SAFETY DATA SHEET

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

Contact information

General

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Chemtrec *(24-hour availability)*:
+1 (800) 424-9300 (USA and Canada)
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Product identifier	Sofosbuvir/Velpatasvir FDC (400/100 mg) Tablets
Synonyms	SOF/VEL Tablets
Trade names	Epclusa®
Chemical family	Mixture
Relevant identified uses of the substance or mixture and uses advised against	Bulk formulated pharmaceutical mixture/Formulated pharmaceutical product/ mixture packaged in final form for patient use.
Note	This SDS 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.** Consult prescribing/packaging information. **The classification and labeling listed below is for bulk drug product.**
Globally Harmonized System [GHS]	Not classified

Label elements

GHS hazard pictogram	None required
GHS signal word	None required

SECTION 2 - HAZARDS IDENTIFICATION …continued

GHS hazard statements None required

GHS precautionary statements None required

Other hazards Coadministration of the single agents SOF 400 mg and Velpatasvir 25mg or 100 mg for up to 12 weeks was well tolerated in over 800 HCV infected patients in Phase 2 studies. There was a low rate of treatment discontinuation for adverse events (AE). There was a low incidence of serious adverse events, of severe or life-threatening AEs and of Grade 3 and 4 laboratory abnormalities.

Note This mixture does not meet criteria for classification 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). Nevertheless, it should be handled with caution as it contains ingredients which are pharmacologically active.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	EINECS/ELINCS#	Amount	GHS Classification
Sofosbuvir	1190307-88-0	N/A	35-45%	Not classified
Velpatasvir	1377049-84-7	N/A	15-20%	CA4: H413
Cellulose	9004-34-6	232-674-9	30-40%	Not classified
Magnesium Stearate	557-04-0	209-150-3	1-2%	Not classified
Titanium dioxide	13463-67-7	236-675-5	0.3-0.9%	Not classified

Note Sofosbuvir and velpatasvir are listed as they are pharmacologically active. Cellulose, magnesium stearate and titanium dioxide are listed because they have OELs. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of GHS classifications. The GHS classification is 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 No. If exposed or concerned: Get medical advice/attention.

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.

SECTION 4 - FIRST AID MEASURES …continued

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	If swallowed, call a physician immediately. 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. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the manufacturer 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, and fluorine- or phosphorus-containing compounds.
Flammability/Explosivity	No explosivity or flammability data identified. High concentrations of finely divided airborne organic particles can potentially explode if ignited.
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.

SECTION 6 - ACCIDENTAL RELEASE MEASURES …continued

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 or broken, do not raise dust. Clean up spill with HEPA-filtered vacuum if available. If not available, add water to allow for the material to enter solution. Collect material with absorbents. Place spill materials into a leak-proof container suitable for disposal. Decontaminate area a second time. Dispose of material in a manner that is compliant with federal, state and local laws.

Reference to other sections

See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling

Follow recommendations for handling bulk formulated/packaged pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Avoid breathing dust. Wash thoroughly after handling.

Conditions for safe storage including any incompatibilities

Store at 25 °C (77 °F); excursions permitted to 15-30 °C (59-86 °F)

Specific end use(s)

No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters/Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Sofosbuvir	Gilead	TWA-8 HR	200 µg/m
Velpatasvir	Gilead	TWA-8 HR	70 µg/m
Cellulose	ACGIH, Australia, Belgium, Estonia, France, Portugal, Romania, Singapore, Spain	TWA-8 HR	10 mg/m
	Ireland, United Kingdom	TWA-8 HR	10 mg/m (inhalable dust); 4 mg/m (respirable dust)
	Ireland	STEL	20 mg/m (total inhalable dust)
	Latvia	TWA-8 HR	2 mg/m

Control Parameters/Occupational Exposure Limit Values
…continued

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

Control Parameters/Occupational Exposure Limit Values
…continued

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

Exposure/Engineering controls
None required for normal handling of packaged product. Control exposures to below the OELs. Otherwise, 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 tablets are crushed or broken or are being put into bottles or other packaging: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine tablet handling tasks, an approved and properly fitted air-purifying respirator with appropriate 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 appropriate 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.

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

Skin protection
None required for normal handling of packaged product. Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely or if handling the tablets. 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
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.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION …continued

Other protective measures	Wash hands in the event of contact with this product, 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). Decontaminate all protective equipment following use.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Diamond-shaped film coated tablet
Color	Pink
Odor	No information identified.
Odor threshold	No information identified.
pH	Not applicable
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	No information identified.
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 inhalation, skin contact and ingestion.

