

# SAFETY DATA SHEET

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## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

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### Contact information

#### General



Celgene Corporation  
556 Morris Avenue, Summit, NJ 07901  
Main: +1 (908) 673-9000  
E-mail: MSDScoordinator@Celgene.com

#### Emergency telephone number

Chemtrec (24-hour availability):  
+1 (800) 424-9300 (USA and Canada)  
+1 (703) 527-3887 (International; collect calls accepted)

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<b>Product identifier</b>	POMALYST®/ IMNOVID® [EU] (pomalidomide capsules) (1-, 2-, 3- or 4-mg strengths)
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<b>Synonyms</b>	Pomalidomide
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<b>Trade names</b>	POMALYST®; IMNOVID®
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<b>Chemical family</b>	Mixture containing a piperidinedione (pomalidomide)
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<b>Relevant identified uses of the substance or mixture and uses advised against</b>	Bulk formulated pharmaceutical product/ Formulated pharmaceutical product packaged in final form for patient use
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<b>Note</b>	The physical, chemical, toxicological and ecological properties of this material and/ or its ingredients have not been fully characterized. This SDS will be revisited as more data become available.
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## SECTION 2 - HAZARDS IDENTIFICATION

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<b>Classification of the substance or mixture</b>	<b>Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada.</b> Please consult the prescribing/packaging information. <b>The classification and labelling listed below is for bulk POMALYST/ IMNOVID capsules</b>
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**SECTION 2 - HAZARDS IDENTIFICATION ...continued**

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**Globally Harmonized System [GHS]**

Specific Target Organ Toxicity (repeated exposure) - Category 2 (hematological, neurological, and gastrointestinal organs)., Reproductive Toxicity - Category 1B. Carcinogenic - Category 2.

**Label elements****GHS hazard pictogram****GHS signal word**

Danger

**GHS hazard statements**

H360D - May damage the unborn child. H373 - May cause damage to hematological, neurological and gastrointestinal systems through prolonged or repeated exposure. H351 - Suspected of causing cancer.

**GHS precautionary statements**

P201 - Obtain special instructions before use. P260 - Do not breathe dust. P281 - Use personal protective equipment as required. P308 + P313 - IF exposed or concerned: get medical advice/attention. P405 - Store locked up. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

**Other hazards**

The most commonly reported effects in clinical trials with pomalidomide include potentially severe hematological toxicity (*e.g.*, neutropenia, thrombocytopenia, anemia), rash, constipation, fatigue, muscle pain, paresthesia, peripheral edema, fever, dizziness and headache. It may also be associated with an increased risk of thrombotic events.

No human studies of pregnancy outcomes after exposure to pomalidomide were identified. However, because it is an analogue of thalidomide (a known human teratogen), causes embryo/fetotoxicity in rats, and is teratogenic to both rats and rabbits, pomalidomide is considered a probable human developmental toxicant.

An increased incidence of second primary malignancies (SPMs) was seen in certain cancer patients treated with pomalidomide in combination with a corticosteroid in comparison to the corticosteroid alone. Although SPM rates were low overall, the data suggest that a potential for pomalidomide to increase neoplasms cannot be excluded if accidental exposure occurs.

**Note**

This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).

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### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

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<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Starch	9005-25-8	232-679-6	50-56%	Not classified
Sodium stearyl fumarate	4070-80-8	N/A	0.2-0.5%	SI2: H315; EI2: H319
Pomalidomide (CC-4047)	19171-19-8	N/A	0.8-1.7%	STOT-R1: H372; RT1B: H360D; Carc2: H351

**Note** The ingredient(s) listed above are considered hazardous. Starch is included because it has an OEL. The remaining components are non-dangerous/not hazardous and/or present at amounts below reportable limits. See Section 16 for full text of GHS classifications.

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### SECTION 4 - FIRST AID MEASURES

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#### Description of first aid measures

##### Immediate Medical Attention Needed

Yes

##### Eye Contact

If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

##### Skin Contact

Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

##### Inhalation

Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

##### Ingestion

Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

##### Protection of first aid responders

See Section 8 for Exposure Controls/Personal Protection recommendations.

##### Most important symptoms and effects, both acute and delayed

See Sections 2 and 11.

