SAFETY DATA SHEET

Confirmed product as not changed on 11-Feb-2019 by KM. Expiry date of MSDS revised to 11-Feb-2022

Reviewed and extended 04-May-2022 BW

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

Contact information

General

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Product identifier

Truvada® - Emtricitabine/Tenofovir Disoproxil Fumarate (200/300 mg) Tablets

Synonyms

Active ingredients:
Tenofovir Disoproxil Fumarate: TDF, Tenofovir DF, bis(POC) PMPA, GS 4331-05
Emtricitabine: FTC, *cis*-(-)-FTC

Trade names

Truvada®

Chemical family

Nucleoside and nucleotide analog mixture

Relevant identified uses of the substance or mixture and uses advised against

Bulk formulated pharmaceutical product/mixture packaged in final form for patient use. Used in combination with other antiretroviral agents for the treatment of HIV- 1 infection in adults.

Note

This SDS for Truvada® Tablets is written to address potential worker health and safety issues associated with the handling of the formulated product.

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada. Please consult the prescribing/packaging information. **The classification and labeling listed below is for bulk Truvada®.**

Globally Harmonized System [GHS]

Irritant (eye) - Category 1

Label elements

SECTION 2 - HAZARDS IDENTIFICATION …continued

GHS hazard pictogram

GHS signal word Danger

GHS hazard statements H318 - Causes serious eye damage.

GHS precautionary statements P280 - Wear eye/face protection. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a Poison Center or doctor/ physician.

Other hazards Adverse effects seen with therapeutic use have included: diarrhea, nausea, abdominal pain, flatulence, pancreatitis, weakness, headache, dizziness, insomnia, abnormal dreams, allergic reactions, skin discoloration, rash, muscular weakness, bone problems, including bone pain, softening or thinning (which may lead to fractures), changes in immune system (Immune Reconstitution Syndrome). Serious effects including lactic acidosis, renal impairment, including cases of acute renal failure, and effects on the liver, including hepatomegaly and developing fat in liver. The recommended dose of Truvada® is one tablet per day.

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).

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	EINECS/ELINCS#	Amount	GHS Classification
Tenofovir Disoproxil Fumarate	202138-50-9	N/A	25-35%	EI1: H318
Cellulose	9004-34-6	232-674-9	25-35%	Not classified
Emtricitabine	143491-57-0	N/A	15-25%	Not classified
Starch	9005-25-8	232-679-6	4-6%	Not classified
Magnesium Stearate	557-04-0	209-150-3	1-2%	Not classified
Titanium dioxide	13463-67-7	236-675-5	0.7-0.8%	Not classified

Note The ingredients listed above are considered hazardous. The ingredients that are designated with GHS classifications are listed because they are classified as hazardous. Emtricitabine and tenofovir disoproxil fumarate are both pharmacologically active and have OELs. Cellulose, pregelatinized starch ("starch"), magnesium stearate, and titanium dioxide are listed because they have OELs. The remaining components are non-hazardous and/or present at amounts

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS …continued

Note …continued	below reportable limits. See Section 16 for full text of GHS classifications. The GHS classifications are based on Regulation (EC) 1272/2008, WHMIS 2015 and Hazard Communication Standard No. 1910.1200.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed	Yes
Eye Contact	In the event of a chemical exposure, immediately irrigate eyes with copious quantities of water for at least 15 minutes. Remove contact lenses as soon as practical. Do not delay irrigation while waiting for contact lens removal. 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	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package or prescribing information for potential drug interactions.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit toxic gases of carbon monoxide, carbon dioxide, oxides of nitrogen, magnesium-containing compounds, and phosphorus-containing compounds.

SECTION 5 - FIREFIGHTING MEASURES …continued

Flammability/Explosivity No information identified.

Advice for firefighters In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.

Environmental precautions Do not empty into drains. Avoid release to the environment.

Methods and material for containment and cleaning up If tablets are spilled, scoop up and dispose of in a manner that is compliant with federal, state or local laws. If tablets are crushed/broken, 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. Scoop up broken pieces. Add excess liquid to allow the material to enter into solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container for disposal in accordance with applicable waste disposal regulations (see section 13). Decontaminate the area twice with an appropriate solvent (see section 9).

Reference to other sections See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling If tablets 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 contact with eyes, skin and other mucous membranes. Avoid breathing dust.

Conditions for safe storage including any incompatibilities Protect from moisture. Store at 25°C (77 °F), excursions permitted to 15-30°C (59- 86°F). Keep container tightly closed; store in original container only.

