

MATERIAL SAFETY DATA SHEET

MSDS DATE: 13/07/06

FILE NO.: ALX-380-002

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Cyclosporin A
SYNONYMS: N/A
PRODUCT CODES: ALX-380-002

MANUFACTURER: ALEXIS Corporation
ADDRESS: Industriestrasse 17
CH-4415 Lausen
Switzerland

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SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

<u>Formula:</u>	<u>CAS #</u>	<u>EC #</u>	<u>Annex I Index #</u>
C ₆₂ H ₁₁₁ N ₁₁ O ₁₂	59865-13-3	N/A	N/A

SECTION 3: HAZARDS IDENTIFICATION

ACUTE HEALTH EFFECTS: TOXIC by inhalation, ingestion, or skin absorption. May be CARCINOGENIC. May be TERATOGENIC.

SECTION 4: FIRST AID MEASURES

EYES: Rinse immediately with plenty of water for 15 minutes. Check for and remove any contact lenses. Seek medical attention if symptoms appear.

SKIN: Wash immediately with water for 15 minutes. Remove contaminated clothing. Seek medical attention if symptoms appear.

INGESTION: Rinse mouth with water. Do not induce vomiting. Seek medical attention if symptoms appear. Provide MSDS and label information if possible.

INHALATION: Take into fresh air. If breathing is difficult, administer oxygen. Get medical attention.

SECTION 5: FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA: Water spray, water foam, polymer foam, carbon dioxide, dry chemicals.

SPECIAL FIRE FIGHTING PROCEDURES: In case of fire, watch out for the formation of toxic smoke and gases. Wear self-contained respiration equipment. Prevent contact with skin and eyes.

UNUSUAL FIRE AND EXPLOSION HAZARDS: N/A

HAZARDOUS DECOMPOSITION PRODUCTS: N/A

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Evacuate area. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves.

ACCIDENTAL RELEASE MEASURES: Avoid formation of dust, sweep up spill and place in sealed container and hold for disposal. Ventilate area and wash spill site after material pickup is complete.

SECTION 7: HANDLING AND STORAGE

HANDLING AND STORAGE: Keep locked up. Keep away from heat, sources of ignition and incompatibles such as oxidizing agents. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Avoid contact with skin and eyes; do not breathe dust. Avoid prolonged or repeated exposure. Immediately remove all contaminated clothing. Wash hands before breaks and after work. Avoid eating, drinking and storage of food in the work room. Store tightly sealed at +4°C.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: Use only in chemical fume hood. Safety shower and eye bath.
VENTILATION: Government approved respirator.
EYE PROTECTION: Chemical safety goggles.
SKIN PROTECTION: Compatible gloves, protective coat or clothing.
SECTION 8 NOTES: Wash thoroughly after handling. Wash contaminated clothing before reuse.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: White to off-white powder.
ODOR: N/A
pH AS SUPPLIED: N/A
BOILING POINT: N/A
MELTING POINT: N/A
FREEZING POINT: N/A
VAPOR PRESSURE (mmHg): N/A
VAPOR DENSITY (AIR = 1): N/A
SPECIFIC GRAVITY (H₂O = 1): N/A
EVAPORATION RATE: N/A
BASIS (=1): N/A
SOLUBILITY: Soluble in methanol, 100% ethanol, acetone, petroleum ether or chloroform; slightly soluble in water.
MOLECULAR WEIGHT: 1202.6

SECTION 10: STABILITY AND REACTIVITY

STABILITY: Stable. Avoid strong oxidizing agents.
HAZARDOUS DECOMPOSITION: Carbon monoxide, carbon dioxide, nitrogen oxides.
HAZARDOUS POLYMERIZATION: Will not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

RTECS # : GZ4120000

TOXICOLOGICAL INFORMATION: Harmful if swallowed. Cancer hazard. Can cause cancer. May cause birth defects based on animal data. May cause damage to the following organs: kidneys, heart, gastrointestinal tract, cardiovascular system, immune system, muscle tissue. Powerful immunosuppressant. Exposure may be associated with the development of lymphomas. Other symptoms of exposure may include hirsutism, rashes, gum hypertrophy, angio-oedema, mild tremor and hypertension. Absorption into the body leads to the formation of methemoglobin which in sufficient concentration causes cyanosis. Onset may be delayed 2 to 4 hours or longer. Exposure may cause tremors, vomiting, nausea, diarrhea, rise in blood pressure. Target organs are immune system, kidneys, liver, blood. To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

LD50: Rat [Oral]: 1'480 mg/kg
Rat [Intraperitoneal]: 147 mg/kg
Rat [Subcutaneous]: 286 mg/kg
Rat [Intravenous]: 24 mg/kg
Mouse [Oral]: 2'329 mg/kg
Mouse [Intravenous]: 96 mg/kg
Rabbit [Oral]: >1'000 mg/kg
Rabbit [Intravenous]: 10 mg/kg

CHRONIC EXPOSURE: Repeated exposure to a highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.

CHRONIC EXPOSURE-CARCINOGEN: Classified 1 (Proven for human) by IARC.
Classified 1 (Known To Be Human Carcinogens) by NTP.
Classified 3 (Possible for human) by European Union.
Classified None by NIOSH.

CHRONIC EXPOSURE-MUTAGEN: Not available.

CHRONIC EXPOSURE-TERATOGEN: Classified POSSIBLE for human.

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SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: N/A

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state, and local environmental regulations.

SECTION 14: TRANSPORT INFORMATION

INTERNATIONAL TRANSPORT REGULATIONS:

LAND – ROAD/RAILWAY: ADR/RID: Not available.
SEA: IMDG: Not available.
AIR: IATA-DGR: Not available.
SPECIAL PROVISIONS FOR TRANSPORT: N/A

SECTION 15: REGULATORY INFORMATION

CLASSIFICATION AND LABELING ACCORDING TO EU DIRECTIVES:

SYMBOL OF DANGER: T, toxic
R-PHRASES: R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.
R40 - Possible risks of irreversible effects.
R45 - May cause cancer.
R60 - May impair fertility.
S-PHRASES: S22 - Do not breathe dust.
S24/25 - Avoid contact with skin and eyes.
S36/37 - Wear suitable protective clothing and gloves.

U.S. FEDERAL REGULATIONS: Not classified.

HCS CLASSIFICATION: CLASS: May cause cancer.
CLASS: Target organ effects.

WHMIS (CANADA): Not classified.

SECTION 16: OTHER INFORMATION

DISCLAIMER: **The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Alexis Corporation shall not be held liable for any damage resulting from handling or from contact with the above product.**

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