##### Indication of immediate medical attention and special treatment needed, if necessary

Treat symptomatically and supportively. Exposure may increase the risk of infections as this substance is an immune modulator. Substance may cause birth defects.

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## SECTION 5 - FIREFIGHTING MEASURES

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<b>Extinguishing media</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
<b>Specific hazards arising from the substance or mixture</b>	No information identified. May emit toxic fumes of carbon monoxide, carbon dioxide, and oxides of nitrogen.
<b>Flammability/Explosivity</b>	No information identified. High concentrations of finely divided organic particles can explode if ignited.
<b>Advice for firefighters</b>	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

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## SECTION 6 - ACCIDENTAL RELEASE MEASURES

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<b>Personal precautions, protective equipment and emergency procedures</b>	If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment (see section 8). Area should be adequately ventilated. Do not breathe dust. Consider the use of appropriate respiratory protection.
<b>Environmental precautions</b>	Do not empty into drains. Avoid release to the environment.
<b>Methods and material for containment and cleaning up</b>	If capsules are broken or crushed, DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice.
<b>Reference to other sections</b>	See Sections 8 and 13 for more information.

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## SECTION 7 - HANDLING AND STORAGE

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<b>Precautions for safe handling</b>	If capsules are crushed or broken, dust containing drug substance may be released. Minimize dust generation and accumulation. Follow recommendations for handling bulk formulated/packaged pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling. Avoid breathing dust. Wash thoroughly after handling.
<b>Conditions for safe storage including any incompatibilities</b>	Store at room temperature away from incompatible materials. Keep out of reach of children. Avoid extreme temperatures. Store locked up.
<b>Specific end use(s)</b>	No information identified.

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## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

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### Control Parameters/ Occupational Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Starch	ACGIH, Belgium, Bulgaria, Portugal, Spain, Singapore	TWA-8 HR	10 mg/m <sup>3</sup>
	Czech Republic, Slovak Republic	TWA-8 HR	4 mg/m <sup>3</sup>
	Greece, NIOSH	TWA-8 HR	10 mg/m <sup>3</sup> (inhalable fraction); 5 mg/m <sup>3</sup> (respirable fraction)
	Ireland, United Kingdom	TWA-8 HR	10 mg/m <sup>3</sup> (inhalable fraction); 4 mg/m <sup>3</sup> (respirable fraction)
	OSHA	TWA-8 HR	15 mg/m <sup>3</sup> (total dust); 5 mg/m <sup>3</sup> (respirable fraction)
	United Kingdom	STEL	30 mg/m <sup>3</sup> (inhalable fraction); 12 mg/m <sup>3</sup> (respirable fraction)
	NIOSH	TWA-10 HR	10 mg/m <sup>3</sup> (total dust); 5 mg/m <sup>3</sup> (respirable fraction)
Sodium stearyl fumarate	--	--	--
Pomalidomide (CC-4047)	Celgene	TWA-8 HR	1 µg/m <sup>3</sup>

### Exposure/Engineering controls

None required for normal handling of packaged product. If handling bulk capsules or capsules are crushed or broken: Control exposures to below the OEL of the active ingredient (if available). Otherwise, selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Open handling should not be performed when handling potent substances, or substances of unknown toxicity. Material should be handled inside a closed process, ventilated enclosure, isolator or device of equivalent or better control that is suitable for dusts and/or aerosols.

### Respiratory protection

None required for normal handling of packaged product. If handling bulk capsules or capsules are crushed or broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly worn powered air-purifying respirator equipped with HEPA filters or combination filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive-pressure air-supplied respirator if there is any

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**

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<b>Respiratory protection</b> ...continued	potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where air purifying respirators may not provide adequate protection.
<b>Hand protection</b>	Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
<b>Skin protection</b>	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
<b>Eye/face protection</b>	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
<b>Environmental Exposure Controls</b>	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
<b>Other protective measures</b>	Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**Information on basic physical and chemical properties**

<b>Appearance</b>	Capsules
<b>Color</b>	1 mg: Dark blue opaque cap and yellow opaque body; 2 mg: Dark blue opaque cap and orange opaque body; 3 mg: Dark blue opaque cap and green opaque body; and 4 mg: Dark blue opaque cap and blue opaque body.  All: "POML" imprinted on cap with white ink and dosage "mg" imprinted on body in black ink.
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	No information identified.
<b>Melting point/ freezing point</b>	No information identified.

