SAFETY DATA SHEET

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

Contact information

General
Alkermes, Inc.
852 Winter Street
Waltham, MA 02451
Main: +1 (781) 609-6000
E-mail: SDScoordinator@alkermes.com

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

Product identifier
VIVITROL® (naltrexone for extended-release injectable suspension)

Trade names
VIVITROL®

Chemical family
Mixture - contains an opioid antagonist

Active ingredient
Naltrexone base anhydrous

Chemical name of active ingredient
(17-(cyclopropylmethyl)-4,5-alpha-epoxy-3,14-dihydroxy- morphaninan-6-one

Relevant identified uses of the substance or mixture and uses advised against
Formulated pharmaceutical product packaged in final form for administration to patients; indicated for the treatment of alcohol and opioid dependence.

Note
This SDS has been developed to meet OSHA requirements. It is intended to classify potential hazards associated with exposure to the drug product; identify appropriate protective measures for exposure; and make such information available for communication to address potential worker health and safety issues associated with exposure to the material.

For information on the risks associated with use of the pharmaceutical product, including risks associated with administration, handling and storage, please consult the FDA-approved Prescribing Information and Medication Guide for VIVITROL.
SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Regulation (EC) Specific Target Organ Toxicity (single exposure) - Category 3.
1272/2008 [GHS]


Label elements

CLP/GHS hazard pictogram

CLP/GHS signal word Warning

CLP/GHS hazard statements H336 - May cause drowsiness or dizziness.

CLP/GHS precautionary statements P261 - Avoid breathing dust. P271 - Use only outdoors or in a well-ventilated area. P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P312 - Call a Poison Center or doctor/physician if you feel unwell. P403 + P233 - Store in a well-ventilated place. Keep container tightly closed. P405 - Store locked up. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

EU symbol/indication of danger None required

Risk (R) Phrase(s) R67 - May cause drowsiness and dizziness.

Safety Advice S22 - Do not breathe dust. S36/37 - Wear suitable protective clothing and gloves.

Other hazards The most common adverse effects associated with the therapeutic use of VIVITROL® include gastrointestinal disturbances (nausea, vomiting, and abdominal pain), injection site reactions (pruritus, nodules, and swelling), muscle cramps, dizziness or syncope, drowsiness or sedation, and decreased appetite. Other effects reported with naltrexone include headache, fatigue, sleepiness, low energy, anxiety, and rash.

Consumption of ethanol may cause CNS depression, liver toxicity and adverse fetal effects when ingested by pregnant women, but this is not applicable with normal use of the product.

US Signal word Attention

US Hazard overview Contains naltrexone, an opioid antagonist. May cause dizziness and drowsiness.

NFPA System Health = 1 Flammability = 1 Reactivity = 0
SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS #</th>
<th>EINECS/ELIN CS#</th>
<th>Amount</th>
<th>EU Classification</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naltrexone</td>
<td>16590-41-3</td>
<td>240-649-9</td>
<td>~34%</td>
<td>Harmful - Xn: R22; R67</td>
<td>ATO4: H302; STOT-R3: H336 FL2: H225</td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>~1.5%</td>
<td>Highly flammable - F: R11</td>
<td>ATO4: H302; ATI4: H332</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>~1.0%</td>
<td>Harmful - Xn: R20/22</td>
<td>-</td>
</tr>
</tbody>
</table>

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 naltrexone, an opioid antagonist. Medical conditions aggravated by exposure: Liver disorders, opioid dependence, and hypersensitivity. Treat symptomatically and supportively. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective pharmaceutical product 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 fumes of carbon monoxide, carbon dioxide and oxides of nitrogen.

Flammability/Explosivity
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
Remove ignition sources. If material 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.

Methods and material for containment and cleaning up
If vials are crushed or 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. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice.

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 formulated pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling.

Conditions for safe storage including any incompatibilities
Store refrigerated between 2 to 8°C to ensure product viability. Keep away from incompatible materials and ignition sources. Keep in tightly sealed containers in a well-ventilated area.

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

**Naltrexone**

<table>
<thead>
<tr>
<th>Issuer</th>
<th>Type</th>
<th>OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkermes</td>
<td>TWA-8 hrs</td>
<td>2.5 mcg/m³</td>
</tr>
</tbody>
</table>

**Ethanol**

<table>
<thead>
<tr>
<th>Issuer</th>
<th>Type</th>
<th>OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH, NIOSH</td>
<td>TWA-8hrs</td>
<td>1000 ppm</td>
</tr>
<tr>
<td>NIOSH</td>
<td>IDLH</td>
<td>3300 ppm</td>
</tr>
</tbody>
</table>

**Benzyl Alcohol**

<table>
<thead>
<tr>
<th>Issuer</th>
<th>Type</th>
<th>OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIHA</td>
<td>TWA-8hrs</td>
<td>10 ppm</td>
</tr>
</tbody>
</table>

**Exposure/Engineering controls**

If vials are opened/crushed/broken: Control exposures to below the OEL (if available). 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, or particle sizing should be done within an approved emission control or containment system.

