



**MATERIAL SAFETY DATA SHEET**  
**for**  
**ADDERALL XR™ Capsules**

**SECTION 1 – CHEMICAL PRODUCT & COMPANY IDENTIFICATION**

Shire Pharmaceuticals, Inc.  
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**Emergency Contacts:**

CHEMTREC (800) 424-9300. For all international transportation emergencies call CHEMTREC at (703) 527-3887, collect calls will be accepted.

**Generic Name:** Mixed salts of a single-entity amphetamine product  
**Trade Name:** Adderall XR  
**Product Code Name:** NDC 54092-381-01, NDC 54092-383-01  
NDC 54092-385-01, NDC 54092-387-01  
NDC 54092-389-01, NDC 54092-391-01  
**Chemical Name:** A – methylphenylamine salts  
**Synonyms:** Amphetamine  
**Intended Use:** Treatment of Attention Deficit Disorder with Hyperactivity (ADHD).

**SECTION 2 – COMPOSITION/INFORMATION OF INGREDIENTS**

<b>Ingredients</b>	<b>(%)</b>	<b>CAS Number</b>	<b>Exposure Limits</b>
Dextroamphetamine Saccharate	<2	N/A	N/A
Amphetamine Aspartate	<2	25333-81-7	N/A
Dextroamphetamine Sulfate USP	<2	51-63-8	N/A
Amphetamine Sulfate USP	<2	60-13-9	N/A
Hydroxypropyl Methylcellulose USP	<1	9004-65-3	N/A
Eudragit L30D-55	<60	9065-11-6	N/A
Talc USP	<3	14807-96-6	2 mg/m <sup>3</sup>
Triethyl Citrate, NF	<3	77-93-0	2 mg/m <sup>3</sup>
Sugar Spheres	<60	N/A	N/A (a)
Opadry Beige	<2	N/A	N/A (a)

### **SECTION 3 – HAZARDS IDENTIFICATION**

#### **A) EMERGENCY OVERVIEW:**

Material contained in bottles or intact capsules should not result in exposure or present a hazard. However, direct contact with the powder may cause skin and/or severe eye irritation. Avoid direct contact with the substance. Wear gloves and promptly remove material on skin, eyes or clothing by rinsing thoroughly with water.

#### **B) EFFECTS OF OVEREXPOSURE:**

Capsules are intended for human consumption under guidance of a physician. Based on animal/clinical data, Adderall XR may be harmful if ingested. Effects of overexposure to Adderall XR may include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states, hyperpyrexia and rhabdomyolysis. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is usually preceded by convulsions and coma.

### **SECTION 4 – FIRST AID MEASURES**

#### **EVACUATE THE CONTAMINATED AREA**

**Inhalation:** In case of inhalation, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult administer oxygen. Seek medical attention immediately.

**Ingestion:** In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Eyes:** In case of eye contact, flush with copious amounts of water for at least 15 minutes. Seek medical attention immediately if irritation develops.

**Skin:** In case of skin contact, remove contaminated clothing. Flush area with large amounts of water for 15 minutes. Use soap if available. Seek medical attention immediately if skin irritation or rash develops.

### **SECTION 5 – FIRE AND EXPLOSION PROPERTIES**

#### **A) FIRE FIGHTING PROCEDURES:**

**Instructions:** Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.

**Hazardous Combustion Products:** When heated to decomposition may emit acrid smoke, irritating fumes, SO<sub>x</sub>, and NO<sub>x</sub>.

**Extinguishing Media:** Use appropriate media including water spray jet, dry powder, foam, carbon dioxide.

## **B) DUST EXPLOSION CHARACTERISTICS:**

Intact capsules are not expected to pose a hazard, however as a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

## **SECTION 6 – ACCIDENTAL RELEASE MEASURES**

**Spill Response Instructions:** Report emergency situations immediately. Non-essential personnel should be evacuated from the affected area. Contain the source of the spill if it is safe to do so. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the clean up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Wet the material with water and collect solution/slurry for disposal. Ventilate the area and clean spill area thoroughly. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance.

## **SECTION 7 – HANDLING AND STORAGE**

**General Handling:** Intact capsules are not expected to be hazardous under normal handling procedures and protective equipment is not required. In a manufacturing or other situation where exposure to the tablet powder may occur appropriate personal protective equipment, including respiratory protection, must be worn. Use good personal hygiene – wash hands and exposed skin thoroughly with soap and water after use.

