Section 1: Identification

Common Name/Trade Name	AMANTADINE HYDROCHLORIDE	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	**IN CASE OF EMERGENCY:** Chemtrec 1 (800) 424-9300 **(24 hours)**
Distributor Name	Bella Corp Trading Pty Ltd 6/34 Dominions Road, Ashmore QLD 4214, Australia Telephone: 07 5597 4169 Email: bellacorp@bellacorp.com.au	
Product Synonym(s)	1-adamantylamine hydrochloride; 1-aminoadamantane hydrochloride; 1-adamantanamine hydrochloride; adamantan-1-amine hydrochloride; Adamin; Adamine; Amazolon; Aminoadamantane hydrochloride; EXP 105-1; Mantadan; Mantadine; Mantadix; Midantan; Midantane; Mydantane; NSC 83653; Symadine; Symmetrel; Virasol; Virofral	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, Oral (Category 4), Skin Irritation (Category 2), Eye Irritation (Category 2), Reproductive toxicity (Category 2), Reproductive toxicity (effects on or via lactation), Specific target organ toxicity repeated exposure (Category 2), Aquatic toxicity (Category 3)	
Signal Word	Warning	
Hazard Statement(s)	H302 H315 H319 H361 H362 H373 H412	Harmful if swallowed Causes skin irritation Causes serious eye irritation Suspected of damaging fertility or the unborn child May cause harm to breast-fed children May cause damage to organs through prolonged or repeated exposure Harmful to aquatic life with long lasting effects
Pictogram(s)		
Precautionary Statement(s)	P201 P263 P273 P280 P305+P351+P338 P308+P313	Obtain special instructions before use. Avoid contact during pregnancy/while nursing. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. continue rinsing. IF exposed or concerned Get medical advice/attention.
Hazards Not Otherwise Classified	No data available	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	Amantadine hydrochloride
Common Name	Amantadine hydrochloride
CAS Number	665-66-7
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Seek medical attention if feel unwell. Delayed effects can be expected after exposure. Show this data sheet to the doctor in attendance. Self-protection of the first-aider: Attention! Performing "mouth to mouth" artificial respiration may be dangerous. Make a contactless artificial respiration.
If Inhaled	If breathed in, move person into fresh air. Give water to drink. If not breathing, give artificial respiration.
In Case of Skin Contact	Wash off with plenty of water at least for 20 minutes. Contaminated clothing should be laundered before reuse.
In Case of Eye Contact	Flush eyes with water as a precaution at least for 20 minutes.
If Swallowed	Never give anything by mouth to an unconscious person. Rinse mouth with water. If ingestion of a large amount does occur, call the ambulance or provide medical attention immediately.

Most Important Symptoms and Effects	Symptoms appear after exposure may include fever, anxiety, severe headache, confusion, hallucinations, agitation, aggression, personality changes, tremor, problems with balance or walking, fast or uneven heart rate, urinating less than usual or not at all, trouble breathing, seizure (convulsion), or fainting. An overdose of amantadine hydrochloride can be fatal (deaths have been reported from overdose with amantadine hydrochloride). The lowest reported acute lethal dose was 1 gram. For more information on potential side effects contact our regulatory department.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Suitable extinguishing media: Water spray. Carbon dioxide (CO2). Dry chemical. Chemical foam. Unsuitable extinguishing media: None.
Special Hazards Arising From the Substance/Mixture	Thermal decomposition can lead to release of acrid smoke or irritating gases and vapours. Emits toxic fumes under fire conditions: carbon monoxide (CO), carbon dioxide (CO2), hydrogen chloride gas (HCl), phosgene and other pyrolysis products typical of burning organic material. May emit corrosive fumes.
Special PPE and/or Precautions for Firefighters	Fire fighter clothing conforming to European standard EN469 provides a basic level of protection for chemical incidents and includes helmets, protective boots and gloves. Clothing not conforming to EN469 may not be suitable in any chemical incident. Use water delivered as a fine spray to control fire and cool adjacent area. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Use personal protective equipment: wear self-contained breathing apparatus, rubber boots and heavy rubber gloves. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation. For non-emergency personnel Protective equipment: Use personal protective equipment. Emergency procedures: Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation. For emergency responders Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Methods and Materials Used for Containment	Environmental precautions - do not let product enter drains.
Cleanup Procedures	For containment Remove all ignition sources. Clean up all spills immediately. Avoid contact with skin and eyes. Control personal contact by using protective equipment. In case of major spills alert Emergency Responders and tell them location and nature of hazard. Prevent, by any means available, spillage from entering drains or watercourses. For cleaning up Use dry clean up procedures and avoid generating dust. Place in a suitable, labelled container for waste disposal. Recover product wherever possible. Wash area down with large amounts of water. If contamination of drains or waterways occurs, advise emergency services.

