1. IDENTIFICATION

Products: Dextroamphetamine Sulfate Tablets 5 mg and 10 mg

Recommended Use of the Chemical and Restrictions On Use: Pharmaceutical Product, Treatment of narcolepsy and attention deficit disorder.

Manufacturer: Nesher Pharmaceuticals (USA) LLC
13910 St Charles Rock Road
Earth City, MO. 63044
Phone: 314-209-4700

Emergency Phone Number: 314-209-4700

2. HAZARDS IDENTIFICATION

Classification:

<table>
<thead>
<tr>
<th>Health</th>
<th>Environmental</th>
<th>Physical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Oral Toxicity Category 4</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Reproductive Toxicity Category 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effects on or via lactation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GHS Label

WARNING!
Harmful if swallowed.
Suspected of damaging the unborn child.
May cause harm to breast-fed children.

Prevention:
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly with soap and water after handling damaged tablets.
Do not eat, drink or smoke when using this product.
Wear protective clothing.

Response:
IF SWALLOWED: Call a poison center or doctor if you feel unwell. Rinse mouth.
IF exposed and concerned: Get medical attention.
Storage:
Store locked up.
Disposal
Dispose of contents in accordance with all local, state and federal regulations.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No.</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextroamphetamine Sulfate</td>
<td>51-63-8</td>
<td>1-4%</td>
</tr>
<tr>
<td>Non-Hazardous Ingredients</td>
<td>Mixture</td>
<td>96-99%</td>
</tr>
</tbody>
</table>

Note: The exact percentage is withheld as a trade secret.
4. FIRST AID MEASURES

Handling solid will not cause adverse health effects. The following first aid applies to contact with broken tablets.

**Eye:** Immediately flush victim's eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Remove contact lenses if present and easy to do. Get medical attention if irritation persists.

**Skin:** Wash skin thoroughly with soap and water after handling broken or damaged tablets. Get medical attention if irritation or symptoms of exposure develop. Remove and launder contaminated clothing before reuse.

**Ingestion:** Do not induce vomiting unless directed to do so by medical personnel. Get immediate medical attention for overdose.

**Inhalation:** Remove victim to fresh air. Get medical attention if irritation or other symptoms persist.

**Most important symptoms/effects, acute and delayed:** This product is an amphetamine. Inhalation or swallowing may cause hypertension (elevated blood pressure), heart palpitations, overstimulation, restlessness, dizziness, insomnia, tremor, headache, diarrhea, constipation and other gastrointestinal disturbances. Contact with damaged tablets may cause mild eye and skin irritation.

**Indication of immediate medical attention and special treatment needed, if necessary:** Seek immediate medical treatment for ingestion overdose or inhalation of dust from crushed tablets.

Consult with a Certified Poison Control Center for up-to-date guidance and advice. Management of acute amphetamine intoxication is largely symptomatic and includes gastric lavage, administration of activated charcoal, administration of a cathartic, and sedation. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Acidification of the urine increases amphetamine excretion, but is believed to increase risk of acute renal failure if myoglobinuria is present. If acute, severe hypertension complicates amphetamine overdosage, administration of intravenous phentolamine has been suggested. However, a gradual drop in blood pressure will usually result when sufficient sedation has been achieved. Chlorpromazine antagonizes the central stimulant effects of amphetamines and can be used to treat amphetamine intoxication.

5. FIRE FIGHTING MEASURES

**Suitable Extinguishing Media:** Use water spray or fog, dry chemical, CO2 or foam. Do not use straight water streams if large amounts of dust are present.

**Specific Hazards Arising from the Chemical:** High concentrations of dust that may be present if tablets are crushed or damaged may present a fire and explosion hazard. Intact tablets may burn under fire conditions. Combustion products may be toxic and include oxides of carbon, sulfur and nitrogen.

**Special Protective Equipment and Precautions for Fire-Fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing.

6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment, and Emergency Procedures:** Wear appropriate protective clothing as described in Section 8. Eliminate sources of ignition. Avoid contact and inhalation of dust if present.

**Methods and Materials for Containment and Cleaning Up:** Carefully sweep up or shovel, avoiding creating airborne dust. Use non-sparking tools and equipment. Use caution to prevent damaging intact tablets. If a vacuum is used, explosion-proof equipment is required. Place in an appropriate containers for disposal. Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.
7. HANDLING AND STORAGE

**Precautions for Safe Handling:** Do not crush or break tablets. Avoid processes that generate dust. Avoid contact with the eyes, skin and clothing. Avoid breathing dust. Wear protective clothing and equipment as described in Section 8. Handle with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Follow good housekeeping procedures to minimize the accumulation of combustible dusts on surfaces, including overhead surfaces. High concentrations of dust may present a fire and explosion hazard.

**Conditions for Safe Storage, including any incompatibilities:** Store in a dry area. Store in a secure area as required by DEA regulations.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Exposure Guidelines:**

<table>
<thead>
<tr>
<th>Dextroamphetamine Sulfate</th>
<th>None Established</th>
</tr>
</thead>
</table>

**Appropriate Engineering Controls:** No special controls are required for handing undamaged tablets. If tablets are damaged, use adequate general or local exhaust ventilation to minimize exposure levels. If dust is generated in handling, explosion-proof equipment is required.

**Respiratory Protection:** No respiratory protection is required for handing undamaged tablets. If tablets are damaged and dust is present, a NIOSH approved respirator with particulate filters or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with OSHA 1910.134 and good industrial hygiene practice.

