

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Alvimopan Formulation

Version  
2.2

Revision Date:  
28.09.2024

SDS Number:  
657613-00018

Date of last issue: 30.09.2023  
Date of first issue: 02.05.2016

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Alvimopan Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### 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.

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

##### Components

Chemical name	CAS-No.	Concentration (%) w/w)
Alvimopan	170098-38-1	>= 1 - < 5

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### 4. FIRST AID MEASURES

- |                                                             |                                                                                                                                                          |
|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| General advice                                              | : In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled                                                  | : If inhaled, remove to fresh air.<br>Get medical attention if symptoms occur.                                                                           |
| In case of skin contact                                     | : Wash with water and soap.<br>Get medical attention if symptoms occur.                                                                                  |
| In case of eye contact                                      | : If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.                                                       |
| If swallowed                                                | : If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>Rinse mouth thoroughly with water.                                |
| Most important symptoms and effects, both acute and delayed | : Contact with dust can cause mechanical irritation or drying of the skin.<br>Dust contact with the eyes can lead to mechanical irritation.              |
| Protection of first-aiders                                  | : No special precautions are necessary for first aid responders.                                                                                         |
| Notes to physician                                          | : Treat symptomatically and supportively.                                                                                                                |
- 

### 5. FIREFIGHTING MEASURES

- |                                               |                                                                                                                                                                                                                                                   |
|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Suitable extinguishing media                  | : Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Exposure to combustion products may be a hazard to health.                   |
| Hazardous combustion products                 | : Carbon oxides                                                                                                                                                                                                                                   |
| Specific extinguishing methods                | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : Wear self-contained breathing apparatus for firefighting if necessary.<br>Use personal protective equipment.                                                                                                                                    |
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### 6. ACCIDENTAL RELEASE MEASURES

- |                                  |                                                                       |
|----------------------------------|-----------------------------------------------------------------------|
| Personal precautions, protection | : Follow safe handling advice (see section 7) and personal protection |
|----------------------------------|-----------------------------------------------------------------------|

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tive equipment and emergency procedures

ective 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 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 items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## 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

- 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 assessment

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	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis

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Alvimopan	170098-38-1	TWA	10 µg/m <sup>3</sup>	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	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).

### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type

Hand protection

: Particulates type

Material

: Chemical-resistant gloves

Remarks

: For prolonged or repeated contact use protective gloves. Wash hands before breaks and at the end of workday.

Eye protection

: Wear the following personal protective equipment: Safety goggles

Skin and body protection

: Skin should be washed after contact.

Hygiene measures

: 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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : No data available

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Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available
Viscosity, kinematic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Molecular weight	: No data available
Particle characteristics	
Particle size	: No data available

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## 10. STABILITY AND REACTIVITY

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
Incompatible materials	: Oxidizing agents
Hazardous decomposition	: No hazardous decomposition products are known.

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products

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

#### Components:

##### **Alvimopan:**

Acute oral toxicity : LD50 (Rat): > 500 mg/kg  
LD50 (Mouse): > 4,000 mg/kg

Acute dermal toxicity : LD50 (Mouse): > 2,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): > 20 mg/kg  
Application Route: Intravenous  
Remarks: No significant adverse effects were reported

#### **Skin corrosion/irritation**

Not classified based on available information.

#### Components:

##### **Alvimopan:**

Species : Rabbit  
Result : Mild skin irritation

#### **Serious eye damage/eye irritation**

Not classified based on available information.

#### Components:

##### **Alvimopan:**

Species : Rabbit  
Result : Mild eye irritation

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### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### **Alvimopan:**

Test Type : Maximisation Test  
Exposure routes : Dermal  
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### **Alvimopan:**

Genotoxicity 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  
  
Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Mouse  
Application Route: Oral  
Result: negative

### Carcinogenicity

Not classified based on available information.

#### Components:

##### **Alvimopan:**

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
NOAEL : 500 mg/kg body weight  
Result : negative

Species : Mouse  
Application Route : Oral  
Exposure time : 2 Years  
LOAEL : 4,000 mg/kg body weight  
Result : positive

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Target Organs

: Bone, Skin

Remarks

: Benign and malignant tumor(s)

Adverse effects were observed in females only.

There is no evidence that these findings are relevant to humans.

### Reproductive toxicity

Not classified based on available information.

#### Components:

##### **Alvimopan:**

Effects 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

Effects on foetal development

: 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  
Developmental Toxicity: NOAEL: 15 mg/kg body weight  
Result: No significant adverse effects were reported

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### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### Components:

##### **Alvimopan:**

Species	:	Mouse
NOAEL	:	1000 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks
Remarks	:	No significant adverse effects were reported
Species	:	Dog
NOAEL	:	1000 mg/kg
Application Route	:	Oral
Exposure time	:	39 Weeks
Remarks	:	No significant adverse effects were reported
Species	:	Rat
NOAEL	:	500 mg/kg
Application Route	:	Oral
Exposure time	:	1 yr
Remarks	:	No significant adverse effects were reported
Species	:	Dog
NOAEL	:	2 mg/kg
Application Route	:	Intravenous
Exposure time	:	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
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## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### **Alvimopan:**

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 17 mg/l Exposure time: 96 h
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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 degradability

### Components:

#### **Alvimopan:**

Biodegradability

: Result: Not readily biodegradable.

Biodegradation: 4 %

Exposure time: 28 d

## Bioaccumulative potential

### Components:

#### **Alvimopan:**

Partition coefficient: n-octanol/water

: log Pow: 0.52

## Mobility in soil

No data available

## Other adverse effects

No data available

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### 13. DISPOSAL CONSIDERATIONS

#### 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.
- 

### 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 IMO instruments

Not applicable for product as supplied.

#### Special precautions for user

Not applicable

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### 15. REGULATORY INFORMATION

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

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

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

### 16. OTHER INFORMATION

Revision Date : 28.09.2024

#### Further information

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

Date format : dd.mm.yyyy

#### Full text of other abbreviations

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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.

IN / EN