

**Alvimopan Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/28/2017  |
| 1.7     | 06/12/2017     | 643703-00006 | Date of first issue: 05/02/2016 |

**SECTION 1. IDENTIFICATION**

Product name : Alvimopan Formulation

**Manufacturer or supplier's details**

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road  
Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Pharmaceutical

**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with 29 CFR 1910.1200**

Combustible dust

**GHS label elements**

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

**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

**Hazardous ingredients**

| Chemical name       | CAS-No.     | Concentration (% w/w) |
|---------------------|-------------|-----------------------|
| Polyethylene glycol | 25322-68-3  | >= 90 - < 100         |
| Alvimopan           | 170098-38-1 | >= 1 - < 5            |

**SECTION 4. FIRST AID MEASURES**

**Alvimopan Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/28/2017  |
| 1.7     | 06/12/2017     | 643703-00006 | Date of first issue: 05/02/2016 |

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

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- |                                                |   |                                                                                                                                                                                                                                                 |
|------------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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          | : | 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 fire-fighters | : | Wear self-contained breathing apparatus for firefighting if necessary.<br>Use personal protective equipment.                                                                                                                                    |

**Alvimopan Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/28/2017  |
| 1.7     | 06/12/2017     | 643703-00006 | Date of first issue: 05/02/2016 |

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Follow safe handling advice and personal protective equipment recommendations.
- Environmental precautions : Discharge into the environment must be avoided.  
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.

**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 : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust.  
Handle in accordance with good industrial hygiene and safety practice.  
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 labeled containers.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

## Alvimopan Formulation

Version 1.7      Revision Date: 06/12/2017      SDS Number: 643703-00006      Date of last issue: 04/28/2017  
 Date of first issue: 05/02/2016

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Ingredients         | CAS-No.     | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis   |
|---------------------|-------------|----------------------------------|------------------------------------------------|---------|
| Polyethylene glycol | 25322-68-3  | TWA (aerosol)                    | 10 mg/m <sup>3</sup>                           | US WEEL |
| Alvimopan           | 170098-38-1 | TWA                              | 10 µg/m <sup>3</sup>                           | Merck   |
|                     |             | Wipe limit                       | 100 µg/100 cm <sup>2</sup>                     | Merck   |

**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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**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** : Ensure that eye flushing systems and safety showers are located close to the working place.  
 When using do not eat, drink or smoke.  
 Wash contaminated clothing before re-use.

**Alvimopan Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/28/2017  |
| 1.7     | 06/12/2017     | 643703-00006 | Date of first issue: 05/02/2016 |

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

|                                                  |   |                                                                                 |
|--------------------------------------------------|---|---------------------------------------------------------------------------------|
| Appearance                                       | : | powder                                                                          |
| Color                                            | : | No data available                                                               |
| Odor                                             | : | No information available.                                                       |
| Odor 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, 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                                                               |
| Vapor pressure                                   | : | No data available                                                               |
| Relative vapor density                           | : | No data available                                                               |
| Density                                          | : | No data available                                                               |
| Solubility(ies)                                  |   |                                                                                 |
| Water solubility                                 | : | No data available                                                               |
| Partition coefficient: n-octanol/water           | : | No data available                                                               |
| Autoignition temperature                         | : | No data available                                                               |
| Decomposition temperature                        | : | No data available                                                               |
| Viscosity                                        |   |                                                                                 |
| Viscosity, dynamic                               | : | No data available                                                               |
| Viscosity, kinematic                             | : | No data available                                                               |
| Explosive properties                             | : | Not explosive                                                                   |

**Alvimopan Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/28/2017  |
| 1.7     | 06/12/2017     | 643703-00006 | Date of first issue: 05/02/2016 |

|                      |   |                                                          |
|----------------------|---|----------------------------------------------------------|
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight     | : | No data available                                        |
| Particle size        | : | No data available                                        |

**SECTION 10. STABILITY AND REACTIVITY**

|                                    |   |                                                                                       |
|------------------------------------|---|---------------------------------------------------------------------------------------|
| Reactivity                         | : | Not classified as a reactivity hazard.                                                |
| Chemical stability                 | : | Stable under normal conditions.                                                       |
| Possibility of hazardous reactions | : | Dust can form an explosive mixture in air.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | None known.                                                                           |
| Incompatible materials             | : | Oxidizing agents                                                                      |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.                                        |

**SECTION 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<br>Method: Calculation method |
| Acute dermal toxicity | : | Acute toxicity estimate: > 5,000 mg/kg<br>Method: Calculation method |

**Ingredients:****Polyethylene glycol:**

|                       |   |                                                                               |
|-----------------------|---|-------------------------------------------------------------------------------|
| Acute oral toxicity   | : | LD50 (Rat): > 5,000 mg/kg                                                     |
| Acute dermal toxicity | : | LD50 (Rabbit): > 5,000 mg/kg<br>Remarks: Based on data from similar materials |

**Alvimopan:**

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

**Alvimopan Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/28/2017  |
| 1.7     | 06/12/2017     | 643703-00006 | Date of first issue: 05/02/2016 |

---

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.