Acute toxicity

Compound	Type	Route	Species	Dose
Sofosbuvir	--	--	--	--
Velpatasvir	--	--	--	--
Cellulose	LC_{50}	Inhalation	Rat	>5800 mg/m /4h
	LD_{50}	Oral	Rat	>5000 mg/kg
	LD_{50}	Dermal	Rabbit	>2000 mg/kg
Magnesium Stearate	LC_{50}	Inhalation	Rat	>2000 mg/m
Titanium dioxide	LD_{50}	Oral	Rat	>10000 mg/kg
	LD_{50}	Oral	Mouse	>10000 mg/kg
	LD_{50}	Dermal	Rabbit	>10000 mg/kg

Irritation/Corrosion	Sofosbuvir was considered a non-irritant to skin in an *in vivo* rabbit study and a non-severe irritant to eyes in an *in vitro* eye irritation study. Velpatasvir was not considered to be a skin irritant in rabbits and was not assigned any classification/prediction in the bovine corneal opacity and permeability test. Velpatasvir was not phototoxic in rats.
Sensitization	Sofosbuvir was negative in a delayed-type hypersensitivity study in mice. Velpatasvir was not a sensitizer in the mouse local lymph node assay.
STOT-single exposure	Single oral doses of GS-9851 (a near 50:50 mixture of sofosbuvir and its diastereoisomer) up to 1800 mg/kg were well tolerated in rats. Velpatasvir was well-tolerated in mice, rats and dogs given single oral doses of up to 1000, 600 and 200 mg/kg/day, respectively.
STOT-repeated exposure/Repeat-dose toxicity	In seven-day oral repeated dose studies, target organs of toxicity of sofosbuvir included the liver in dogs and the gastrointestinal (GI) tract and heart in both rats and dogs. The seven-day No-Observed-Adverse-Effect Level (NOAEL) was considered to be 250 and 150 mg/kg in rats and dogs, respectively. Adverse effects identified at doses of 2000 (rat) or 1500 (dog) mg/kg/day in seven-day dose range-finding studies (correlating to exposures approximately 29- and 123-fold greater than the human exposure at sofosbuvir, 400 mg) were not observed in studies of longer duration. No target organs were identified in rodents treated with sofosbuvir for up to 13 (mice) or 26 (rats) weeks. The NOAEL in the 13-week mouse study was 100/300 (male/female) mg/kg/day. In repeat-dose oral rat studies with sofosbuvir, of up to 26 weeks' duration, effects seen in the longest study were those characteristic of the vehicle. A NOAEL identified in this study was 500 mg/kg/day Sofosbuvir was also orally administered in studies with dogs, for up to 39 weeks. In a 13-week study, local GI irritation, soft feces, emesis, and a slight decrease in erythron mass were seen at the high dose of 500 mg/kg/day. In a 39-week study, one male treated with 500 mg/kg/day experienced sudden onset of intestinal hemorrhage; clinical and postmortem findings were consistent with idiopathic hemorrhagic gastroenteritis, a condition which occurs spontaneously in young dogs. The NOAEL in both of these 13- and 39-week studies was identified as 100 mg/kg/day. No findings were observed in 14-day repeat oral dose toxicity studies with velpatasvir up to the highest dose tested in rats (200 mg/kg/day) and dogs (100 mg/ kg/day). Velpatasvir was well-tolerated, with no treatment-related effects on clinical observations, body weight, food consumption, ophthalmic observations, or clinical and anatomic pathology and no test-article related deaths in a 26-week oral study in rats; the NOEL was 200 mg/kg/day, the highest dose tested.

STOT-repeated exposure/Repeat-dose toxicity …continued	No velpatasvir-related changes on mortality, body weight/body weight gain, food consumption and no ophthalmic, ECG, clinical, or anatomical pathology findings were observed in a 39-week oral study in dogs; the NOAEL was 100 mg/kg/day.
Reproductive toxicity	Sofosbuvir administered at oral doses up to 500 mg/kg/day had no adverse effects on mating, fertility and embryo survival in rats. No significant effects were noted in reproductive toxicity studies with velpatasivr. In a rat fertility study, the NOEL for reproductive parameters was 200 mg/kg/day.
Developmental toxicity	Sofosbuvir administered at oral doses up to 500 mg/kg/day in rats and 300 mg/kg/day in rabbits had no adverse effects on embryo-fetal development. Velpatasvir administered at oral doses up to 200 mg/kg/day in rats and 300 mg/kg/day in rabbits had no adverse effects on embryo-fetal development.
Genotoxicity	Sofosbuvir was negative in the Ames bacterial cell mutagenicity screening assay, in a chromosomal aberration assay using unspecified mammalian cells, and in an *in vivo* mouse micronucleus assay. Velpatasvir was negative in an Ames bacterial cell mutagenicity assay, a chromosomal aberration assay, and an *in vivo* rat bone marrow micronucleus assay.
Carcinogenicity	Sofosbuvir was not carcinogenic in two-year studies in mice or rats at dose levels up to 600 mg/kg/day and 750 mg/kg/day, respectively. 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.
Aspiration hazard	No data available.
Human health data	See "Section 2 - Other Hazards"

