

SAFETY DATA SHEET

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

Contact information

General



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Product identifier	Estradiol Valerate Injection, USP
Synonyms	Delestrogen
Trade names	Delesrogen®
Chemical family	Mixture - contains estradiol valerate (hormone)
Relevant identified uses of the substance or mixture and uses advised against	Bulk formulated pharmaceutical mixture/Formulated pharmaceutical product packaged in final form for patient use; indicated for the treatment of moderate to severe vasomotor symptoms and/or symptoms of vulvar and vaginal atrophy associated with menopause, hypoestrogenism, and advanced androgen-dependent carcinoma of the prostate.
Note	The physical, chemical, toxicological and ecological properties of this product/mixture has not been fully characterized. This SDS will be revisited as more data become available.
Issue Date	16 October 2014

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 Estradiol Valerate Injection, USP.**

SECTION 2 - HAZARDS IDENTIFICATION ...continued

Regulation (EC) 1272/2008 [GHS] Reproductive Toxicity - Category 1A. Carcinogenic - Category 1A. Aquatic toxicity (acute) - Category 1.

Directive 67/548/EEC or 1999/45/EC T: R45 (Carc. Cat. 1); R60 (Repr. Cat 1); R63 (Repr. Cat. 3); N: R50

Label elements

CLP/GHS hazard pictogram



CLP/GHS signal word

Danger

CLP/GHS hazard statements

H350 - May cause cancer. H360Fd - May damage fertility, Suspected of damaging the unborn child. H400 - Very toxic to aquatic life.

CLP/GHS precautionary statements

P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P273 - Avoid release to the environment. P281 - Use personal protective equipment as required. P308 + P313 - If exposed or concerned: get medical advice/attention. P391 - Collect spillage. P405 - Store locked up. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

EU symbol/indication of danger



T - Toxic



N - Dangerous for the environment

Risk (R) Phrase(s)

R45 - May cause cancer. R50 - Very toxic to aquatic organisms. R60 - May impair fertility. R63 - Possible risk of harm to the unborn child.

Safety Advice

S36/37 - Wear suitable protective clothing and gloves. S53 - Avoid exposure - Obtain special instructions before use. S60 - This material and its container must be disposed of as hazardous waste. S61 - Avoid release to the environment. Refer to special instructions/safety data sheets.

SECTION 2 - HAZARDS IDENTIFICATION ...continued

Other hazards	Estradiol valerate is an ester of a natural estrogen, 17 β -estradiol. Estrogens are steroid hormones that are largely responsible for the development and maintenance of the female reproductive system and secondary sexual characteristics. Adverse effects associated with estrogen therapy include changes in genitourinary system (e.g., changes in vaginal bleeding patterns, spotting, vaginitis); tenderness/pain/enlargement of breasts, galactorrhea, cardiovascular disturbances (e.g., deep vein thrombosis, pulmonary embolism, stroke, myocardial infarction), gastrointestinal disturbances (e.g., nausea, vomiting, abdominal pain), rash, unexpected hair loss or growth, headache, dizziness, mood disturbances, dementia, changes in libido, and metabolic changes (e.g., weight gain or loss, hypoglycemia, reduced carbohydrate tolerance). Estrogens are known to be human carcinogens and are associated with the development of a number of cancers including breast, ovarian, and endometrial cancers.
US Signal word	Danger
US Hazard overview	Contains estradiol valerate, a steroid hormone and benzyl benzoate. Cancer hazard - Can cause cancer. Reproductive hazard- Can cause damage fertility. Possible developmental hazard - may cause damage the unborn child. Very toxic to aquatic life.
Note	This mixture is classified as dangerous/hazardous according to directive 1999/45/EC, Regulation (EC) No 1272/2008 (EU CLP) and applicable US regulations. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 67/548/EEC or 1999/45/EC. The GHS classifications are based on Regulation (EC) 1272/2008. See Section 16 for full text of EU and GHS classifications.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>EU Classification</u>	<u>GHS Classification</u>
Benzyl benzoate	120-51-4	204-402-9	40-50%	Harmful - Xn: R22; Dang for Env - N: R50	ATO4: H302; AA1: H400
Estradiol valerate	979-32-8	213-559-2	1-4%	Toxic - T: R45; R60/63; Dang for Env - N: R51/ 53	Carc. 1A: H350; RT1A: H360Fd; CA2: H411
Benzyl alcohol	100-51-6	202-859-9	1-3%	Harmful - Xn: R20/22	ATO4: H302; AT14: H332

Note The ingredient(s) listed above are considered dangerous/hazardous. The remaining components are non-dangerous/not hazardous and/or present at amounts below reportable limits. See Section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.

SECTION 4 - FIRST AID MEASURES

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	Contains estradiol valerate, steroid hormone. Medical conditions aggravated by exposure: endometrial, breast, and ovarian cancer, as well as fertility, and menstrual and cardiovascular disorders. 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 fumes of carbon monoxide and carbon dioxide.
Flammability/Explosivity	No specific information identified for the product/mixture. Contains residual amounts of flammable materials. Keep away from heat, sparks and flame.
Advice for firefighters	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.