Section 7: Handling and Storage

Precautions for Safe Handling	Protective measures: Measures to prevent fire: Avoid contact with incompatible materials, heat, direct sunlight, water and moisture. Keep away from sources of ignition. Measures to prevent aerosol and dust generation: Use in a well-ventilated area. Prevent concentration in hollows and sumps. DO NOT enter confined spaces until atmosphere has been checked. Avoid all personal contact, including inhalation. Measures to protect the environment: Wear protective clothing when risk of exposure occurs. Keep containers securely sealed when not in use. Avoid physical damage to containers. Advice on general occupational hygiene: Use good occupational work practice. Observe manufacturer's storing and handling recommendations. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Launder contaminated clothing before re-use.
Conditions for Safe Storage	Technical measures and storage conditions: Store in original containers at dark and dry place. Protect from moisture and light. Keep container tightly closed when not in use. Check that all containers are clearly labelled. Protect containers against physical damage and check regularly for leaks. Packing materials: Tied polyethylene bag, which is placed into polyethylene vat or other polymer container with a tight-fitting and sealable cover. Requirements for storage rooms and vessels: For quality assurance store at temperature below 25°C. Protect from light and humidity.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	Occupational exposure limit values: The national occupational exposure limit values that corresponds to Union occupational exposure limit values (Directive 98/24/EC) not available. The national occupational exposure limit values that correspond to Union limit values (Directive 2004/37/EC) not available. Any other national occupational exposure limit values 1 mg/m3 (Russia). The national biological limit values that correspond to Union limit values (Directive 98/24/EC) not available. Information on currently recommended monitoring procedures not available. Exposure controls: Occupational exposure to amantadine hydrochloride may occur through inhalation and dermal contact with this compound at workplaces where it is produced or used. Individual protection measures, such as personal protective equipment.
Appropriate Engineering Controls	Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction. Exhaust ventilation should be designed to prevent recirculation of particulates and accumulation in the workplace.
PPE - Eye/Face Protection	For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs - chemical goggles. Full-face shield may be required for supplementary but never for primary protection of eyes. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. DO NOT wear contact lenses.
PPE - Skin Protection	Choose body protection according to the amount and concentration of the dangerous substance at the work place. Hand protection: The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 and US F739. Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include such as frequency and duration of contact, chemical resistance of glove material, glove thickness and dexterity. When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended. When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended. Contaminated gloves should be replaced. Glove material natural rubber, nitrile rubber, neoprene or PVC. Full contact Material: nitrile rubber Minimum layer thickness: 0.11 mm Break through time: 480 min Test method: EN 374 Splash contact Material: nitrile rubber Minimum layer thickness: 0.11 mm Break through time: 480 min Test method: EN 374 Other skin protection: Barrier cream, skin-cleansing cream, eye wash unit.
PPE - Body Protection	Choose body protection according to the amount and concentration of the dangerous substance at the work place. Hand protection: The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 and US F739. Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include such as frequency and duration of contact, chemical resistance of glove material, glove thickness and dexterity. When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended. When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended. Contaminated gloves should be replaced. Glove material natural rubber, nitrile rubber, neoprene or PVC. Full contact Material: nitrile rubber Minimum layer thickness: 0.11 mm Break through time: 480 min Test method: EN 374 Splash contact Material: nitrile rubber Minimum layer thickness: 0.11 mm Break through time: 480 min Test method: EN 374 Other skin protection: Barrier cream, skin-cleansing cream, eye wash unit.
PPE - Respiratory Protection	Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 (US) or type P1 (EN 143) respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures. The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option). Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program. Use approved positive flow mask if significant quantities of dust become airborne.