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued**

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<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	No information identified.
<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapor pressure</b>	No information identified.
<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	No information identified.
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (n-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	No information identified.
<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular formula</b>	Not applicable (Mixture)
<b>Molecular weight</b>	Not applicable (Mixture)

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**SECTION 10 - STABILITY AND REACTIVITY**

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<b>Reactivity</b>	No information identified.
<b>Chemical stability</b>	Chemically stable; pharmacological stability not guaranteed beyond expiration date imprinted on package.
<b>Possibility of hazardous reactions</b>	Not expected to occur.

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**SECTION 10 - STABILITY AND REACTIVITY ...continued**

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**Conditions to avoid** Avoid extreme temperatures.  
**Incompatible materials** Strong oxidizer (pomalidomide).  
**Hazardous decomposition products** No information identified.

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**SECTION 11 - TOXICOLOGICAL INFORMATION**

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**Note** The following data describe the active ingredient and/or the individual ingredients where applicable.

**Information on toxicological effects**

**Route of entry** May be absorbed by inhalation, skin contact and ingestion.

**Acute toxicity**

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Starch	--	--	--	--
Sodium stearyl fumarate	--	--	--	--
Pomalidomide (CC-4047)	Minimum lethal dose	Oral	Rat/Mouse	>2000 mg/kg
	Minimum lethal dose	IV	Mice	>80 mg/kg
	Minimum lethal dose	IV	Rat	50-80 mg/kg

**Irritation/Corrosion** No data available.

**Sensitization** No data available.

**STOT-single exposure** Clinical signs of acute toxicity in rodents treated with pomalidomide included increased breathing rate, lethargy, piloerection and eyelid closure.

**STOT-repeated exposure/Repeat-dose toxicity** No significant effects were observed in rats orally treated with pomalidomide.

The following data were identified in rats:  
NOAEL (28-day; oral) = 2000 mg/kg/day.  
NOAEL (13-week; oral) = 1500 mg/kg/day.  
NOAEL (6-month; oral) = 1000 mg/kg/day.

Monkeys were significantly more sensitive to the effects of pomalidomide in comparison to rats. Overall, the principal adverse effects were on the hematopoietic and lymphoid systems.

NOAEL (28 day; oral) = 0.2 mg/kg/day. Decreased white blood cell count was observed (day 14-21) at the 2 mg/kg/day dose.

NOAEL (13-week; oral) = 0.2 mg/kg/day. Hematological and acute

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**SECTION 11 - TOXICOLOGICAL INFORMATION ...continued**

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<b>STOT-repeated exposure/Repeat-dose toxicity</b> ...continued	immunological toxicity (systemic inflammation) were observed at $\geq 2$ mg/kg/day. Target organs included the bone marrow, spleen and thymus.  NOAEL (9-month; oral) = 0.1 mg/kg/day. Immunosuppressive effects (decreased peripheral blood lymphocytes, lymphoid depletion, and hypocellularity of bone marrow) and infection were noted at 1 mg/kg/day.
<b>Reproductive toxicity</b>	In a fertility and early embryonic development study in rats, drug-treated males were mated with untreated or treated females. Pomalidomide was administered to males and females at doses of 25 to 1000 mg/kg/day. When treated males were mated with treated females, there was an increase in post-implantation loss and a decrease in mean number of viable embryos at all dose levels. There were no other effects on reproductive functions or the number of pregnancies. The lowest dose tested in animals resulted in an exposure (AUC) approximately 100-fold of the exposure in patients at the recommended dose of 4 mg/day. When treated males on this study were mated with untreated females, all uterine parameters were comparable to the controls. Based on these results, the observed effects were attributed to the treatment of females.
<b>Developmental toxicity</b>	<p>Pomalidomide was teratogenic in both rats and rabbits in the embryofetal developmental studies, when administered during the period of organogenesis.</p> <p>In rats, pomalidomide was administered orally to pregnant animals at doses of 25 to 1000 mg per kg per day. Fetal malformations were observed at all dose levels. There was no maternal toxicity observed in this study. The lowest dose in rats resulted in an exposure (AUC) approximately 85-fold of the human exposure at the recommended dose of 4 mg per day. Other embryofetal toxicities included increased resorptions leading to decreased number of viable fetuses.</p> <p>In rabbits, pomalidomide was administered orally to pregnant animals at doses of 10 to 250 mg per kg per day. Fetal malformations were seen at all doses. No maternal toxicity was observed at the low dose (10 mg per kg per day) that resulted in cardiac anomalies in fetuses; this dose resulted in an exposure (AUC) approximately equal to that reported in humans at the recommended dose of 4 mg per day. Additional embryofetal toxicity included increased resorption.</p>
<b>Genotoxicity</b>	Pomalidomide was not mutagenic or clastogenic in a battery of tests, including the bacteria reverse mutation assay (Ames test), an <i>in vitro</i> chromosomal aberrations assay using human peripheral blood lymphocytes and an <i>in vivo</i> micronucleus test in orally treated rats administered doses up to 2000 mg/kg/day.
<b>Carcinogenicity</b>	No carcinogenicity studies with pomalidomide have been conducted. One of twelve monkeys dosed with 1 mg/kg of pomalidomide (an exposure comparable to about 15 times the exposure at the RHD) developed acute myeloid leukemia in a 9-month repeat-dose toxicology study. No other components of the product present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
<b>Aspiration hazard</b>	No data available.

