1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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PRODUCT NAME: MYTELASE® CHLORIDE

CHEMICAL NAME: [Oxalylbis(iminoethylene)] bis[(*o*-chlorobenzyl)diethylammonium] dichloride

SYNONYMS: Ambenonium Chloride Tablets

CHEMICAL FAMILY: Cholinesterase Inhibitor

2. COMPOSITION/INFORMATION ON INGREDIENTS

ACTIVE INGREDIENT: Ambenonium chloride, 6.7% by weight, 10 mg caplet
CAS NUMBER: 115-79-7

INACTIVE INGREDIENTS:

INGREDIENT	CAS NUMBER
Starch	9005-25-8
Lactose	63-42-3
Sucrose	57-50-1

3. HAZARDS IDENTIFICATION

Warning: **Following exposure there is a narrow margin between the first appearance of effects and production of serious, and potentially fatal, toxic effects. Since warning signs of overexposure are minimal, medical attention should be sought immediately if exposure is suspected. This is a pharmaceutical product available only with a prescription - use only as directed.**

MYTELASE® is supplied as a scored caplet.

TARGET ORGANS: Nervous system

POTENTIAL HEALTH EFFECTS:

INGESTION Toxic by ingestion

INHALATION Toxic by inhalation of dust

SKIN AND EYE IRRITATION Toxic on skin and eye contact. Eye contact may lead to blurring of vision.

4. FIRST AID MEASURES

EYES
In case of contact with dust from crushed or broken tablets, flush eyes thoroughly with running water. Seek medical attention if irritation develops.

SKIN
Overt contamination of clothing is unlikely. However, in the event dust from broken or crushed tablets comes in contact with skin and clothing, remove contaminated clothing and wash thoroughly with running water. Use soap if available. Seek medical attention if irritation develops.

INGESTION
In case of acute overdose by ingestion, seek immediate medical attention.

INHALATION
Dust containing drug substance could be inhaled if tablets are crushed or broken. If dust is inhaled, remove to fresh air. Seek medical attention.

NOTE TO PHYSICIAN: This product is a cholinesterase inhibitor with prolonged duration of action. Mytelase has all the pharmacological actions of acetylcholine (both the muscurinic and nicotinic). **If there are strong indications of acute mytelase overexposure, including signs of cholinergic crises, treatment with intravenous atropine sulfate should be initiated immediately. Do not wait for a laboratory diagnosis.**

5. FIRE FIGHTING MEASURES

If drug product handling produces dust, a risk assessment of the procedure should be performed.

FIRE AND EXPLOSION HAZARDS
May emit hydrogen chloride, nitrogen oxide and sulfur oxides under fire conditions.

EXTINGUISHING MEDIA
Water spray, carbon dioxide or dry chemical powder.

FIRE FIGHTING INSTRUCTIONS
As in any fire, use pressure demand self-contained breathing apparatus (SCBA) and protective clothing to prevent contact with skin and eyes. Use water spray to keep fire exposed containers cool.

6. ACCIDENTAL RELEASE MEASURES

If tablets are crushed or broken, dust containing drug substance may be released. Minimize dust generation and accumulation. Do not breathe dust.

Personal protective equipment should be worn when cleaning up a spill [See Section 8].

Wet-down all dusts and soak up contents of broken tablets with an absorbent material. Carefully collect material and place in a properly labeled waste container for disposal. Wash area of spill to remove from surfaces. Wash skin thoroughly after handling.

7. HANDLING AND STORAGE

HANDLING AND STORAGE PRECAUTIONS
Keep this and all drugs out of the reach of children.

WORK/HYGIENIC PRACTICES
If tablets are crushed or broken, dust containing drug substance may be released. Avoid breathing dust and avoid contact with skin, eyes and clothing. Use local exhaust ventilation or respiratory protection for operations that generate dust. (If drug product handling produces dust, a risk assessment of the procedure should be performed.) Wash thoroughly after handling.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

If drug product handling produces dust, a risk assessment of the procedure should be performed.

ENGINEERING CONTROLS
If tablets are crushed or broken, dust containing drug substance may be released. If dust is generated, local exhaust ventilation may be required.

EYE/FACE PROTECTION
Avoid eye contact with dust. Wear safety glasses with side shields or goggles where risk of eye exposure exists.