Section 9: Physical and Chemical Properties

Appearance	Crystalline powder. White or practically white.
Upper/Lower Flammability or Explosive Limits	lower flammability limits – 17,5 g/m^3 at dispersion 50 – 63 µ
Odor	Odorless
Vapor Pressure	0.13 mm Hg at 25°C (est., lit.)
Odor Threshold	No data available
Vapor Density	No data available
pH	4.9 – 5.1 (20 % solution, exp.) saturated solution pH 5 (eksp.)
Relative Density	1.17 g/cm^3
Melting Point/Freezing Point	255 C; 300 - 360 C (lit.)
Solubility	Very soluble in water (100 g/100 mL) in water at 23°C and at 20.0°C is ≥ 35.0 g/100 g <39.8 g/100 g, pH 4.2 - 4.4 Very soluble in 96% ethanol Slightly soluble in chloroform Practically insoluble in ether
Initial Boiling Point and Boiling Range	225.7 ± 8.0°C at 760 mmHg (est., lit.) 292.4°C (exp., lit.)
Flash Point	96°C (exp., lit.)
Evaporation Rate	No data available
Flammability (Solid, Gas)	214 C (lit.)
Partition Coefficient	2.22 – 2.44 (est., lit.) - 1.64 at 23°C and pH 6.3 (exp., lit.)
Auto-Ignition Temperature	No self-heating detected
Decomposition Temperature	>310°C (lit.)
Viscosity	No applicable

Section 10: Stability and Reactivity

Reactivity	No dangerous reactions known.
Chemical Stability	Stable in light and air.
Possibility of Hazardous Reactions	Hazardous decomposition products formed under fire conditions (see 10.6.). Hazardous polymerization products are unknown.
Conditions to Avoid	Sources of ignition, exposure to moist air or water, and exposure to light.
Incompatible Materials	Strong oxidizing agents, acids, acid anhydrides, and acid chlorides.
Hazardous Decomposition Products	Hazardous decomposition products formed under fire conditions