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. Do not breathe mist/spray.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	If vials are crushed or broken, DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper 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 vials are opened, crushed or broken, follow recommendations for handling potent pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed).
Conditions for safe storage including any incompatibilities	Store at controlled room temperature 20 to 25° C. Protect from light. Retain carton until time of use.
Specific end use(s)	No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Note Dispose of broken vials in a sharps container.

Control Parameters/ Occupational Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Benzyl benzoate	--	--	--
Estradiol valerate	--	--	--
Benzyl alcohol	AIHA	TWA-8 HR	10 ppm
	Bulgaria, Latvia	TWA-8 HR	5 mg/m ³
	Czech Republic	TWA-8 HR	40 mg/m ³
	Czech Republic	Ceiling	80 mg/m ³
	Lithuania	TWA-8 HR	5 mg/m ³ (skin)

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

**Control Parameters/
Occupational Exposure
Limit Values ...continued**

<u>Compound</u>	<u>Issuer</u> Poland	<u>Type</u> TWA-8 HR	<u>OEL</u> 240 mg/m ³
Exposure/Engineering controls	If handling bulk product or if vials are opened/crushed/broken: Control exposures to below the OEL of the active pharmaceutical ingredient. 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	If handling bulk product or if vials are opened/crushed/broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine handling tasks, an approved and properly worn powered air-purifying respirator equipped with appropriate 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 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.		
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered.		
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	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.		
Other protective measures	Wash hands in the event of contact with this mixture, 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**

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

Appearance	Liquid solution in pre-filled vial.
Color	Clear
Odor	Slightly fatty at room temperature.
Odor threshold	No information identified.
pH	4.8-5.2
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)	Not applicable.
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	Insoluble in water
Solvent solubility	No information identified.
Partition coefficient (<i>n</i>-octanol/water)	No information identified.
Auto-ignition temperature	No information identified.
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	Light sensitive
Possibility of hazardous reactions	No information identified.
Conditions to avoid	Avoid extreme temperatures.
Incompatible materials	No information identified.
Hazardous decomposition products	No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Note No toxicology data for the product/mixture were identified. 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>
Benzyl benzoate	LD ₅₀	Oral	Rat	1700 mg/kg
	LD ₅₀	Dermal	Rat	4000 mg/kg
	LD ₅₀	Oral	Rabbit	1680 mg/kg
	LD ₅₀	Dermal	Rabbit	4000 mg/kg
Estradiol valerate	LD ₅₀	Oral	Mouse	1400 mg/kg
	LD ₅₀	Oral	Mouse	> 3000 mg/kg
Benzyl alcohol	LC ₅₀	Inhalation	Rat	8.8 mg/L/4 hours
	LD ₅₀	Oral	Rat	1230 - 3100 mg/kg
	LD ₅₀	Dermal	Rabbit	2000 mg/kg
	LD ₅₀	Oral	Mouse	1150 - 1580 mg/kg

Irritation/Corrosion Benzyl alcohol was slightly irritating to rabbit skin and irritating to rabbit eyes. 17 β -estradiol was not a skin irritant in rabbits.

Sensitization Benzyl alcohol and 17 β -estradiol are not skin sensitizers in guinea pigs.

STOT-single exposure No studies identified.

STOT-repeated exposure/Repeat-dose toxicity No specific studies for estradiol valerate were identified. Administration of percutaneous 17 β -estradiol to female rats, at a dose of 0.5 g/animal/day for 13 weeks, resulted in the disappearance of a normal oestral cycle after 4 weeks and the appearance of a permanent oestrus after 12 weeks. A higher dose of 2.5 g/animal/day produced the disappearance of a normal oestral cycle after 2 weeks and the appearance of a permanent oestrus after 4 weeks. The estrogenic stimulation

SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

STOT-repeated exposure/Repeat-dose toxicity ...continued	resulted in a slight decrease in ovarian weight and a significant increase in uterine weight. Histological examination of 19 organs revealed no modification, which would imply a toxic effect.
Reproductive toxicity	No specific studies identified for estradiol valerate. Multi-generational reproductive study was carried out in rats with dietary administration of 0.1, 0.7 and 4 µg/kg/day of ethinyl estradiol. Ethinyl estradiol accelerated puberty and disrupted the estrous cycle in F1 and F2 females, and induced male mammary gland hyperplasia (F ₀ thorough F3) and mild mineralization of renal tubes (F1 and F2).
Developmental toxicity	<p>Estradiol administration to pregnant rats at doses ranging from 0.8-35 mg during the 12th to 19th day of gestation resulted in feminization of the external genitalia of male fetuses (further details not specified). Administration of estradiol to pregnant mice resulted in congenital malformations (cleft pate) and fetal toxicity (ovarian hyperplasia in females and ovotestes and intra-abdominal testes in males) at 1 mg and ≥0.2 mg/kg/day, respectively, on gestation days 11-17.</p> <p>Administration of benzyl benzoate at dietary doses up to 10,000 ppm to pregnant rats from gestation through day 21 of lactation did not result in any fetal or developmental toxicity.</p>
Genotoxicity	<p>17β-estradiol induced chromosomal aberrations in human embryonic cells, fibroblasts, and renal epithelial cells, but did not induced detectable chromosomal aberrations <i>in vivo</i> (rat bone marrow micronucleus assay).</p> <p>Benzyl benzoate was not genotoxic in the Ames bacterial mutagenicity assay.</p> <p>Benzyl alcohol was negative in a battery of <i>in vitro</i> and <i>in vivo</i> genotoxicity screening tests.</p>
Carcinogenicity	Benzyl alcohol was not carcinogenic to rats and mice orally treated with up to 400 and 200 mg/kg/day, respectively, for 5 days/week, for 2 years. Long-term continuous administration of natural and synthetic estrogens in certain animal species increases the frequency of carcinoma of the breast, cervix, vagina, and liver. Estorgens are classified as group 1 carcinogens by IARC and as known human carcinogens by NTP. 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.
Aspiration hazard	No data available.
Human health data	See Section 2 - "Other hazards"

