

Alvimopan Formulation

Vers 2.2		Revision Date: 2024/09/28		S Number: 693-00018	Date of last issue: 2023/09/30 Date of first issue: 2016/05/02
1 0		T AND COMPANY IDI			
1. FI	RODUC			IFICATION	
	Produc	t name	:	Alvimopan Form	ulation
	Manufa	acturer or supplier's d	letai	ls	
	Compa	ny	:	MSD	
	Addres	S	:	126 E. Lincoln Av Rahway, New Je	venue vrsey U.S.A. 07065
	Teleph	one	:	908-740-4000	
	Emerge	ency telephone number	r:	1-908-423-6000	
	E-mail	address	:	EHSDATASTEW	/ARD@msd.com
	Recom	mended use of the cl	nem	ical and restriction	ons on use
		mended use tions on use	:	Pharmaceutical Not applicable	

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 which do not result in classification

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Alvimopan	170098-38-1	< 10

4. FIRST AID MEASURES

General advice

: In the case of accident or if you feel unwell, seek medical ad-



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In ca If swa Most and e delay Prote	se of skin contact se of eye contact allowed important symptoms effects, both acute and		advice. If inhaled, reme Get medical at Wash with wat Get medical at If in eyes, rinse Get medical at If swallowed, D Get medical at Rinse mouth th Contact with de the skin. Dust contact w No special pres	ns persist or in all cases of doubt seek medical ove to fresh air. tention if symptoms occur.
5. FIREFI	GHTING MEASURES			
Suita	ble extinguishing media	:	Water spray Alcohol-resista Carbon dioxide Dry chemical	
Unsu medi	itable extinguishing a	:	None known.	
Spec fightii	ific hazards during fire- ng	:	: Avoid generating dust; fine dust dispersed in air in suffic concentrations, and in the presence of an ignition source potential dust explosion hazard. Exposure to combustion products may be a hazard to here	
Haza ucts	rdous combustion prod-	:	Carbon oxides	
Spec ods	ific extinguishing meth-	:	cumstances ar Use water spra	ing measures that are appropriate to local cir- ind the surrounding environment. ay to cool unopened containers. naged containers from fire area if it is safe to do
	ial protective equipment efighters	:	essary.	ained breathing apparatus for firefighting if nec- protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :	Follow safe handling advice (see section 7) and personal pro-
tive equipment and emer-	tective equipment recommendations (see section 8).
gency procedures	



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Envi	ronmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
	nods and materials for ainment and cleaning up	:	tainer for disposa Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the att Local or national posal of this mate employed in the of mine which regula Sections 13 and	f dust in the air (i.e., clearing dust surfaces
7. HAND	LING AND STORAGE			
Tecł	nnical measures	:	causing an explos	precautions, such as electrical grounding

		and bonding, or inert atmospheres.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe dust.
		Handle in accordance with good industrial hygiene and safety
		practice, based on the results of the workplace exposure as- sessment
		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 discharges.
		Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labelled containers.
-		Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components C		Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
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Alvim	nopan		170098-38-1	TWA	10 μg/m3	Internal			
				Wipe limit	100 µg/100 cm ²	Internal			
Engi	neering measures	:	Minimize work Apply measur Ensure that d dust collectors signed in a magnet	<pre>xplace exposure res to prevent du ust-handling sys s, vessels, and p anner to prevent</pre>	especially in confined concentrations. ist explosions. tems (such as exhau processing equipmen the escape of dust i kage from the equipr	ist ducts, t) are de- nto the			
Pers	onal protective equip	ment							
Resp	piratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.						
	llter type protection	:	Particulates type						
М	laterial	:	Chemical-resi	stant gloves					
R	emarks	:	 For prolonged or repeated contact use protective gloves. Wash hands before breaks and at the end of workday. 						
Eye p	Eye protection		Wear the following personal protective equipment: Safety goggles						
Skin and body protection : Hygiene measures :			Skin should be washed after contact. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work- ing place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.						

