

BEGIN MSDS WALPB056

SECTION 1 CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

WYETH-AYERST LABORATORIES
P.O. BOX 8299
Philadelphia, PA 19101
610-688-4400

24 HR. Emergency Medical Information:
610-688-4400
CHEMTREC(R) USA, CAN, PR: 800-424-9300
International: 202-483-7616

SUBSTANCE: CORDARONE

TRADE NAMES/SYNONYMS:
CORDARONE INJECTION; WALPB056

PRODUCT USE: pharmaceutical

CREATION DATE: Sep 06 1995
REVISION DATE: Oct 31 2000

SECTION 2 COMPOSITION, INFORMATION ON INGREDIENTS

COMPONENT: AMIODARONE HYDROCHLORIDE
CAS NUMBER: 19774-82-4
EC NUMBER (EINECS): 243-293-2
PERCENTAGE: 5

COMPONENT: POLYOXYETHYLENE (20) SORBITAN MONOOLEATE
CAS NUMBER: 9005-65-6
EC NUMBER: Not assigned.
PERCENTAGE: >1

COMPONENT: BENZYL ALCOHOL
CAS NUMBER: 100-51-6
EC NUMBER (EINECS): 202-859-9
PERCENTAGE: >1

COMPONENT: WATER
CAS NUMBER: 7732-18-5
EC NUMBER (EINECS): 231-791-2
PERCENTAGE: >1

SECTION 3 HAZARDS IDENTIFICATION

NFPA RATINGS (SCALE 0-4): HEALTH=1 FIRE=1 REACTIVITY=0

EC CLASSIFICATION (CALCULATED): Not determined.

EMERGENCY OVERVIEW:
COLOR: yellow
PHYSICAL FORM: solution
MAJOR HEALTH HAZARDS: No significant target effects reported.

POTENTIAL HEALTH EFFECTS:

INHALATION:

SHORT TERM EXPOSURE: irritation

LONG TERM EXPOSURE: no information is available

SKIN CONTACT:

SHORT TERM EXPOSURE: irritation

LONG TERM EXPOSURE: no information is available

EYE CONTACT:

SHORT TERM EXPOSURE: irritation

LONG TERM EXPOSURE: no information is available

INGESTION:

SHORT TERM EXPOSURE: nausea, vomiting, irregular heartbeat, headache, lung damage

LONG TERM EXPOSURE: same as effects reported in short term exposure, visual disturbances

CARCINOGEN STATUS:

OSHA: N

NTP: N

IARC: N

SECTION 4 FIRST AID MEASURES

INHALATION: If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

SKIN CONTACT: Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

EYE CONTACT: Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

INGESTION: If a large amount is swallowed, get medical attention.

SECTION 5 FIRE FIGHTING MEASURES

FIRE AND EXPLOSION HAZARDS: Slight fire hazard.

EXTINGUISHING MEDIA: regular dry chemical, carbon dioxide, water, regular foam

Large fires: Use regular foam or flood with fine water spray.

FIRE FIGHTING: Move container from fire area if it can be done without risk. Do not scatter spilled material with high-pressure water streams. Dike for later disposal. Use extinguishing agents appropriate for surrounding fire. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

FLASH POINT: No data available.

SECTION 6 ACCIDENTAL RELEASE MEASURES

OCCUPATIONAL RELEASE:

Avoid heat, flames, sparks and other sources of ignition. Remove sources of ignition. Stop leak if possible without personal risk. Reduce vapors with water spray. Small spills: Absorb with sand or other non-combustible material. Collect spilled material in appropriate container for disposal. Large spills: Dike for later disposal. Keep unnecessary people away, isolate hazard area and deny entry. Stay upwind and keep out of low areas.

SECTION 7 HANDLING AND STORAGE

Store and handle in accordance with all current regulations and standards. Keep separated from incompatible substances. Store with acids. See original container for storage recommendations.

Handle as a corrosive liquid. When mixing, slowly add to water to minimize heat generation and spattering. Keep emergency spill kit near storage and use areas.

SECTION 8 EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE LIMITS:

AMIODARONE HYDROCHLORIDE:

100 ug/m³ recommended TWA 8 hour(s) (AHP OEG)

VENTILATION: Based on available information, additional ventilation is not required. Ensure compliance with applicable exposure limits.

EYE PROTECTION: Eye protection not required, but recommended.

CLOTHING: Under normal conditions of use, wear suitable clothing to prevent contact with skin.

GLOVES: Wear appropriate chemical resistant gloves.

RESPIRATOR: No respirator is required under normal conditions of use. Under conditions of frequent use or heavy exposure, respiratory protection may be needed.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: liquid

APPEARANCE: clear

COLOR: yellow

PHYSICAL FORM: solution

ODOR: Not available

BOILING POINT: Not available

FREEZING POINT: Not available

VAPOR PRESSURE: Not available

VAPOR DENSITY: Not available
SPECIFIC GRAVITY: Not available
WATER SOLUBILITY: Not available
PH: 3.5-4.5
VOLATILITY: Not available
ODOR THRESHOLD: Not available
EVAPORATION RATE: Not available
COEFFICIENT OF WATER/OIL DISTRIBUTION: Not available

SECTION 10 STABILITY AND REACTIVITY

REACTIVITY: Stable at normal temperatures and pressure.