**Ingredients:****Polyethylene glycol:**

Species: Rabbit  
Result: No skin irritation  
Remarks: Based on data from similar materials

**Alvimopan:**

Species: Rabbit  
Result: Mild skin irritant

**Serious eye damage/eye irritation**

Not classified based on available information.

**Ingredients:****Polyethylene glycol:**

Species: Rabbit  
Result: No eye irritation  
Remarks: Based on data from similar materials

**Alvimopan:**

Species: Rabbit  
Result: Mild eye irritant

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Ingredients:****Alvimopan:**

Test Type: Maximization Test  
Routes of exposure: Dermal  
Result: negative

**Germ cell mutagenicity**

Not classified based on available information.

**Alvimopan Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/28/2017  |
| 1.7     | 06/12/2017     | 643703-00006 | Date of first issue: 05/02/2016 |

---

**Ingredients:****Polyethylene glycol:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

**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  
Species: 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.

**Ingredients:****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)  
Adverse effects were observed in females only.  
These is no evidence that these findings are relevant to humans.

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or

**Alvimopan Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/28/2017  |
| 1.7     | 06/12/2017     | 643703-00006 | Date of first issue: 05/02/2016 |

---

equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**

Not classified based on available information.

**Ingredients:****Polyethylene glycol:**

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test  
Species: Rabbit  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

**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 fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 100 mg/kg body weight

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 200 mg/kg body weight  
Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development  
Species: Rat

**Alvimopan Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/28/2017  |
| 1.7     | 06/12/2017     | 643703-00006 | Date of first issue: 05/02/2016 |

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Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 10 mg/kg body weight  
Result: No significant adverse effects were reported

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 15 mg/kg body weight  
Result: No significant adverse effects were reported

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Ingredients:****Polyethylene glycol:**

Species: Rat  
NOAEL: 1,100 mg/kg  
Application Route: Ingestion  
Exposure time: 13 Weeks  
Remarks: Based on data from similar materials

**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 y  
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.

## Alvimopan Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/28/2017  |
| 1.7     | 06/12/2017     | 643703-00006 | Date of first issue: 05/02/2016 |

**Experience with human exposure****Ingredients:****Alvimopan:**

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

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Ingredients:****Polyethylene glycol:**

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 100 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

**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 : 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

**Alvimopan Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/28/2017  |
| 1.7     | 06/12/2017     | 643703-00006 | Date of first issue: 05/02/2016 |

---

**Persistence and degradability****Ingredients:****Polyethylene glycol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 68 %  
Exposure time: 28 d  
Remarks: Based on data from similar materials

**Alvimopan:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 4 %  
Exposure time: 28 d

**Bioaccumulative potential****Ingredients:****Polyethylene glycol:**

Bioaccumulation : Species: Fish  
Bioconcentration factor (BCF): 3.2  
Remarks: Based on data from similar materials

**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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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : 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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**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

**Alvimopan Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/28/2017  |
| 1.7     | 06/12/2017     | 643703-00006 | Date of first issue: 05/02/2016 |

---

**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****49 CFR**

Not regulated as a dangerous good

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**SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know****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** : Fire Hazard**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 Know**Polyethylene glycol  
Alvimopan25322-68-3  
170098-38-1**California Prop. 65**

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

**The ingredients of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

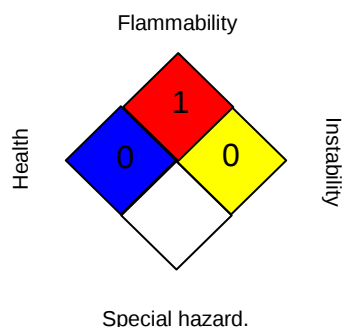
## Alvimopan Formulation

Version 1.7      Revision Date: 06/12/2017      SDS Number: 643703-00006      Date of last issue: 04/28/2017  
 Date of first issue: 05/02/2016

### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA:



##### HMIS® IV:

|                 |   |   |
|-----------------|---|---|
| HEALTH          | / | 0 |
| FLAMMABILITY    |   | 3 |
| PHYSICAL HAZARD |   | 0 |

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)  
 US WEEL / TWA : 8-hr TWA

AICS - Australian Inventory of Chemical Substances; 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 Prevention 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 Amend-

**Alvimopan Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/28/2017  |
| 1.7     | 06/12/2017     | 643703-00006 | Date of first issue: 05/02/2016 |

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ments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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 Agency, <http://echa.europa.eu/>

Revision Date : 06/12/2017

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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US / Z8