**Respiratory protection**

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 powder handling tasks, 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.

**Hand protection**

If vials are opened/crushed/broken: Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

**Skin protection**

If vials are opened/crushed/broken: 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.
SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION…continued

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 material, 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>VIVITROL is supplied in single-use cartons. Each carton contains one 380-mg vial of VIVITROL microspheres.</td>
</tr>
<tr>
<td>Color</td>
<td>Off-white to light tan powder (naltrexone)</td>
</tr>
<tr>
<td>Odor</td>
<td>No information identified.</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information identified.</td>
</tr>
<tr>
<td>pH</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>168-170°C (naltrexone)</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No information identified.</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td>No information identified.</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No information identified</td>
</tr>
<tr>
<td>Vapor density</td>
<td>No information identified</td>
</tr>
<tr>
<td>Relative density</td>
<td>No information identified</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Sparingly soluble in water (naltrexone)</td>
</tr>
<tr>
<td>Solvent solubility</td>
<td>No information identified</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
<td>No information identified</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No information identified</td>
</tr>
</tbody>
</table>
SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

- Decomposition temperature: No information identified.
- Viscosity: No information identified.
- Explosive properties: No information identified.
- Oxidizing properties: No information identified.

Other information
- Molecular weight: 65-95 kDaltons (341.4 g/mol for naltrexone anhydrous)
- Molecular formula: C_{20}H_{23}NO_4 (naltrexone anhydrous)

SECTION 10 - STABILITY AND REACTIVITY

- Reactivity: No information identified.
- Chemical stability: Chemically stable; pharmacological stability not guaranteed beyond expiration date imprinted on package.
- 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…continued

<table>
<thead>
<tr>
<th>Compound</th>
<th>Type</th>
<th>Route</th>
<th>Species</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Oral</td>
<td>Rat</td>
<td>7060 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Oral</td>
<td>Mouse</td>
<td>3400 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LC&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Inhalation</td>
<td>Rat</td>
<td>20000 ppm/10 hours</td>
</tr>
<tr>
<td></td>
<td>LC&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Inhalation</td>
<td>Mouse</td>
<td>39 g/m&lt;sup&gt;3&lt;/sup&gt;/4 hours</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>LC&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Inhalation</td>
<td>Rat</td>
<td>8.8 mg/L/4 hours</td>
</tr>
<tr>
<td></td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Oral</td>
<td>Rat</td>
<td>1230 - 3100 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Dermal</td>
<td>Rabbit</td>
<td>2000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Oral</td>
<td>Mouse</td>
<td>1150 - 1580 mg/kg</td>
</tr>
</tbody>
</table>

**Irritation/Corrosion**

Naltrexone is not irritating to the skin of guinea pigs. Benzyl alcohol was slightly irritating to rabbit skin and irritating to rabbit eyes. Ethanol is a skin and eye irritant in animals.

**Sensitization**

Naltrexone and benzyl alcohol were negative for sensitization in guinea pigs.

**STOT-single exposure**

In the acute toxicity studies with rats, mice, and dogs (LD<sub>50</sub> values listed above), deaths were the result of clonic-tonic convulsions and/or respiratory failure following naltrexone administration.

**STOT-repeated exposure/Repeat-dose toxicity**

No significant findings were seen in dogs orally treated with naltrexone at up to 40 mg/kg/day for 90 days; an increase in vomiting was noted at doses ≥100 mg/kg/day.

NOAELs of ≥400 and ≥200 mg/kg/day were identified in rats and mice, respectively, orally treated with benzyl alcohol in repeat-dose toxicity studies for 2 years; higher doses affected body weight, and caused lesions of the brain, thymus, skeletal muscle, and kidneys.

**Reproductive toxicity**

An increased incidence of pseudopregnancy and decrease in pregnancy rate was noted in female rats orally treated with 100 mg/kg/day naltrexone in a fertility study; no effects were seen in male rats at the same dose.

**Developmental toxicity**

An increased incidence of early fetal loss was seen in rats and rabbits orally treated with ≥30 and ≥60 mg/kg/day naltrexone, respectively. However, no teratogenicity was observed in the surviving rat and rabbit offspring at oral doses up to 200 mg/kg/day.

