SAFETY DATA SHEET

ISSUE DATE: AUGUST 26, 2016

The information contained herein is not intended for therapeutic or patient use. Please refer to package insert for therapeutic and prescribing information. For other applications, the information provided is believed to be complete and accurate at the time of issue. This document provides occupational health, safety, and environmental data applicable in manufacturing, industrial and workplace settings. It is not a specification sheet and none of the displayed data or lack of data should be construed as a specification. Forest Laboratories Inc., and its subsidiaries assume no liability or responsibility resulting from the use or reliance on this information.

SECTION 1: IDENTIFICATION OF SUBSTANCE/MIXTURE AND COMPANY INFORMATION

PRODUCT NAME: Viibryd

SYNONYMS: Vilazodone - EMD 68843, SB 659746, SB 659746A, 5-{4-[4-(5-Cyano-3-indolyl)-butyl] 1-piperazinyl} -benzofuran-2 carboxamide hydrochloride

PRODUCT CODES:

RESPONSIBLE PARTY U.S.:
Allergan
400 Interpace Parkway, Morris Corporate Center III
Parsippany, NJ 07054, USA

U.S. ADDRESS:

U.S. BUSINESS PHONE/GENERAL SDS INFORMATION: 1-800-272-5525

RESPONSIBLE PARTY EUROPE:

EUROPEAN ADDRESS:

EUROPEAN BUSINESS PHONE:

EMERGENCY PHONE (U.S./NORTH AMERICA): CHEMTREC: 1-800-424-9300 (24 hours) U.S., Canada, Puerto Rico

EMERGENCY PHONE (OUTSIDE U.S.): CHEMTREC: +1-703-527-3887 (24 hours) Outside North America

Email: SDS@allergan.com

CHEMICAL NAME: Vilazodone Hydrochloride

CHEMICAL FAMILY: Indolealkylamine (Vilazodone)

CHEMICAL FORMULA: Mixture, final oral solid dosage tablet.

PRODUCT USE: Pharmaceutical product

PREPARED BY: Environmental Health and Safety Department
## SECTION 2: HAZARDS IDENTIFICATION

<table>
<thead>
<tr>
<th>Compound</th>
<th>Issuer</th>
<th>Type</th>
<th>OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ACGIH, Australia, Belgium, Estonia, France, Portugal, Romania, Singapore, Spain</td>
<td>TWA-8 HR</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Ireland, United Kingdom</td>
<td>TWA-8HR</td>
<td>10 mg/m³ (inhalable dust); 4 mg/m³ (respirable dust)</td>
</tr>
<tr>
<td></td>
<td>Ireland</td>
<td>STEL</td>
<td>20 mg/m³ (total inhalable dust)</td>
</tr>
<tr>
<td></td>
<td>Latvia</td>
<td>TWA-8 HR</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Mexico</td>
<td>TWA-8 HR/STEL</td>
<td>10/20 mg/m³</td>
</tr>
<tr>
<td></td>
<td>NIOSH</td>
<td>TWA-8 HR</td>
<td>10 mg/m³ (total dust); 5 mg/m³ (respirable dust)</td>
</tr>
<tr>
<td></td>
<td>OSHA</td>
<td>TWA-8 HR</td>
<td>15 mg/m³ (total dust); 5 mg/m³ (respirable fraction)</td>
</tr>
<tr>
<td></td>
<td>United Kingdom</td>
<td>STEL</td>
<td>20 mg/m³ (inhalable dust); 12 mg/m³ (respirable dust)</td>
</tr>
</tbody>
</table>

### Vilazodone

<table>
<thead>
<tr>
<th></th>
<th>ppm</th>
<th>mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL-TWA:</td>
<td>Not Established</td>
<td>Not established</td>
</tr>
<tr>
<td>OSHA PEL STEL:</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
<tr>
<td>OSHA PEL CEILING:</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
</tbody>
</table>

ACGIH TLV-TWA: Not Established
ACGIH TLV STEL: Not Established
ACGIH TLV CEILING: Not Established

