exposure time: 72 Method: OECD T	
Toxi	city to microorganisms	:	EC50: > 920 mg/l Exposure time: 3 Test Type: Respir Method: OECD T	h ration inhibition



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Persis	stence and degrada	bility		
<u>Comp</u>	oonents:			
Alvim	opan:			
Biode	gradability	:	Result: Not rea Biodegradation Exposure time:	
Bioac	cumulative potentia	al		
Comp	oonents:			
Partiti	o pan: on coefficient: n- ol/water	:	log Pow: 0.52	
Mobil	ity in soil			
No da	ta available			
Other	adverse effects			
No da	ta available			

Disposal methods	
Waste from residues	: Do not dispose of waste into sewer.
	Dispose of in accordance with local regulations.
Contaminated packaging	 Empty containers should be taken to an approved waste 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

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

Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT



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Not re	egulated as a danger	ous good	
Spec	ial precautions for u	iser	
Not a	pplicable		
SECTION	15. REGULATORY I	NFORMATION	
Safet	y, health and enviro	nmental regulations/	legislation specific for the substance or
esser	ire ral Law for the control ntial chemical product	s and machinery for	rs, : Not applicable
Feder esser produ	re ral Law for the control ntial chemical product icing capsules, tablets	s and machinery for s and pills.	rs, : Not applicable
Feder esser produ	re ral Law for the control ntial chemical product icing capsules, tablets ngredients of this p	s and machinery for s and pills. roduct are reported in	rs, : Not applicable
Feder esser produ The i AICS	re ral Law for the control ntial chemical product icing capsules, tablets ngredients of this p	s and machinery for s and pills. roduct are reported in : not determined	rs, : Not applicable n the following inventories:
Feder esser produ	re ral Law for the control ntial chemical product icing capsules, tablets ngredients of this p	s and machinery for s and pills. roduct are reported in	rs, : Not applicable n the following inventories:

SECTION 16. OTHER INFORMATION

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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 Tempera-



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ture; 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 compile the Material Safety Data Sheet

: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, 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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