Safety Data Sheet

1. IDENTIFICATION

Products: Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets 5 mg, 7.5 mg, 10 mg, 12 mg, 15 mg, 20 mg, and 30 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:

Health	Environmental	Physical
Acute Oral Toxicity Category 4 Reproductive Toxicity Category 2 Effects on or via lactation	None	None

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

Component	CAS No.	Amount
Amphetamine Aspartate	25333-81-7	1-2%
Amphetamine Sulfate	60-13-9	1-2%
Dextroamphetamine Sulfate	51-63-8	1-2%
Dextroamphetamine Saccharate	None Assigned	1-2%
Non-Hazardous Ingredients	Mixture	92-96%

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:

Amphetamine Aspartate	None Established
Amphetamine Sulfate	None Established
Dextroamphetamine Sulfate	None Established
Dextroamphetamine Saccharate	None Established

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

Appearance: Tablets, green or yellow	**Odor:** None
Viscosity: Not applicable	**Odor Threshold:** Not applicable
Vapor Density: Not applicable	**Boiling Point/Range:** Not applicable
Solubilities: Partially soluble in water	**Vapor Pressure:** Not applicable
Relative Density: Not determined	**Evaporation Rate:** Not applicable
Melting Point/Freezing Point: Not determined	**pH:** Not applicable
Decomposition Temperature: Not determined	**Partition Coefficient(n- Octanol/Water):** Not determined
Flashpoint: None	**Autoignition Temperature:** Not applicable
Flammable Limits: LFL: Not applicable **UFL**: Not applicable	**Flammability (solid, gas):** No applicable data available

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: Amphetamine, in the enantiomer ratio present in dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, and amphetamine sulfate tablets (d- to l- ratio of 3:1), had no apparent effects on embryofetal morphological development or survival when orally administered to pregnant rats and rabbits throughout the period of organogenesis at doses of up to 6 and 16 mg/kg/day, respectively. These doses are approximately 1.5 and 8 times, respectively, the maximum recommended human dose of 30 mg/day [child] on a mg/m2 body surface area basis. Fetal malformations and death have been reported in mice following parenteral administration of d-amphetamine doses of 50 mg/kg/day (approximately 6 times that of a human dose of 30 mg/day [child] on a mg/m2 basis) or greater to pregnant animals. Administration of these doses was also associated with severe maternal toxicity. A number of studies in rodents indicate that prenatal or early postnatal exposure to amphetamine (d- or d,l-), at doses similar to those used clinically, can result in long-term neurochemical and behavioral alterations. Reported behavioral effects include learning and memory deficits, altered locomotor activity, and changes in sexual function. 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: Components were 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
Dextroamphetamine Saccharate, Amphetamine Aspartate and Amphetamine Sulfate: estimated LD50 oral rat 55 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 Section 313 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.