Occupational Exposure Limit (OEL): Not Established

### Cellulose

<table>
<thead>
<tr>
<th></th>
<th>ppm</th>
<th>mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL-TWA:</td>
<td>.77 PPM</td>
<td>15 mg/m³ (dust); 5mg/m³ (respirable dust)</td>
</tr>
<tr>
<td>PEL STEL:</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
<tr>
<td>OSHA PEL CEILING:</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
<tr>
<td>ACGIH TLV-TWA:</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
<tr>
<td>ACGIH TLV STEL:</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
<tr>
<td>ACGIH TLV CEILING:</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
</tbody>
</table>

Occupational Exposure Limit (OEL): 10 mg/m³ (total)
5 mg/m³ resp.)
SIGNAL WORD: Attention

US HAZARD OVERVIEW: Possible developmental hazard - May adversely affect the developing fetus (based on effects in animals at moderate to high doses). Overexposure may cause gastrointestinal (nausea, diarrhea, dry mouth, vomiting), psychiatric (insomnia, abnormal dreams, anxiety, nightmares), and nervous system (headache, dizziness, somnolence, tremor) effects. If tablets are crushed/broken: Dust clouds are sensitive to electrostatic ignition. Ignition of dust clouds produces a strong explosion.

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.

REGULATION (EC) 1272/2008 [GHS]: Not Required
DIRECTIVE 67/548/EEC OR 1999/45/EC: Not Required

LABEL ELEMENTS/CLP/GHS HAZARD PICTOGRAM: Not Required
CLP/GHS SIGNAL WORD: Not Required
CLP HAZARD STATEMENT: Not Required
CLP/GHS PERCAUTIONARY STATEMENTS: Not Required

OTHER HAZARDS: In the dose range most commonly tested of between 10 and 100 mg/day by oral administration, the most frequently reported adverse effects included gastrointestinal (nausea, diarrhea, dry mouth, vomiting), psychiatric (insomnia, abnormal dreams, anxiety, nightmares), and nervous system (headache, dizziness, somnolence, tremor).

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: Not tested.

CARCINOGENICITY
OSHA: Not tested.
ACGIH: Not tested.
NTP: Not tested.
IARC: Not tested.

SECTION 2 NOTES: 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.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>EINECS/ELINCS</th>
<th>CAS Number</th>
<th>EU Classification</th>
<th>Concentration</th>
<th>GHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vilazodone Hydrochloride</td>
<td>N/A</td>
<td>163521-08-2</td>
<td>Harmful - Xn:R63</td>
<td>5-15%</td>
<td>R12:H361d</td>
</tr>
<tr>
<td>Cellulose</td>
<td>232-674-9</td>
<td>9004-34-6</td>
<td>Not Classified</td>
<td>10-30%</td>
<td>Not Classified</td>
</tr>
</tbody>
</table>

SECTION 3 NOTES: The ingredient listed above is considered dangerous/hazardous by EU and EU-CLP/GHS classifications. See section 16 for full text of EU and EU-CLP/GHS classifications.

SECTION 4: FIRST AID MEASURES

IMMEDIATE MEDICAL ATTENTION NEEDED: Yes

EYES: If easy to do so, 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: Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, 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.

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.
MOST IMPORTANT SYMPTOMS AND EFFECTS, ACUTE AND DELAYED:
See Sections 2 and 11

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED, IF NECESSARY:
Contains vilazodone which is a selective serotonin reuptake inhibitor with additional 5-hydroxytryptamine-1A partial agonist properties. Medical conditions aggravated by exposure: Incompatible with monoamine oxidize inhibitors. Treat symptomatically and supportively. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package insert or prescribing information for potential drug interactions.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: 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: FIRE-FIGHTING MEASURES

<table>
<thead>
<tr>
<th>FLAMMABLE LIMITS IN AIR (% BY VOLUME)</th>
<th>UPPER Explosive Limit (UEL):</th>
<th>Not Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOWER Explosive Limit (LEL):</td>
<td>Not Tested</td>
<td></td>
</tr>
</tbody>
</table>

**FLASH POINT**
- F: Not Tested
- C: Not Tested

**Method Used:** Not Tested

**AUTOIGNITION TEMPERATURE:**
- F: Not Tested
- C: Not Tested

**Method Used:** Not Tested

**EXTINGUISHING MEDIA:** Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.

**FLAMMABILITY/EXPLOSIVITY:** Not tested. The flammability of this material has not been determined. As with many organic dusts, explosions can occur if this material is dispersed as a dust cloud and ignited

**UNUSUAL FIRE AND EXPLOSION HAZARDS:** Not tested. May emit toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, and chlorine-containing compounds.