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Benzyl benzoate	LC ₅₀ /96h	Danio rerio (zebra fish)	1.34 mg/L
	EC ₅₀ /72h	Algae	0.475 mg/L
	LC ₅₀ /24h	Gammarus fasciatus (fresh water shrimp)	9.8 mg/L
Estradiol valerate	LC ₅₀ /96h	Gammarus fasciatus (fresh water shrimp)	4.8 mg/L
	EC ₅₀ /24h	Daphnia magna	1.5 mg/L (17β-estradiol)
	LC ₅₀ /72h	Oryzias latipes (Japanese rice fish)	3.5 mg/L (17β-estradiol)
	EC ₅₀ /48h	Daphnia magna	2.87 mg/L (17β-estradiol)
Benzyl alcohol	EC ₅₀ /19 days	Fathead minnow	0.00012 mg/L (17β-estradiol)
	LC ₅₀ /48h	<i>Leuciscus idus</i> (freshwater fish)	646 mg/L
	LC ₅₀ /96h	Fathead minnow	460 mg/L
	EC ₅₀ /48h	Daphnia magna	≥100-360 mg/L
	EC ₅₀ /48h	Bacteria (<i>E.coli</i>)	1000 mg/L

Persistence and Degradability

Benzyl alcohol is readily biodegradable under aerobic and anaerobic conditions.

Bioaccumulative potential

The potential for bioaccumulation for estradiol in aquatic organisms is high, provided the compound is not metabolized by the organisms. Benzyl alcohol is not expected to bioaccumulate.

Mobility in soil

Estradiol is expected to be immobile in soil.

Results of PBT and vPvB assessment

Not performed.

Other adverse effects

No data identified.

Note

The environmental characteristics of this mixture have not been fully investigated. The above data are for the active ingredient and/or any other ingredient(s) where applicable. Releases to the environment should be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods

Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. 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 on-site wastewater treatment facility.

SECTION 14 - TRANSPORT INFORMATION

Transport	Based on the available data, this product/mixture is regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number	3077
UN proper shipping name	Environmentally Hazardous Substance, liquid, n.o.s (contains Lamotrigine)
Transport hazard classes and packing group	Hazard Class - 9; Packing Group III.
Environmental hazards	Based on the available data, this product/mixture is 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 complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local/regional authorities for more information.
Chemical safety assessment	Not conducted.
OSHA Hazardous	Danger. Contains estradiol valerate, a steroid hormone and benzyl benzoate. Cancer hazard - Can cause cancer. Reproductive hazard- Can cause damage fertility. Possible developmental hazard - may cause damage the unborn child. Very toxic to aquatic life.
WHMIS classification	Not required. Drugs are not subject to WHMIS. This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations. If this product/mixture were not a drug, it would be classified as: D2B - Toxic - Materials causing other toxic effects.
TSCA status	Drugs are exempt from TSCA.
SARA section 313	Not listed.
California proposition 65	Estradiol is listed as a carcinogen.
Additional information	No other information identified.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications

Xn - Harmful. R20/22 - Harmful by inhalation and if swallowed. R22 - Harmful if swallowed. T - Toxic. Carc. Cat. 1 - Carcinogenic Category 1. R45 - May cause cancer. Repr. Cat. 1 - Toxic for reproduction Category 1. R60 - May impair fertility. R63 - Possible risk of harm to the unborn child. N - Dangerous for the Environment. R50 - Very toxic to aquatic organisms. R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Full text of H phrases, P phrases and GHS classification

ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. AT14 - Acute Toxicity (Inhalation) Category 4. H332 - Harmful if inhaled. Carc1 - Carcinogenicity Category 1 (1A). H350 - May cause cancer. RT1A - Reproductive toxicity Category 1A. H360Fd - May damage fertility. Suspected of damaging the unborn child. H336 - May cause drowsiness or dizziness. AA1 - Acute aquatic toxicity Category 1. H400 - Very toxic to aquatic life. CA2 - Chronic Aquatic Toxicity Category 2. H411 - Toxic to aquatic life with long lasting effects.

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; 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; 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

Revisions

This is the first 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

SECTION 16 - OTHER INFORMATION ...continued

Disclaimer ...continued

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.