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

Compound	Type	Species	Concentration
Sofosbuvir	--	--	--
Velpatasvir	EC_{50}/21-day survival	Daphnia Magna	>0.017 mg/L
	NOEC (21-day survival)	Daphnia Magna	0.017 mg/L
	LOEC (21-day survival)	Daphnia Magna	>0.017 mg/L
	EC_{50}/21-day reproduction	Daphnia Magna	0.012 mg/L
	NOEC (21-day reproduction)	Daphnia Magna	0.0066 mg/L
	LOEC (21-day reproduction)	Daphnia Magna	0.017 mg/L
	NOEC/28 days (hatch, post-hatch, growth)	Pimephales promelas (fathead minnow)	0.2 mg/L
	LOEC/28 days (hatch, post-hatch, growth)	Pimephales promelas (fathead minnow)	>0.2 mg/L
	ErC_{50}/EbC_{50}	Pseudokirchneriella subcapitata (Algae)	>0.049 mg/L
	NOEC (72h) (yield, biomass, growth rate)	Pseudokirchneriella subcapitata (Algae)	0.049 mg/L
	EC_{10} (3h respiratory inhibition test)	Activated sludge microorganisms	≥1000 mg/L
	NOEC (3h respiratory inhibition test)	Activated sludge microorganisms	≥105 mg/L
Cellulose	--	--	--
Magnesium Stearate	--	--	--
Titanium dioxide	LC_{50}/48h	Leuciscus idus	>1000 mg/L

Additional toxicity information

Testing of environmental fate and effects has been performed on the major excretory metabolite of sofosbuvir, i.e., GS-331007, an inactive nucleoside. The following results were obtained:

- In a respiratory inhibition study, the compound is not considered inhibitory to activated sludge microorganisms at a concentration of 1000 mg/L.
- In an early life cycle study in fathead minnows, the No-Observed-Effect-Concentration (NOEC) was ≥10 mg/L.
- In a daphnia reproduction study, the 21 day NOEC for immobilization, reproduction and growth, was determined to be 26 mg/L.
- The compound did not have a significant effect on algal growth rate.
- The results of environmental fate studies indicated that GS-331007 would not be significantly degraded in sewage treatment facilities, or be removed from the aqueous phase *via* sorption to sewage biosolids.

Persistence and Degradability

Sofosbuvir (as GS-331007):
System DT_{50} (dissipation): 60-66 days
System DT_{50} (degradation): >100 days

Velpatasvir is not considered to be readily biodegradable:
System DT_{50}: 62.4-99.9 days
Sediment DT_{50} 109-136 days in sediment @ 20 °C

Bioaccumulative potential

Sofosbuvir: -0.417 (pH 4); 0.576 (pH 7); -1.28 (pH 9)
Velpatasvir - Log D 6.31 (pH 8)

Mobility in soil

The environmentally relevant residues of sofosbuvir (as GS-331007) and velpatasvir have disctinctly different fates in the environment. While sofosbuvir tends to remain in aqueous phase, velpatasvir dissipates rapidly in water but is somewhat persistent in sediment. However, although velpatasvir is considered to be somewhat persistent in sediment, it is indicated to have sufficiently low concentrations in the sediment environment that its toxicity is unlikely to present a risk to aquatic ecosystems. The PNEC in sediment was 41.43 mg/kg_{dwt}^{-1}.
Sediment degradation data suggests that these residues partition (to different degrees) to sediment (*e.g.*, >10% applied radioactivity shifted after 14 days).

Results of PBT and vPvB assessment

Sofosbuvir (as GS-331007): PBT not required.

Velpatasvir:

Persistence - P fulfilled
Bioaccumulation - Possibly B
Toxicity - T fulfilled

SECTION 12 - ECOLOGICAL INFORMATION …continued

Other adverse effects	The environmentally relevant residues of sofosbuvir and velpatasvir are essentially non-toxic to sewage microbes and will likely not interfere with the normal operation of sewage treatment facilities.
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	Mixture not fully tested - avoid exposure.
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	CA4 - Chronic Aquatic Toxicity Category 4. H413 - May cause long-lasting harmful effects to aquatic life.
Sources of data	Information from published literature and internal company data.
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	23 September 2016
Revisions	This is the second version of this SDS.

SECTION 16 - OTHER INFORMATION …continued

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.