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	No data available
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	:	Not applicable



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Eva	poration rate	:	No data available	9
Flan	nmability (solid, gas)	:	May form explos dling or other me	ive dust-air mixture during processing, han- ans.
Flan	nmability (liquids)	:	No data available	9
	er explosion limit / Upper mability limit	:	No data available	9
	er explosion limit / Lower mability limit	:	No data available	9
Vap	our pressure	:	No data available	9
Rela	ative vapour density	:	No data available	9
Den	sity	:	No data available	9
	ıbility(ies) Vater solubility	:	No data available	9
	ition coefficient: n- nol/water	:	No data available	9
	-ignition temperature	:	No data available	9
Dec	omposition temperature	:	No data available	9
	osity /iscosity, dynamic	:	No data available	9
١	/iscosity, kinematic	:	No data available	9
Exp	losive properties	:	Not explosive	
Oxic	lizing properties	:	The substance o	r mixture is not classified as oxidizing.
Mole	ecular weight	:	No data available	9
	icle characteristics icle size	:	No data available	9
10. STAE	BILITY AND REACTIVITY	(
Che	ctivity mical stability sibility of hazardous reac- s	:	Stable under nor May form explos dling or other me	ive dust-air mixture during processing, han-
Con	ditions to avoid	:	Heat, flames and	l sparks.



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	ible materials us decomposition	:	Avoid dust forma Oxidizing agents No hazardous de	
TOXICOL	OGICAL INFORMAT		1	
Informati exposure	on on likely routes of	:	Inhalation Skin contact Ingestion Eye contact	
Acute to	•			
	ified based on availa	ble	information.	
Product: Acute ora	-	:	Acute toxicity esti Method: Calculati	mate: > 2,000 mg/kg on method
<u>Compon</u>	ents:			
Alvimop	an:			
Acute ora	al toxicity	:	LD50 (Rat): > 500) mg/kg
			LD50 (Mouse): >	4,000 mg/kg
Acute de	rmal toxicity	:	LD50 (Mouse): >	2,000 mg/kg
Acute tox administr	ticity (other routes of ation)	:	LD50 (Rat): > 20 Application Route Remarks: No sigr	
Skin cor	rosion/irritation			
Not class	ified based on availa	ble	information.	
<u>Compon</u>	ents:			
Alvimop	an:			
Species Result		:	Rabbit Mild skin irritation	
	eye damage/eye irri ified based on availa			
<u>Compon</u>	ents:			
Alvimop	an:			
Species Result		:	Rabbit Mild eye irritation	



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Resp	iratory or skin sens	itisatic	n	
-	sensitisation lassified based on av	ailable	information.	
-	iratory sensitisation lassified based on avail		information.	
<u>Com</u>	ponents:			
Test	sure routes	:	Maximisation T Dermal negative	est
	cell mutagenicity lassified based on ava	ailable	information.	
Com	ponents:			
	10pan: toxicity in vitro	:	Test Type: Bao Result: negativ	cterial reverse mutation assay (AMES) re
			Test Type: Chr Result: negativ	romosome aberration test in vitro
				ritro mammalian cell gene mutation test nouse lymphoma cells re
Geno	toxicity in vivo	:		ute: Oral
	i nogenicity lassified based on ava	ailable	information.	
Com	ponents:			
Speci Applio	cation Route sure time EL		Rat Oral 2 Years 500 mg/kg bod negative	ly weight



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LOA Resu Targ Rem	ılt et Organs	 4,000 mg/kg body weight positive Bone, Skin Benign and malignant tumor(s) Adverse effects were observed in females only. There is no evidence that these findings are relevant to humans.
-	roductive toxicity classified based on avai	lable information.
Com	ponents:	
	nopan: cts 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 Fertility: NOAEL: 200 mg/kg body weight Result: No effects on fertility
		Test Type: Fertility/early embryonic development Species: Rabbit Application Route: Intravenous Fertility: NOAEL: 15 mg/kg body weight Result: No effects on fertility
Effec men	cts on foetal develop- t	 Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 100 mg/kg body weight
		Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 200 mg/kg body weight Result: Embryo-foetal toxicity
		Test Type: Embryo-foetal development Species: Rat Application Route: Intravenous injection Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: No significant adverse effects were reported
		Test Type: Embryo-foetal development Species: Rabbit Application Route: Intravenous injection