Specific end use(s) No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters/Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Tenofovir Disoproxil Fumarate	Gilead	TWA-8 HR	300 µg/m³
Cellulose	ACGIH, Australia, Belgium, Estonia, France, Portugal, Romania, Singapore, Spain	TWA-8 HR	10 mg/m³
	Ireland, United Kingdom	TWA-8 HR	10 mg/m³ (inhalable dust); 4 mg/m³ (respirable dust)
	Ireland	STEL	20 mg/m³ (total inhalable dust)
	Latvia	TWA-8 HR	2 mg/m³
	Mexico	TWA-8 HR/STEL	10/20 mg/m³
	NIOSH	TWA-8 HR	10 mg/m³ (total dust); 5 mg/m³ (respirable dust)
	OSHA	TWA-8 HR	15 mg/m³ (total dust); 5 mg/m³ (respirable fraction)
	United Kingdom	STEL	20 mg/m³ (inhalable dust); 12 mg/m³ (respirable dust)
Emtricitabine	Gilead	TWA-8 HR	1 mg/m³
Starch	ACGIH, Belgium, Bulgaria, Portugal, Spain, Singapore	TWA-8 HR	10 mg/m³
	Czech Republic, Slovak Republic	TWA-8 HR	4 mg/m³
	Greece, NIOSH	TWA-8 HR	10 mg/m³ (inhalable fraction); 5 mg/m³ (respirable fraction)
	Ireland, United Kingdom	TWA-8 HR	10 mg/m³ (inhalable fraction); 4 mg/m³ (respirable fraction)

Control Parameters/Occupational Exposure Limit Values
…continued

Compound	Issuer	Type	OEL
Starch	OSHA	TWA-8 HR	15 mg/m³ (total dust); 5 mg/m³ (respirable fraction)
	United Kingdom	STEL	30 mg/m³ (inhalable fraction); 12 mg/m³ (respirable fraction)
	NIOSH	TWA-10 HR	10 mg/m³ (total dust); 5 mg/m³ (respirable fraction)
Magnesium Stearate	ACGIH	TWA-8 HR	10 mg/m³ (stearates)
	Lithuania	TWA-8 HR	3 mg/m³
	Sweden	TWA-8 HR	5 mg/m³
Titanium dioxide	ACGIH, Australia, Belgium, Bulgaria, Latvia, Poland, Portugal, Romania, Singapore, Spain, OSHA (vacated)	TWA-8 HR	10 mg/m³
	Austria	TWA-8 HR	5 mg/m³ (respirable fraction)
	Austria	STEL (2 x 60 min)	10 mg/m³ (respirable fraction)
	Denmark	TWA-8 HR	6 mg/m³ (as Ti)
	Estonia, Lithuania, Sweden	TWA-8 HR	5 mg/m³
	France, Mexico	TWA-8 HR	10 mg/m³ (as Ti)
	Greece	TWA-8 HR	10 mg/m³ (inhalable fraction); 5 mg/m³ (respirable fraction)
	Ireland, United Kingdom	TWA-8 HR	10 mg/m³ (total inhalable dust); 4 mg/m³ (respirable dust)
	Mexico	STEL	20 mg/m³ (as Ti)
	NIOSH	IDLH	5000 mg/m³

Control Parameters/Occupational Exposure Limit Values
…continued

Compound	Issuer	Type	OEL
Titanium dioxide	Romania	STEL	15 mg/m³
	United Kingdom	STEL	30 mg/m³ (total inhalable); 12 mg/m³ (respirable)

Exposure/Engineering controls
None required for normal handling of packaged product. If handling bulk tablets or if tablets are crushed or broken: Control exposures to below the OEL(s). The objective of containment, controls and work practices should be to maintain worker breathing zone concentrations below the respective OEL for each task or operation. In general, the handling practices below are capable of achieving the OELs. However, verification of the acceptability of these recommended containment, controls and work practices to meet OELs through industrial hygiene monitoring of tasks or operations is recommended. Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/ or enclosure at dust-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling of powders. High-energy operations such as milling, particle sizing, spraying or fluidizing should be done within an approved emission control or containment system.

Respiratory protection
None required for normal handling of packaged product. If while handling, tablets are crushed or broken: the choice of respiratory protection should be appropriate to the task, considering the level of existing engineering controls. An approved and properly fitted air-purifying respirator with HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with HEPA filters or combination filters or a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection. The assigned protection factor (APF) of the selected PAPR should be at least 1000.

Hand protection
None required for normal handling of packaged product. Wear nitrile or other impervious gloves if skin contact with tablets is possible.

Skin protection
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.

Eye/face protection
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.

Environmental Exposure Controls
Should not be required during normal handling of material. In case of spill, do not release to drains. Avoid release to the environment.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION …continued

Other protective measures	Wash hands in the event of contact with the tablets, 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).