A NOAEL of 550 mg/kg/day for benzyl alcohol was identified in an oral developmental toxicity study with mice.
SECTION 11 - TOXICOLOGICAL INFORMATION…continued

Genotoxicity

Naltrexone was not genotoxic in bacterial, mammalian, or tissue culture systems, which included the Ames test, heritable translocations assay, sister chromatid exchange assay in Chinese hamster ovary cells, a mouse lymphoma assay, and in vivo mouse micronucleus assay. In contrast, naltrexone tested positive in the following assays: Drosophila recessive lethal frequency assay, non-specific DNA damage in repair tests with E.Coli and WI-38 cells, and urinalysis for methylated histidine residues.

Ethanol was positive in a number of genotoxicity assays. These effects may be due to a metabolite, acetaldehyde. Benzyl alcohol was negative in a battery of in vitro and in vivo genotoxicity screening tests.

Carcinogenicity

In 2-year carcinogenicity studies with rats and mice, no tumors were seen following oral treatment with naltrexone at doses up to 30 and 100 mg/kg/day, respectively. In rats, small increases in the incidence of testicular mesotheliomas in males and vascular tumors in males and females were noted at 100 mg/kg/day. Except for the vascular tumors in males, the incidences of these tumors exceeded the range seen in historical control groups.

Ethanol is considered a confirmed animal carcinogen with unknown relevance to humans by ACGIH and consumption of alcohol is listed by IARC as a group 1 carcinogen (carcinogenic to humans). 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. 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

<table>
<thead>
<tr>
<th>Compound</th>
<th>Type</th>
<th>Species</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naltrexone</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Ethanol</td>
<td>LC₅₀/96h</td>
<td>Rainbow trout</td>
<td>12900 mg/L (flow through)</td>
</tr>
<tr>
<td>Ethanol</td>
<td>LC₅₀/96h</td>
<td>Fathead minnow</td>
<td>15000 mg/L</td>
</tr>
<tr>
<td>Ethanol</td>
<td>EC₅₀/48h</td>
<td>Daphnia magna</td>
<td>9268 mg/L</td>
</tr>
<tr>
<td>Ethanol</td>
<td>EC₅₀/5-30 min</td>
<td>Photobacterium phosphoreum</td>
<td>~35000 mg/L</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>LC₅₀/48h</td>
<td>Leuciscus idus (freshwater fish)</td>
<td>646 mg/L</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>LC₅₀/96h</td>
<td>Fathead minnow</td>
<td>460 mg/L</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>EC₅₀/48h</td>
<td>Daphnia magna</td>
<td>≥100-360 mg/L</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>EC₅₀/48h</td>
<td>Bacteria (E.coli)</td>
<td>1000 mg/L</td>
</tr>
</tbody>
</table>
SECTION 12 - ECOLOGICAL INFORMATION…continued

Persistence and Degradability  Benzyl alcohol and ethanol are readily biodegradable under aerobic and anaerobic conditions.

Bioaccumulative potential  Naltrexone and benzyl alcohol are not expected to bioaccumulate.

Mobility in soil  Naltrexone is expected to be highly mobile in soil.

Results of PBT and vPvB assessment  Not performed.

Other adverse effects  No data identified.

Note  No ecological information is available on VIVITROL®. The ecology data above are for its ingredient.

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 and in compliance with applicable environmental laws, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

SECTION 14 - TRANSPORT INFORMATION

Transport  Based on the available data, this product 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 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 MARPOL 73/78 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 current applicable regulations in the US and generally complies with relevant regulations in EU and Canada. Consult your local or regional authorities for more information.

**Chemical safety assessment**

Not conducted.

**OSHA Hazardous**

Yes. Attention. May cause dizziness or drowsiness.

**WHMIS classification**

Not required. 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.

**SARA section 313**

Not listed.

**California proposition 65**

Ethanol as contained in alcoholic beverages (and consumed) is listed as a reproductive toxicant, but this is not applicable with normal use of this product.

**Additional information**

No other information identified.

### SECTION 16 - OTHER INFORMATION

**Full text of R phrases and EU Classifications**


**Full text of H phrases, P phrases and GHS classification**


**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

3rd.

Limitations

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 exposures and 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 associated with the use of the material. 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 known 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.

Caution should be used in the handling and use of the material because it is a pharmaceutical product. For information on the risks associated with use of the product, including risks associated with administration, handling and storage, please consult the FDA-approved Prescribing Information and Medication Guide for VIVITROL.