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				oxicity: NOAEL: 15 mg/kg body weight cant adverse effects were reported
Not c STO	Γ - single exposure lassified based on avail Γ - repeated exposure lassified based on avail			
Repe	ated dose toxicity			
Com	ponents:			
Spec NOAI Appli	EL cation Route sure time		Mouse 1000 mg/kg Oral 13 Weeks No significant adv	verse effects were reported
	EL cation Route sure time	::	Dog 1000 mg/kg Oral 39 Weeks No significant adv	verse effects were reported
	EL cation Route sure time	: : :	Rat 500 mg/kg Oral 1 yr No significant adv	verse effects were reported

Species NOAEL		Dog 2 mg/kg
Application Route Exposure time	:	Intravenous 1 Months
Remarks	:	No significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Alvimopan:

Ingestion

: Symptoms: stomach discomfort, Gastrointestinal disturbance, Nausea, Vomiting, Abdominal pain

Components:



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12 ECOL							
12. ECOL	12. ECOLOGICAL INFORMATION						
Ecot	oxicity						
	-						

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Alvimopan:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 17 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 17 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic plants	:	EC50 (Scenedesmus subspicatus): > 17 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
		NOEC (Scenedesmus subspicatus): 17 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
Toxicity to microorganisms	:	EC50: > 920 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
		NOEC: 920 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Persistence and degradabilit	ty	
Components:		
Alvimopan:		
Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 4 % Exposure time: 28 d
Bioaccumulative potential		

Components:

Alvimopan:



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	ion coefficient: n- ol/water	:	log Pow: 0.52	
	lity in soil ata available			
	r adverse effects ata available			
13. DISPC	SAL CONSIDERATION	IS		
-	osal methods e from residues	:		of waste into sewer.
Conta	aminated packaging	:	 Dispose of in accordance with local regulations. Empty containers should be taken to an approved wasted dling site for recycling or disposal. If not otherwise specified: Dispose of as unused production of the statement of the statemen	
14. TRAN	SPORT INFORMATION	l		
Interi	national Regulations			
Prope Class Subs Packi Label	umber er shipping name i idiary risk ing group		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable no	
UN/IE Prope Class Subs Packi Label Packi aircra Packi	er shipping name idiary risk ing group Is ing instruction (cargo		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	
IMDG UN ni Prope Class Subs Packi Label EmS	G-Code umber er shipping name idiary risk ing group		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	



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	sport in bulk accord pplicable for product	-	RPOL 73/78 and the IBC Code
Not a	ial precautions for upplicable		
	LATORY INFORMA	-	legislation specific for the substance or mix
ter of	Industry Regulatio		PER/4/2013 concerning the Revision of Mini /2009 concerning Globally Harmonized Sys als.
	lation of the Minister rdous to Health	er of Health No. 472 of	1996 on the Safeguarding of Substances
		at must be registered	: Not applicable
Gove stanc	-	No. 74 of 2001 on the	Management of Hazardous and Toxic Sub-
Haza	rdous substances ap	proved for use	: Not applicable
Prohi	bited substances		: Not applicable
Restr	icted substances		: Not applicable
Regu Mate		y of Trade No. 7 of 20	22 on Distribution and Control of Hazardou
	of hazardous materia ol, Annex I	als subject to distributio	n and : Not applicable
	of hazardous materia ol, Annex II	als subject to distributio	n and : Not applicable
The of AICS	•	product are reported : not determined	in the following inventories:
DSL		: not determined	ł
IECS	С	: not determined	i
. OTHE	R INFORMATION		
	ion Date er information	: 2024/09/28	



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Date format : yyyy/mm/dd

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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