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD50 Oral - rat - 800 mg/kg
Acute Toxicity - Inhalation	LD50 (oral) – rat – 800 – 1275 mg/kg, LD50 (oral) – mouse – 700 mg/kg, LD50 (oral) – guinea pig – 360 mg/kg, LDLo (oral) – man – 28.571 mg/kg, LDLo (oral) – man – 286 mg/kg, LDLo (oral) – woman – 50 mg/kg, TDLo (oral) – man – 24 mg/kg/1D- I, TDLo (oral) – man – 13 mg/kg/5D- I, LD50 (intraperitoneal) – rat – 150 mg/kg. Further information available upon request.
Acute Toxicity - Dermal	No data available
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	cause skin irritation. Substance shows a corrosion potential in the EpiDerm skin corrosion test.
Serious Eye Damage/Irritation	cause eye irritation.
Respiratory or Skin Sensitization	no sensitizing effect known
Germ Cell Mutagenicity	Amantadine was not mutagenic in the Ames microbial test using Salmonella typhimurium or a mammalian mutagen assay using Chinese hamster ovary cells when the tests were performed with or without metabolic activation. There was no evidence of chromosome damage in an in vitro test using freshly derived and stimulated human peripheral blood lymphocytes (with or without metabolic activation) or an in vivo mouse bone marrow micronucleus test (140-550 mg/kg; estimated human equivalent dosage of 11.7-45.8 mg/kg based on body surface area conversion). For Amantadine: genetic toxicity in vitro: Species / strain / cell line: Chinese hamster Ovary (CHO) Metabolic activation: with and without Test system: all strains/cell types tested Genotoxicity: negative
Carcinogenicity IARC	not identified as probable, possible or confirmed human carcinogen by IARC.
Carcinogenicity ACGIH	No data available
Carcinogenicity NTP	No data available
Carcinogenicity OSHA	No data available.
Reproductive Toxicity	TDLo (oral) - Human – woman, 1-91 day(s) after conception, 182 mg/kg Reproductive - Specific Developmental Abnormalities – cardiovascular (circulatory) system. TDLo (oral) Human Woman 4-6 weeks after conception 14 mg/kg Reproductive - Specific Developmental Abnormalities- musculoskeletal system. Reproductive- Specific Developmental Abnormalities- cardiovascular (circulatory) system, Reproductive - Effects on Newborn- Apgar score (human only) Further information available upon request.
Specific Target Organ Toxicity - Single Exposure	No data available
Specific Target Organ Toxicity - Repeated Exposure	Specific target organ toxicity, repeated exposure, Central nervous system, cardiovascular system, Hazard Category 2.
Aspiration Hazard	No data available

Section 12: Ecological Information

Toxicity	Amantadine hydrochloride: Short-term toxicity to fish: LC50 = 25 mg/L (4 days) Short-term toxicity to aquatic invertebrates: EC50 = 24.4 mg/L (48 h) Toxicity to aquatic algae and cyanobacteria: EC50 = 62.1 mg/L (72 h); EC10 = 30.8 mg/L (72 h) Toxicity to microorganisms: EC50 = 300 mg/L (3 h); EC10 = 32 mg/L (3 h)
Persistence and Degradability	Amantadine hydrochloride: under test conditions no biodegradation observed; 65 % degradation after 14 days - poorly biodegradable. log Kow = 2,22 2,44 (pred., lit.) show that substance is stable in the environment if log Kow > 1.
Bio-accumulative Potential	Amantadine: BCF = 1 (pH 5.5; 7.4); BCF = 15.09 (pred., lit.) show that bio-accumulative potential of substance is low.
Mobility in Soil	Amantadine: Koc = 1 (pH 5.5; 7.4); Koc = 384.6 (pred., lit.) indicate that substance less likely to move unless soil erosion occurs.
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Contact a licensed professional waste disposal service to dispose of this material. All waste must be handled in accordance with local, state and federal regulations. Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area. Decontaminate empty containers
Waste Treatment Methods Packaging	160508 Discarded organic chemicals consisting of or containing hazardous substances 150102 Plastic packaging 150107 Glass containers Amantadine hydrochloride containing hazardous waste: HP 6 Acute Tox. 4, H302, if c 25 % HP 4 Skin Irrit. 2, H315, if c 10 % HP 4 Eye Irrit. 2, H319, if c 20 % HP 10 Repr.2, H360f d, if c 3.0 %HP 5 - STOT RE 2, H373 if c 10 %Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Recycle wherever possible. Disposal via sewage is strongly prohibited. Consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified. Dispose in Incineration in a licensed apparatus (after admixture with suitable combustible material). Observe all label safeguards until containers are cleaned and destroyed.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	Not dangerous goods
UN Proper Shipping Name	N/A
Transport Hazard Class(es)	N/A
Packaging Group	N/A
Environmental Hazards	N/A

Section 15: Regulatory Information

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Commission regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Regulation (EC) No 286/2011 of the European Parliament and of the Council of 10 March 2011 on amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. Commission regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Commission regulation (EU) 2016/918 of 19 May 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

Section 16: Other Information

Additional Information	N/A
Prepared By	Scarlotte Smith
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