

## Alvimopan Formulation

Version 2.1      Revision Date: 2023/09/30      SDS Number: 643693-00017      Date of last issue: 2023/04/04  
Date of first issue: 2016/05/02

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Alvimopan Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : JL Raya Pandaan KM. 48  
Pandaan, Jawa Timur - Indonesia

Telephone : 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****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 | < 10                  |

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**4. FIRST AID MEASURES**

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

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vice 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.

Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.  
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.

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**5. FIREFIGHTING MEASURES**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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.

Hazardous combustion products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.

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**6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency 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.

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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 parameters / Permissible concentration | Basis    |
|------------|-------------|-------------------------------|--|----------|
| Alvimopan  | 170098-38-1 | TWA                           | 10 µg/m <sup>3</sup>                           | Internal |
|            |             | Wipe limit                    | 100 µg/100 cm <sup>2</sup>                     | Internal |

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**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 : Particulates type

Hand protection

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.

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**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

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

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|  |  |
|--|--|
|  | dling 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 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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : Heat, flames and sparks.<br>Avoid dust formation.  |
| Incompatible materials             | : Oxidizing agents   |
| Hazardous decomposition            | : No hazardous decomposition products are known.   |

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**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: > 2,000 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

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

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### 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)<br>Result: negative  |
|                       |   | Test Type: Chromosome aberration test in vitro<br>Result: negative  |
|                       |   | Test Type: In vitro mammalian cell gene mutation test<br>Test system: mouse lymphoma cells<br>Result: negative  |
| Genotoxicity in vivo  | : | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Mouse<br>Application Route: Oral<br>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  |
| Target Organs     | : | Bone, Skin  |
| Remarks           | : | Benign and malignant tumor(s)<br>Adverse effects were observed in females only. |

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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<br>Species: Rat<br>Application Route: Intravenous injection<br>Fertility: NOAEL: 5 mg/kg body weight<br>Result: No effects on fertility                           |
|                               |   | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 200 mg/kg body weight<br>Result: No effects on fertility  |
|                               |   | Test Type: Fertility/early embryonic development<br>Species: Rabbit<br>Application Route: Intravenous<br>Fertility: NOAEL: 15 mg/kg body weight<br>Result: No effects on fertility                                 |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 100 mg/kg body weight  |
|                               |   | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 200 mg/kg body weight<br>Result: Embryo-foetal toxicity  |
|                               |   | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Intravenous injection<br>Developmental Toxicity: NOAEL: 10 mg/kg body weight<br>Result: No significant adverse effects were reported    |
|                               |   | Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Intravenous injection<br>Developmental Toxicity: NOAEL: 15 mg/kg body weight<br>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:**

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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 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.

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**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable

**IATA-DGR**

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

**IMDG-Code**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

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

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**

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

**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 : 2023/09/30

**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 : yyyy/mm/dd

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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 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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