**Skin Protection:** Wear impervious gloves such as rubber or nitrile to avoid skin contact when handling tablets. Wear protective clothing as needed to avoid skin contact and prevent contamination of personal clothing.

**Eye Protection:** Chemical safety goggles or safety glasses recommended if eye contact is possible.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Appearance: Tablets, orange</th>
<th>Odor: None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viscosity: Not applicable</td>
<td>Odor Threshold: Not applicable</td>
</tr>
<tr>
<td>Vapor Density: Not applicable</td>
<td>Boiling Point/Range: Not applicable</td>
</tr>
<tr>
<td>Solubilities: Partially soluble in water</td>
<td>Vapor Pressure: Not applicable</td>
</tr>
<tr>
<td>Relative Density: Not determined</td>
<td>Evaporation Rate: Not applicable</td>
</tr>
<tr>
<td>Melting Point/Freezing Point: Not determined</td>
<td>pH: Not applicable</td>
</tr>
<tr>
<td>Decomposition Temperature: Not determined</td>
<td>Partition Coefficient(n-Octanol/Water): Not determined</td>
</tr>
<tr>
<td>Flashpoint: None</td>
<td>Autoignition Temperature: Not applicable</td>
</tr>
<tr>
<td>Flammable Limits: LFL: Not applicable</td>
<td>Flammability (solid, gas): No applicable data available</td>
</tr>
<tr>
<td>UFL: Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

**Reactivity:** Not considered reactive.

**Chemical Stability:** Stable under normal storage and handling conditions.

**Possibility of Hazardous Reactions:** May react with strong oxidizers generating heat.

**Conditions to Avoid:** Avoid damaging tablets and creating dust.

**Incompatible Materials:** Strong acids, bases and oxidizers.
Hazardous Decomposition Products: Thermal decomposition or combustion will generate oxides of carbon, sulfur and nitrogen.

11. TOXICOLOGICAL INFORMATION

Handling solid tablets will not cause adverse health effects. The following health effects apply to contact with broken tablets.

Ingestion: May be harmful if swallowed. This product is an amphetamine. Inhalation or swallowing may cause hypertension (elevated blood pressure), heart palpitations, overstimulation, restlessness, dizziness, insomnia, tremor, headache, diarrhea, constipation and other gastrointestinal disturbances.

Inhalation: Inhalation of dust may cause irritation of the nose, throat and upper respiratory tract and symptoms of overdose similar to ingestion.

Eye: May cause mild irritation of the eyes with redness and tearing.

Skin: May cause mild skin irritation.

Chronic Effects: Amphetamines have been extensively abused. Tolerance, extreme psychological dependence and severe social disability have occurred. There are reports of patients who have increased the dosage to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with amphetamines include severe dermatoses, marked insomnia, irritability, hyperactivity and personality changes. The most severe manifestation of chronic intoxication is psychosis, often clinically indistinguishable from schizophrenia. This is rare with oral amphetamines.

Carcinogenicity: Experiments with a similar substance showed no evidence of carcinogenicity in rats and mice. None of the components is listed as a carcinogen or suspected carcinogen by ACGIH, IARC, NTP or OSHA.

Reproductive Toxicity: Dextroamphetamine has been shown to have embryotoxic and teratogenic effects when administered to mice in doses approximately 41 times the maximum human dose. Embryotoxic effects were not seen in New Zealand white rabbits given the drug in doses 7 times the human dose nor in rats given 12.5 times the maximum human dose. While there are no adequate and well-controlled studies in pregnant women, there has been one report of severe congenital bony deformity in a baby born to a woman who took dextroamphetamine sulfate with lovastatin during the first trimester of pregnancy. Dextroamphetamine sulfate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers dependent on amphetamines have an increased risk of premature delivery and low birth weight. Also, these infants may experience symptoms of withdrawal as demonstrated by dysphoria, including agitation, and significant lassitude. Amphetamines are excreted in human milk. Mothers taking amphetamines should be advised to refrain from nursing.

Germ Cell Mutagenicity: Experiments with a similar substance was negative in the sister chromatid exchange and chromosome aberration test, equivocal in the AMES assay.

Numerical Measures of Toxicity:
Dextroamphetamine Sulfate: LD50 oral rat 32 mg/kg

12. ECOLOGICAL INFORMATION

No data is currently available. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with local, state and federal environmental regulations for controlled substances. Due to controlled substances regulation, the amount of material for disposal should be assessed and documented.
14. TRANSPORT INFORMATION

Transportation of Dangerous Goods Description:
Proper Shipping Name: Not regulated
UN Number: None
Hazard Class/Packing Group: None
Labels Required: None

15. REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting. Many states have more stringent spill reporting requirements. Report spill in compliance with all federal, state and local requirements.

SARA TITLE III:

Hazard Category for Section 311/312: Acute Health, Chronic Health

Section 313 Toxic Chemicals: This product contains the following chemicals subject to SARA Title III Reporting requirements: None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: This product is a drug and not subject to TSCA.

STATE REGULATIONS:

California Proposition 65: These products contain the following substances known to the State of California to cause cancer and/or reproductive harm: None known

16. OTHER INFORMATION

SDS Date of Preparation/Revision: February 8, 2014

DISCLAIMER
The information in this SAFETY DATA SHEET should be provided to all who will use, handle, store, transport, or otherwise be exposed to this material. This information has been prepared for the guidance of plant engineering, operations, and management, and for persons working with or handling this material. Nesher Pharmaceuticals (USA) LLC believes this information to be reliable and up-to-date as of the date of publication, but makes no warranty that it is.