**Storage:** When not in use, tightly seal the container and store at controlled room temperature, 15-30°C (59-86°F). Keep away from ignition sources including electrostatic charge, heat, sparks, and open flame. In case of insufficient ventilation, wear suitable respiratory protection. Keep this drug out of the reach of children.

## **SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Exposure Limits:** Occupational exposure limits have not been established by OSHA, ACGIH or NIOSH.

**Engineering Controls:** In a manufacturing setting, local exhaust ventilation must be used. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not be a substitute for engineering controls.

**Personal Protective Equipment:** Eye protection, compatible chemical-resistant gloves, and lab coat should be worn. In a manufacturing setting, more elaborate forms of personal protective equipment may be

required.

## SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical Form:</b>	Capsules
<b>Color:</b>	5 mg capsules – clear/blue 10 mg capsules – blue/blue 15 mg capsules – blue/white 20 mg capsules – orange/orange 25 mg capsules – orange/white 30 mg capsules – natural/orange
<b>Melting Point:</b>	Not applicable to the mixture
<b>Molecular Weight:</b>	Not applicable to the mixture.
<b>Molecular Formula:</b>	Not applicable to the mixture.
<b>Solubility:</b>	Not determined
<b>pH:</b>	Not determined

## SECTION 10 – STABILITY AND REACTIVITY

<b>Stability:</b>	Stable
<b>Reactivity:</b>	Not fully determined. As a precautionary measure, keep away from sources of ignition and heat, and strong oxidizers. Hazardous polymerization will not occur.

## SECTION 11 – TOXICOLOGY INFORMATION

<b>Acute Exposure:</b>	<b>Species, Route</b>	<b>Lethal Dose 50%</b>
	Mouse, Oral:	N/A
	Rat, Oral:	96.8 mg/kg
	Mouse, Intravenous:	N/A
	Rat, Intravenous:	N/A
	Mouse, Intraperitoneal:	N/A
	Rat, Intraperitoneal:	N/A
	Dog, Oral:	N/A
	Dog, Intravenous:	N/A
<b>Repeated Exposure:</b>	Amphetamines have been extensively abused. Tolerance, extreme psychological dependence, and severe social disability have occurred.	
<b>Eye Effects:</b>	No information available.	
<b>Skin Effects:</b>	No information available.	
<b>Reproductive and Developmental Effects:</b>	Amphetamine has been shown to have embryo toxic and teratogenic effects when administered to mice in doses approximately 41 times the maximum human dose. Infants born to mothers dependent on amphetamines have an increased risk of pre-mature delivery and low birth weights.	
<b>Genotoxicity:</b>	No information available.	
<b>Sensitization Potential:</b>	No information available.	
<b>Carcinogenicity:</b>	Long-term studies to determine the carcinogenic potential of Adderall have not been performed.	

## SECTION 12 – ECOLOGICAL INFORMATION

### Ecological Info.:

Ecological impact data has not been determined for the mixture.

## SECTION 13 – DISPOSAL INFORMATION

**Disposal Procedure:** Must dispose of in accordance with all local, state, and federal regulations.

## SECTION 14 – TRANSPORTATION INFORMATION

**Transportation Info:** Contact Shire Pharmaceuticals, Inc. for transportation information.

## SECTION 15 – REGULATORY INFORMATION

**EEC Classification:** Xn (Harmful)

Xi (Irritant)

**Risk Phrases:** R 22 – Harmful if swallowed.

R 41 – Risk of serious damage to the eyes.

**Safety Phrases:** S 26 – In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 36/37/39 – Wear suitable protective clothing, gloves, and eye/face protection.

S 45 – In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

**TSCA Status:** Not currently in inventory.

**Prop 65** The ingredients included in this compound are listed in California's Proposition 65

**Reporting Requirements:** The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity for releases of this material. This product does not contain any ingredients which are regulated on the USEPA List of Toxic Chemicals (40 CFR 372), and is therefore not subject to reporting under section 313 of EPCRA.

## SECTION 16 – OTHER INFORMATION

**Disclaimer:** Shire Pharmaceuticals believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied.

The information contained herein is designated only as guidance for safe handling, storage and use of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals. Shire Pharmaceuticals, Inc. shall not be held liable for any loss, injury or damage from contact with the product.