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**SECTION 11 - TOXICOLOGICAL INFORMATION** ...continued

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**Human health data** See "Section 2 - Other Hazards"

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**SECTION 12 - ECOLOGICAL INFORMATION**

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**Toxicity**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Starch	--	--	--
Sodium stearyl fumarate	--	--	--
Pomalidomide (CC-4047)	--	--	--

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**Persistence and Degradability** No data available.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Results of PBT and vPvB assessment** Not performed.

**Other adverse effects** No data available.

**Note** The environmental characteristics of this product/mixture have not been fully investigated. Releases to the environment should be avoided.

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**SECTION 13 - DISPOSAL CONSIDERATIONS**

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**Waste treatment methods** Dispose of wastes by appropriately permitted chemical waste incinerator in accordance to prescribed federal, state, and local guidelines. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, *e.g.*, appropriately permitted municipal or onsite wastewater treatment facility.

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**SECTION 14 - TRANSPORT INFORMATION**

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**Transport** Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.

**UN number** None assigned.

**UN proper shipping name** None assigned.

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**SECTION 14 - TRANSPORT INFORMATION ...continued**

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<b>Transport hazard classes and packing group</b>	None assigned.
<b>Environmental hazards</b>	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
<b>Special precautions for users</b>	Due to lack of data, avoid release to the environment.
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

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**SECTION 15 - REGULATORY INFORMATION**

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<b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
<b>Chemical safety assessment</b>	Not conducted.
<b>TSCA status</b>	Drugs are exempt from TSCA.
<b>SARA section 313</b>	Not listed.
<b>California proposition 65</b>	Not listed.
<b>Additional information</b>	No other information identified.

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**SECTION 16 - OTHER INFORMATION**

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<b>Full text of H phrases and GHS classifications</b>	STOT-R2 - Specific Target Organ Toxicity Following Repeated Exposure Category 2. STOT-R1 - Specific Target Organ Toxicity Following Repeat Exposure Category 1. SI2 - Skin irritant Category 2. EI2 - Eye irritant Category 2. H373 - May cause damage to hematological, neurological and gastrointestinal systems through prolonged or repeated exposure. H372 - Causes damage to hematological, neurological, and gastrointestinal systems through prolonged or repeated exposure. RT1B - Reproductive toxicity Category 1B. H360D - May damage the unborn child. H315 - Causes skin irritation. H319 - Causes serious eye irritation. Carc2 - Carcinogenicity Category 2. H351 - Suspected of causing cancer.
<b>Sources of data</b>	Information from published literature and internal company data.

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**SECTION 16 - OTHER INFORMATION ...continued**

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**Abbreviations**

ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

**Issue Date**

30 October 2018

**Revisions**

Updated data and labeling in Section 2.

**Disclaimer**

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a potent pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.