**ADVICE FOR FIREFIGHTERS:** Wear full protective clothing and a self-containing breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use. Use special protective equipment. Keep containers cool with water spray if necessary.

**HAZARDOUS COMBUSTION PRODUCTS:** Not tested. Toxic, corrosive or flammable thermal decomposition products are expected when the material is exposed to fire.
SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: 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 dust.

ENVIRONMENTAL PRECAUTIONS: Do not empty into drains. Avoid release to the environment.

CLEAN-UP METHODS: If tablets 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 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).

DECONTAMINATION PROCEDURES: No specified decontamination or detoxification procedures have been identified for this material. Consider use of water, detergent solutions, or other soluble solvents for clean-up and decontamination operations.

SECTION 7: HANDLING AND STORAGE

GENERAL 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 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. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures.

STORAGE: Store at 25°C away from incompatible materials and ignition sources; excursions permitted between 15 and 30°C. Keep container upright and tightly closed. Keep away from moisture and heat. Store locked up.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

FOREST OCCUPATIONAL HEALTH CATEGORIZATION SUMMARY: Category Occupational Health

Categorization:
Material is assigned to Exposure Control Band 2 of 4, based on the therapeutic dose range (an indicator of pharmacological potency), its mechanism of action, and the relatively benign nature of observed clinical effects (e.g., diarrhea, nausea, headache, and insomnia) as well as the nonclinical toxicity profile. Although consideration was given to potential developmental/neonatal effects (based on the pharmacological class), no compound-specific data were identified. Consult manufacturer for more information.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Issuer</th>
<th>Type</th>
<th>Control Band</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vilazodone HCL</td>
<td>Forest Laboratories, Inc.</td>
<td>Dust</td>
<td>2 of 4 in a 4 category system</td>
</tr>
</tbody>
</table>

EXPOSURE/ENGINEERING CONTROLS AND VENTILATION: None required for normal handling of packaged product. If tablets are crushed or broken: Control exposures to below the OEL. 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 tablets 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 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.

EYE PROTECTION: None required for normal handling of packaged product. 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.

HAND/ARM/SKIN PROTECTION: None required for normal handling of packaged product. Wear nitrile or other impervious gloves if skin contact is possible. None required for normal handling of packaged product. Wear appropriate gloves, lab coat, or other protective over garment 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.
HYGIENE: Not tested

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 NOTES: Wash hands, face and other potentially exposed areas immediately in the event of physical contact. 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).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHYSICAL STATE:</td>
<td>Solid</td>
</tr>
<tr>
<td>PHYSICAL FORM:</td>
<td>Tablet</td>
</tr>
<tr>
<td>COLOR:</td>
<td>Pink, Orange, or Blue</td>
</tr>
<tr>
<td>ODOR:</td>
<td>Not tested</td>
</tr>
<tr>
<td>ODOR THRESHOLD:</td>
<td>Not tested</td>
</tr>
<tr>
<td>EMPirical FORMula:</td>
<td>Not tested</td>
</tr>
<tr>
<td>MOLECULAR WEIGHT:</td>
<td>Not tested</td>
</tr>
<tr>
<td>BOILING POINT:</td>
<td>Not tested</td>
</tr>
<tr>
<td>EVAPORATION RATE:</td>
<td>Not tested</td>
</tr>
<tr>
<td>MELTING POINT:</td>
<td>283-285°C (Vilazodone)</td>
</tr>
<tr>
<td>FREEZING POINT:</td>
<td>283-285°C (Vilazodone)</td>
</tr>
<tr>
<td>VAPOR PRESSURE:</td>
<td>Not tested</td>
</tr>
<tr>
<td>VAPOR DENSITY:</td>
<td>Not tested</td>
</tr>
<tr>
<td>RELATIVE DENSITY:</td>
<td>Not tested</td>
</tr>
<tr>
<td>SPECIFIC GRAVITY:</td>
<td>Not tested</td>
</tr>
<tr>
<td>WATER SOLUBILITY:</td>
<td>32 mg/100 mL (Vilazodone)</td>
</tr>
<tr>
<td>SOLVENT SOLUBILITY:</td>
<td>Ethanol- 31 mg/100 mL, Methanol-116/100mL (Vilazodone)</td>
</tr>
<tr>
<td>COEFFICIENT OF WATER/OIL DISTRIBUTION:</td>
<td>Not tested</td>
</tr>
<tr>
<td>DECOMPOSITION TEMPERATURE:</td>
<td>Not tested</td>
</tr>
<tr>
<td>VOLATILITY:</td>
<td>Not tested</td>
</tr>
<tr>
<td>VISCOSITY:</td>
<td>Not tested</td>
</tr>
<tr>
<td>pH:</td>
<td>Not tested</td>
</tr>
</tbody>
</table>