SKIN PROTECTION
Avoid skin contact with dust. Impervious gloves should be worn.

RESPIRATORY PROTECTION
None normally required. However, a respiratory protection program that meets OSHA 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant respirator usage.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE
Scored caplets.

Unless stated otherwise, the following data describes the active drug substance, ambenonium chloride.

BASIC PHYSICAL PROPERTIES
SOLUBILITY: Soluble in water
MELTING POINT (^{0}C): 196-199

10. STABILITY AND REACTIVITY

STABILITY
Stable

INCOMPATIBLE MATERIALS
None known.

HAZARDOUS DECOMPOSITION PRODUCTS
None known.

HAZARDOUS POLYMERIZATION
Will not occur.

11. TOXICOLOGICAL INFORMATION

HUMAN CLINICAL DATA

POTENTIAL HEALTH EFFECTS:

INGESTION
Effects of a Single Exposure:
Cholinesterase inhibitor. In general, early symptoms are minimal, but may include headache, nausea, and dizziness. Effects generally progress rapidly, and may include excessive salivation, abdominal cramps, diarrhea, contraction of the pupils in the eyes, blurring of vision, urgent need to urinate, cold sweating, paleness, and vomiting.

In cases of serious overexposure effects may progress to include muscle twitching, weakness and paralysis of voluntary muscles including the tongue (producing a sensation of "thick tongue," along with difficulty swallowing), shoulders, neck and arms. Blood pressure may increase, with or without a slowing of heart rate. A sensation of internal trembling, severe anxiety, and panic may result. Death may occur rapidly if untreated.

Effects of Repeated Exposures:
Repeated exposure to significant amounts (but in amounts not sufficient to produce immediate effects) may cause persistent loss of appetite, weakness, and malaise.

INHALATION
The effects of inhaling dust from crushed or broken tablets have not been determined: Effects may be presumed to be similar to those, which may occur following ingestion.

SKIN AND EYE IRRITATION
The irritant properties of dust from crushed or broken tablets have not been determined. Dust may be absorbed through the eye. In rabbits, application to the eye produced adverse systemic effects and deaths.

ANIMAL STUDIES

ACUTE EFFECTS (SINGLE DOSES)

Species	Route	LD50 (mg/kg)
Mouse	Intravenous	2.7
	Subcutaneous	5.0
	Oral	150 $\pm$ 44
Cat	Oral	5.0 (approx.)
Rabbit	Eye	1.56 (approx.)

Effects in mice included respiratory depression, respiratory arrest, salivation, watering eyes, tremors and convulsions. The minimum lethal dose in cats was 1.6 mg/kg (1 of 7 animals). Oral (200 to 800 micrograms), or intramuscular (5 or 10 micrograms) administration to cats produced salivation, pupil contraction, and muscle twitching. Additional effects included gastrointestinal effects (intramuscular route), and prostration (oral route). In a dog oral study 0.1 mg/kg produced tremors. Higher non-lethal doses produced increased rate of breathing, salivation, muscle twitching and weakness. Similar effects were produced in monkeys.

Absorbed through the eye in a rabbit study. A 0.5 % solution produced salivation. A 5 % (1.8 to 2 mg/kg) solution produced death.

EFFECTS OF REPEATED DOSES
In a 5-day repeated dose rat study (0.5 to 4 mg/kg) effects included muscle twitching, watering eyes, convulsions, difficulty breathing, thirst, serious weight loss, and lung and intestinal congestion.

EYE AND SKIN IRRITATION The irritant properties of dust from crushed or broken tablets have not been determined.

GENOTOXIC EFFECTS Not available

CARCINOGENIC EFFECTS Not classified as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

None available.

13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with local, state and federal regulations.

14. TRANSPORT INFORMATION

Not regulated by USDOT as a hazardous material.
Not regulated by IATA as a dangerous good.

15. REGULATORY INFORMATION

U.S. FEDERAL REGULATORY INFORMATION
This product does not contain any ingredients which are regulated on the U.S. EPA List of Toxic Chemicals (40 CFR 372), and is therefore not subject to release reporting under section 313 of EPCRA, (SARA Title III).

TARGET ORGANS: Nervous System.

16. OTHER INFORMATION

N/A = Not Applicable N/D = Not Determined ~ = Approximately Equal To

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