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Capsule-shaped, film-coated tablet
Color	Blue
Odor	No information identified.
Odor threshold	No information identified.
pH	No information identified.
Melting point/freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified.
Vapor density	No information identified.
Relative density	No information identified.
Water solubility	No information identified.
Solvent solubility	No information identified.
Partition coefficient (*n-octanol/water*)	No information identified.
Auto-ignition temperature	No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES …continued

Decomposition temperature No information identified.

Viscosity No information identified.

Explosive properties No information identified.

Oxidizing properties No information identified.

Other information

Molecular weight Not applicable (Mixture)

Molecular formula Not applicable (Mixture)

SECTION 10 - STABILITY AND REACTIVITY

Reactivity No information identified.

Chemical stability Stable

Possibility of hazardous reactions Not expected to occur.

Conditions to avoid No information identified.

Incompatible materials No information identified.

Hazardous decomposition products No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

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 ingestion. Absorption by inhalation or skin contact is not likely for packaged product, but may occur if tablets are crushed/broken.

Acute toxicity

Compound	Type	Route	Species	Dose
Tenofovir Disoproxil Fumarate	NOEL	Oral	Rat	>1500 mg/kg
Cellulose	LC_{50}	Inhalation	Rat	>5800 mg/m³/4h
	LD_{50}	Oral	Rat	>5000 mg/kg
	LD_{50}	Dermal	Rabbit	>2000 mg/kg
Emtricitabine	LD_{50}	Oral	Rat/Mouse	>4000 mg/kg
Starch	--	--	--	--

Acute toxicity
…continued

Compound	Type	Route	Species	Dose
Magnesium Stearate	LC_{50}	Inhalation	Rat	>2000 mg/m³
Titanium dioxide	LD_{50}	Oral	Rat	>10000 mg/kg
	LD_{50}	Oral	Mouse	>10000 mg/kg
	LD_{50}	Dermal	Rabbit	>10000 mg/kg

Additional acute toxicity information Administration of TDF/FTC by once daily oral gavage was well tolerated in rats at levels of 30/20, 100/67 and 300/200 mg/kg/day for 14 days. The NOAEL was considered to be 300/200 mg/kg/day for TDF/FTC.

Irritation/Corrosion Tenofovir disoproxil fumarate was a severe eye irritant and a slight skin irritant in rabbits. No information identified for emtricitabine.

Sensitization Tenofovir disoproxil fumarate was not a contact sensitizer in guinea pigs. No information identified for emtricitabine.

STOT-single exposure Oral NOELs of >1,500 and >30 mg/kg were reported in rats and dogs, respectively, following single oral doses of tenofovir disoproxil fumarate.

STOT-repeated exposure/Repeat-dose toxicity NOELs associated with repeat doses were <30 and <3 mg/kg/day tenofovir disoproxil fumarate in rats and dogs, respectively. Target organs of toxicity included the bone and kidney. Oral NOELs of 500, 600 and 200 mg/kg/day emtricitabine were identified in repeat-dose toxicity studies in mice (6-month), rats (3-month) and monkeys (12-month), respectively.

Reproductive toxicity An oral reproductive NOEL of 300 mg/kg/day tenofovir disoproxil fumarate was identified in rats. No effects on fertility were observed in mice and rats treated with oral doses up to >1000 and 750 mg/kg/day emtricitabine, respectively.

Developmental toxicity Reproduction studies performed in rats and rabbits revealed no evidence of harm to the fetus due to tenofovir disoproxil fumarate. The incidence of fetal variations/ malformations was not increased in the offspring of mice or rabbits treated orally with emtricitabine at doses 60- and 120-fold higher, respectively, than those used in humans (based on exposure levels).

Genotoxicity Tenofovir disoproxil fumarate was mutagenic in the *in vitro* mouse lymphoma assay, but was negative in both the Ames bacterial mutagenicity test and an *in vivo* mouse micronucleus assay. Emtricitabine was negative in the Ames bacterial mutagenicity assay, a mutation assay in mouse lymphoma cells and an *in vivo* mouse micronucleus assay.

Carcinogenicity Titanium dioxide has been classified by the International Agency for Research on Cancer (IARC) as an IARC Group 2B carcinogen "possibly carcinogenic to humans". This classification is based upon animal inhalation studies. Epidemiology studies do not suggest an increased risk of cancer in humans from occupational exposure to titanium dioxide. None of the other components of the mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen. In long-term oral carcinogenicity studies, no evidence of carcinogenicity was observed in rats at doses up to 5 times the recommended therapeutic dose of tenofovir disoproxil fumarate in humans.