SECTION 9 NOTES:
SECTION 10: STABILITY AND REACTIVITY

STABILITY: Chemically stable; pharmacological stability not guaranteed beyond expiration date imprinted on package.

CONDITIONS TO AVOID: Avoid dispersion as a dust cloud. Avoid contact with heat, sparks, flames, or other ignition sources. Avoid direct sunlight and conditions that might generate heat.

INCOMPATIBILITY (MATERIALS TO AVOID): Not tested

HAZARDOUS POLYMERIZATION: Not tested

REACTIVITY: Not tested

POSSIBILITY OF HAZARDOUS REACTION: Not tested.

HAZARDOUS DECOMPOSITION PRODUCTS: Not tested

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICITY DATA: No data was identified for the formulated product. The hazards are considered to be similar to those of Vilazodone Hydrochloride, the active ingredient in Viibryd. THE TOXICOLOGY DATA BELOW IS FOR VILAZODONE HYDROCHLORIDE.

ACUTE TOXICITY:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Type</th>
<th>Route</th>
<th>Species</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>LD50</td>
<td>Oral</td>
<td>Rat</td>
<td>&gt;5000</td>
</tr>
<tr>
<td></td>
<td>LC50</td>
<td>Inhalation</td>
<td>Rat</td>
<td>&gt;5800</td>
</tr>
<tr>
<td></td>
<td>LD50</td>
<td>Oral</td>
<td>Rat</td>
<td>&gt;5000</td>
</tr>
<tr>
<td></td>
<td>LD50</td>
<td>Dermal</td>
<td>rabbit</td>
<td>&gt;2000</td>
</tr>
</tbody>
</table>

ROUTES OF ENTRY: If tablets are crushed or broken; May be absorbed by inhalation, skin contact, and ingestion. Tablets can be absorbed via ingestions.

IRRITATION/CORROSION: Vilazodone was slightly irritating to the rabbit's eyes and non-irritating to rabbit's skin.

SENSITIZATION: No skin sensitization was observed in guinea pigs.

STOT-SINGLE EXPOSURE: No data available

STOT-REPEATED EXPOSURE/DOSE TOXICITY: Mouse, 13-week oral: NOEL = 45 mg/kg/day. Target organs included the liver, spleen, lymph nodes and female mammary gland and genital system. Dog, 52-week oral: NOAEL = 10 mg/kg/day. NOEL = 2.5 mg/kg/day. Target organs included the eyes (generally reversible). Rat, 26 week oral: NOAEL = 15 mg/kg/day. Target organs included the mammary gland.

REPRODUCTIVE DATA: Female - NOAEL = 125 mg/kg/day. Male - NOEL = 25 mg/kg/day. Marginal effects on fertility in males were seen at 125 mg/kg/day.

DEVELOPMENTAL DATA: No teratogenicity was observed in oral developmental toxicity studies in rats and rabbits. At moderate to high doses or at doses generally associated with some maternal toxicity, other developmental effects (decreased fetal weight, weaker/ delayed skeletal ossifications, post-implantation loss) were observed. Rat, Embryofetal development - F0 Female NOAEL = 40 mg/kg/day. F1 NOEL = 40 mg/kg/day. Rabbit, Embryofetal development - F0 Female NOAEL = 10 mg/kg/day. F1 NOEL = 2 mg/kg/day. Rat, Pre-and Postnatal development - F0 Female NOAEL = 5 mg/kg/day. F1 NOEL = 5 mg/kg/day.