CONDITIONS TO AVOID: Avoid heat, flames, sparks and other sources of ignition.
Avoid contact with incompatible materials.

INCOMPATIBILITIES:
May be incompatible with acids, bases, and oxidizers.

HAZARDOUS DECOMPOSITION:
Thermal decomposition products: miscellaneous decomposition products

POLYMERIZATION: Will not polymerize.

SECTION 11 TOXICOLOGICAL INFORMATION

AMIODARONE HYDROCHLORIDE:

TOXICITY DATA:

3129 mg/kg/3 year(s) intermittent oral-man LDLo; 240 mg/kg/6 week(s) intermittent oral-man TDLo; 1128 mg/kg/56 week(s) intermittent oral-woman TDLo; 2480 mg/kg/43 week(s) intermittent oral-woman TDLo; 171 mg/kg/30 day(s) intermittent oral-man TDLo; 120 mg/kg/10 day(s) intermittent oral-woman TDLo; >3 gm/kg oral-rat LD50; 610 mg/kg intraperitoneal-rat LD50; 170 mg/kg intravenous-rat LD50; >3 gm/kg oral-mouse LD50; 450 mg/kg intraperitoneal-mouse LD50; >5 gm/kg oral-dog LD50; 5 gm/kg intravenous-dog LD50; 210 mg/kg/21 day(s) intermittent intratracheal-hamster TDLo

ACUTE TOXICITY LEVEL: Insufficient Data.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: heart or respiratory disorders, liver and/or kidney disorders

REPRODUCTIVE EFFECTS DATA:

245 mg/kg oral-rat TDLo 16-22 day(s) pregnant female continuous; 900 mg/kg oral-rat TDLo 6-15 day(s) pregnant female continuous; 300 mg/kg oral-rat TDLo 6-15 day(s) pregnant female continuous; 1 gm/kg oral-rat TDLo 6-15 day(s) pregnant female continuous

ADDITIONAL DATA: May cross the placenta. Interactions with drugs may occur.
This compound is used as a class III anti-arrhythmic drug.

HEALTH EFFECTS:

INHALATION:

ACUTE EXPOSURE:

AMIODARONE HYDROCHLORIDE: May cause irritation of the respiratory passages.

CHRONIC EXPOSURE:

AMIODARONE HYDROCHLORIDE: No data available.

SKIN CONTACT:

ACUTE EXPOSURE:

AMIODARONE HYDROCHLORIDE: May cause irritation.

CHRONIC EXPOSURE:

AMIODARONE HYDROCHLORIDE: No data available.

EYE CONTACT:

ACUTE EXPOSURE:

AMIODARONE HYDROCHLORIDE: May cause irritation.

CHRONIC EXPOSURE:

AMIODARONE HYDROCHLORIDE: No data available.

INGESTION:

ACUTE EXPOSURE:

AMIODARONE HYDROCHLORIDE: May cause cardiovascular effects such as hypotension, congestive heart failure, cardiac arrhythmias and severe bradycardia. Effects on the central nervous system may include ataxia, depression, nightmares and hallucinations. Other effects may include nausea, vomiting, headaches, pulmonary fibrosis, hyper or hypothyroidism, decreased libido, photosensitivity, hepatic toxicity and liver dysfunction.

CHRONIC EXPOSURE:

AMIODARONE HYDROCHLORIDE: In addition to the effects of acute exposure corneal microdeposits and impaired vision may occur. Reproductive effects have been reported in animals.

SECTION 12 ECOLOGICAL INFORMATION

Not available

SECTION 13 DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations.

SECTION 14 TRANSPORT INFORMATION

No classification assigned.

LAND TRANSPORT ADR/RID: No classification assigned.

AIR TRANSPORT IATA/ICAO: No classification assigned.

MARITIME TRANSPORT IMDG: No classification assigned.

SECTION 15 REGULATORY INFORMATION

U.S. REGULATIONS:

TSCA INVENTORY STATUS: E

TSCA 12(b) EXPORT NOTIFICATION: Not listed.

CERCLA SECTION 103 (40CFR302.4): N

SARA SECTION 302 (40CFR355.30): N

SARA SECTION 304 (40CFR355.40): N

SARA SECTION 313 (40CFR372.65): N

SARA HAZARD CATEGORIES, SARA SECTIONS 311/312 (40CFR370.21):

ACUTE: N

CHRONIC: N

FIRE: N

REACTIVE: N

SUDDEN RELEASE: N

OSHA PROCESS SAFETY (29CFR1910.119): N

STATE REGULATIONS:

California Proposition 65: N

EUROPEAN REGULATIONS:

EC NUMBER: Not assigned.

SECTION 16 OTHER INFORMATION

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