SECTION 11 - TOXICOLOGICAL INFORMATION …continued

Carcinogenicity …continued

In similar studies with mice, an increase in duodenal tumors was noted in female mice at 600 mg/kg/ day; however, this was likely related to high local concentrations in the gastrointestinal tract. No drug-related increases in tumor incidence were observed in mice or rats treated with oral doses as high as 750 and 600 mg/kg/day emtricitabine, respectively.

Aspiration hazard

No data available.

Human health data

See "Section 2 - Other Hazards".

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

Compound	Type	Species	Concentration
Tenofovir Disoproxil Fumarate	EC_{50}/72h	Freshwater green algae	47 mg/L
	EC_{50}/48h	Daphnia magna	>98 mg/L
	LC_{50}/96h	Rainbow trout	>92 mg/L
	NOEC/21 days reproduction	Daphnia magna	13 mg/L
	Early Life Cycle NOEC	Fathead minnow	1.9 mg/L
Cellulose	--	--	--
Emtricitabine	EC_{50}/72h	Freshwater green algae	>110 mg/L
	EC_{50}/48h	Daphnia magna	>110 mg/L
	LC_{50}/96h	Rainbow trout	>110 mg/L
	NOEC/21 days reproduction	Daphnia magna	110 mg/L
	Early Life Cycle NOEC	Fathead minnow	6.1 mg/L
	NOEC (3-hr)	Activated sludge microorganisms	940 mg/L
Starch	--	--	--
Magnesium Stearate	--	--	--
Titanium dioxide	LC_{50}/48h	Leuciscus idus	>1000 mg/L

Additional toxicity information

EC_{50}s of 940 and >1000 mg a.i./L were identified for tenofovir disoproxil fumarate and emtricitabine, respectively, in a respiratory inhibition study.

The results of tenofovir (TFV) early-life stage (ELS) test in fathead minnows (*Pimephales promelas)* led to the following conclusions:

1. Tenofovir did not induce any statistically significant effects on embryonic survival at 10 mg/L. Hence, both the NOEC and LOEC for embryonic survival were >10 mg/L;
2. Tenofovir did not induce any statistically significant effects on larval survival at 10 mg/L. Hence, the both the NOEC and LOEC for larval survival were >10 mg/ L;
3. Tenofovir did not induce any statistically significant effects on larval growth at 10 mg/L. Hence, both the NOEC and LOEC for larval growth were >10 mg/L.

SECTION 12 - ECOLOGICAL INFORMATION …continued

Additional toxicity information …continued	Tenofovir did not induce any statistically significant effects on parental growth at 100 mg/L. Hence, the NOEC and LOEC for parental growth were 100 and >100 mg/L, respectively. Mean parental body length was not significantly reduced at any of the test concentrations.
Persistence and Degradability	Tenofovir disoproxil fumarate and emtricitabine are not readily biodegradable. Emtricitabine is not expected to pose a risk to the environment. The results of environmental fate studies indicate that TFV would not be significantly degraded in sewage treatment facilities, or be removed from the aqueous phase *via* sorption to sewage biosolids. The results of a sediment water transformation study indicated that the half-life of TFV was approximately 10-33 days.
Bioaccumulative potential	Tenofovir disoproxil fumarate and emtricitabine are unlikely to bioaccumulate, based on their respective octanol/water partition coefficients.
Mobility in soil	The data suggest that tenofovir disoproxil fumarate and emtricitabine will partition into the aquatic environment rather than the sediment.
Adsorption coefficient (Koc)	The mean log K_{OC} for tenofovir disoproxil fumarate was 1.3 indicating that it would not be bound to or desorb from sludge. Emtricitabine did not adsorb significantly to activated sludge. K_{OC} values ranged from 21.1 to 45.6.
Results of PBT and vPvB assessment	Tenofovir disoproxil fumarate and emtricitabine have not been evaluated for PBT because of low log K_{OW} values.
Other adverse effects	No data available.
Note	Releases to the environment should be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

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

SECTION 14 - TRANSPORT INFORMATION

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

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	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.
Chemical safety assessment	Not conducted.
TSCA status	Drugs are exempt from TSCA.
SARA section 313	Not listed.
California proposition 65	Not listed.
Additional information	No other information identified.

SECTION 16 - OTHER INFORMATION

Full text of H phrases and GHS classifications	EI1 - Eye irritant Category 1. H318 - Causes serious eye damage.
Sources of data	Information from published literature and internal company data.

SECTION 16 - OTHER INFORMATION …continued

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

7 March 2016

Revisions

This is the fifth version of this SDS.

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 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.