MUTAGENIC/GENOTOXICITY DATA: Vilazodone caused chromosomal aberrations in two in vitro tests, but only at concentrations that were cytotoxic. It was negative in two in vitro tests for mutagenicity and a test for the induction of p53 response elements in mammalian cells. Vilazodone was negative in three in vivo tests for genotoxicity.
CARCINOGENICITY DATA: No evidence of an increased cancer risk was observed in rats at oral doses as high as 150 mg/kg/day. An increased incidence of several tumor types was observed in mice treated with oral doses ranging from 15-135 mg/kg/day, however these effects are of questionable clinical relevance and/or may be related to species-specific effects. This substance is not listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

ASPIRATION HAZARD DATA: Not tested.

HUMAN HEALTH DATA: See Section 2

SECTION 11 NOTES:

SECTION 12: ECOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Compound</th>
<th>Type</th>
<th>Species</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vilazodone Hydrochloride</td>
<td>Formulated product not tested</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

PERSISTENCE AND DEGRADABILITY: Formulated product not tested

BIOACCUMULATIVE POTENTIAL: Formulated product not tested

MOBILITY IN SOIL: Formulated product not tested

RESULTS OF PBT AND vPvB ASSESSMENT: Formulated product not tested

ECOLOGICAL INFORMATION: Do not allow materials to enter sewage system, surface water or groundwater. Do not discharge unused or waste materials to drains. Drum wastewaters for proper disposal. Packaging and materials that have contacted Vilazodone and cannot be cleaned should be treated as product waste.

OTHER ADVERSE EFFECTS: Not tested

SECTION 12 NOTES:

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Substance should be disposed according to local, state, and federal regulations. 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. 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.

RCRA HAZARD CLASS: Not Regulated.

SECTION 14: TRANSPORT INFORMATION

TRANSPORT: Based on the available data, this substance is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG

U.S. DEPARTMENT OF TRANSPORTATION PROPER SHIPPING NAME: Not Regulated

Hazard Class: Not Regulated

ID NUMBER: PACKING GROUP: LABEL STATEMENT:

WATER TRANSPORTATION PROPER SHIPPING NAME:
HAZARD CLASS: Not Regulated
ID NUMBER:
PACKING GROUP:
LABEL
STATEMENT:

AIR TRANSPORTATION
PROPER SHIPPING NAME:
HAZARD CLASS: Not Regulated
ID NUMBER:
PACKING GROUP:
LABEL
STATEMENT:

TRANSPORTATION IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE
IBC CODE SHIPMENT QUANTITY:
PROPER SHIPPING NAME: Not Regulated
HAZARD CLASS:
ID NUMBER:
PACKING GROUP:
LABEL
STATEMENT:

OTHER AGENCIES:

SECTION 14 NOTES:

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. Drugs packaged for final use by the patient/consumer are not subject to labeling in the US, EU or Canada. Please consult the prescribing/packaging information. Consult your local or regional authorities for more information.

U.S. FEDERAL REGULATIONS
TSCA (TOXIC SUBSTANCE CONTROL ACT): Drugs are exempt from TSCA
OSHA HAZARDOUS: Not Required
CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): Not identified.
SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT): Not identified.
311/312 HAZARD CATEGORIES: Not identified.
313 REPORTABLE INGREDIENTS: Not identified.
CALIFORNIA PROPOSITION 65: Not identified.

WHIMS 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.

SECTION 15 NOTES:
SECTION 16: OTHER INFORMATION

FULL TEXT OF R PHRASES AND EU CLASSIFICATIONS: Xn - Harmful. R63 - Possible risk of harm to the unborn child. Repr. Cat. 3 - Toxic for Reproduction Category 3.

FULL TEXT OF H PHRASES, P PHRASES, AND GHS CLASSIFICATION: RT2 - Reproductive toxicity Category 2. H361d - Suspected of damaging the unborn child.

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

SOURCES OF DATA: Information retrieved from published literature and internal company data.

REVISIONS: 1.0

DISCLAIMER: The information contained herein is not intended for therapeutic or patient use. Please refer to package insert and for therapeutic and prescribing information. For other applications, the information provided is believed to be complete and accurate at the time of issue. This document provides occupational health, safety, and environmental data applicable in manufacturing, industrial and workplace settings. It is not a specification sheet and none of the displayed data or lack of data should be construed as a specification. Forest Laboratories Inc., and its subsidiaries assume no liability or responsibility resulting from the use or reliance on this information.

END OF DOCUMENT