

BEGIN MSDS ESIPB127

SECTION 1 CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

ESI-LEDERLE GENERICS 24 HR. Emergency Medical Information:
P.O. Box 8299 610-688-4400
Philadelphia, PA 19101 CHEMTREC(R) USA, CAN, PR: 800-424-9300
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SUBSTANCE: DIPHENHYDRAMINE HYDROCHLORIDE

TRADE NAMES/SYNONYMS:
DIPHENHYDRAMINE HYDROCHLORIDE INJECTION; ESIPB127

PRODUCT USE: pharmaceutical

CREATION DATE: Sep 17 1991
REVISION DATE: Apr 16 2001

SECTION 2 COMPOSITION, INFORMATION ON INGREDIENTS

COMPONENT: DIPHENHYDRAMINE HYDROCHLORIDE
CAS NUMBER: 147-24-0
EC NUMBER (EINECS): 205-687-2
PERCENTAGE: 5.2

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=2 FIRE=0 REACTIVITY=0

EMERGENCY OVERVIEW:
PHYSICAL DESCRIPTION: Clear, colorless solution.
MAJOR HEALTH HAZARDS: harmful if swallowed, central nervous system depression

POTENTIAL HEALTH EFFECTS:

INHALATION:

SHORT TERM EXPOSURE: no information on significant adverse effects

LONG TERM EXPOSURE: no information on significant adverse effects

SKIN CONTACT:

SHORT TERM EXPOSURE: no information on significant adverse effects

LONG TERM EXPOSURE: no information on significant adverse effects

EYE CONTACT:

SHORT TERM EXPOSURE: no information on significant adverse effects

LONG TERM EXPOSURE: no information on significant adverse effects

INGESTION:

SHORT TERM EXPOSURE: allergic reactions, rash, ringing in the ears, nausea,
vomiting, diarrhea, wheezing, irregular heartbeat, headache, symptoms of

drunkenness, visual disturbances, blood disorders, convulsions
LONG TERM EXPOSURE: reproductive effects

CARCINOGEN STATUS:

OSHA: No
NTP: No
IARC: No

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: No hazard expected.

EXTINGUISHING MEDIA: Use extinguishing agents appropriate for surrounding fire.

FIRE FIGHTING: Move container from fire area if it can be done without risk. 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:

Do not touch spilled material. Absorb with sand or other non-combustible material. Collect spilled material in appropriate container for disposal.

SECTION 7 HANDLING AND STORAGE

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

SECTION 8 EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE LIMITS:

DIPHENHYDRAMINE HYDROCHLORIDE:

110 ug/m3 TWA (AHP OEG)

VENTILATION: Under normal conditions of use, no special ventilation equipment is needed.

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.

Respiratory protection is ranked in order from minimum to maximum.

Consider warning properties before use.

Any dust and mist respirator.

Any air-purifying respirator with a high-efficiency particulate filter.

For Unknown Concentrations or Immediately Dangerous to Life or Health -

Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode.

Any self-contained breathing apparatus.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL DESCRIPTION: Clear, colorless solution.

BOILING POINT: Not available

FREEZING POINT: Not available

VAPOR PRESSURE: Not available

VAPOR DENSITY: Not available

SPECIFIC GRAVITY: Not available

WATER SOLUBILITY: soluble

PH: 4.0-6.5

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: None reported.

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

DIPHENHYDRAMINE HYDROCHLORIDE:

TOXICITY DATA:

12500 ug/kg oral-child TDLo; 10714 ug/kg oral-man TDLo; 83 mg/kg oral-woman TDLo; 60 mg/kg/6 hour(s) intermittent skin-child TDLo; 500 mg/kg oral-rat LD50; 82 mg/kg intraperitoneal-rat LD50; 201 mg/kg subcutaneous-rat LD50; 35 mg/kg intravenous-rat LD50; 164 mg/kg oral-mouse LD50; 56 mg/kg intraperitoneal-mouse LD50; 99200 ug/kg subcutaneous-mouse LD50; 20 mg/kg intravenous-mouse LD50; 24 mg/kg intravenous-dog LD50; 10 mg/kg intravenous-rabbit LD50; 280 mg/kg oral-guinea pig LD50; 75 mg/kg intraperitoneal-guinea pig LD50; 40 mg/kg subcutaneous-guinea pig LD50; 18 mg/kg intravenous-hamster LD50; 63 mg/kg intramuscular-pigeon LD50; 80 mg/kg intraperitoneal-mammal LD50; 1750 mg/kg/14 day(s) continuous oral-rat TDLo; 5687 mg/kg/13 week(s) continuous oral-rat TDLo; 6796 ug/kg/14 day(s) intermittent subcutaneous-rat TDLo; 3706 mg/kg/14 day(s) continuous oral-mouse TDLo; 3418 mg/kg/13 week(s) continuous oral-mouse TDLo; 1440 mg/kg/5 week(s) intermittent oral-dog TDLo

ACUTE TOXICITY LEVEL:

Toxic: ingestion

TARGET ORGANS: central nervous system

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: high blood pressure, eye disorders, heart or cardiovascular disorders, heart problems, hormonal disorders, respiratory disorders

TUMORIGENIC DATA:

27037 mg/kg oral-rat TDLo/2 year(s) continuous

MUTAGENIC DATA:

DNA damage - rat liver 100 umol/L; micronucleus test - hamster lung 200 mg/L; cytogenetic analysis - hamster ovary 100 mg/L

REPRODUCTIVE EFFECTS DATA:

1 gm/kg oral-rat TDLo 6-15 day(s) pregnant female continuous; 39 mg/kg oral-rat TDLo 6-15 day(s) pregnant female continuous; 12 mg/kg parenteral-rat TDLo 10 day(s) pregnant female continuous; 48 mg/kg parenteral-rat TDLo 13-16 day(s) pregnant female continuous; 12 mg/kg parenteral-rat TDLo 5 day(s) pregnant female continuous; 420 mg/kg oral-mouse TDLo 1-21 day(s) pregnant female continuous; 4200 mg/kg oral-mouse TDLo 1-21 day(s) pregnant female continuous; 320 mg/kg oral-mouse TDLo 11-14 day(s) pregnant female continuous; 800 mg/kg oral-mouse TDLo 8-12 day(s) pregnant female continuous; 50 mg/kg subcutaneous-mouse TDLo 8 day(s) pregnant female continuous; 100 mg/kg subcutaneous-mouse TDLo 8 day(s) pregnant female continuous; 1600 mg/kg unreported-mouse TDLo 6-15 day(s) pregnant female continuous

ADDITIONAL DATA: May cross the placenta. Alcohol may enhance the toxic effects. Interactions with drugs may occur.

HEALTH EFFECTS:

INHALATION:

ACUTE EXPOSURE:

DIPHENHYDRAMINE HYDROCHLORIDE: Application of antihistamines to mucous membranes may cause sensitivity reactions in previously exposed persons.

CHRONIC EXPOSURE:

DIPHENHYDRAMINE HYDROCHLORIDE: Prolonged or repeated exposure to antihistamines may cause sensitization.

SKIN CONTACT:

ACUTE EXPOSURE:

DIPHENHYDRAMINE HYDROCHLORIDE: Contact with antihistamines may cause sensitivity reactions in previously exposed persons. Skin absorption may occur causing symptoms reported in ingestion.

CHRONIC EXPOSURE:

DIPHENHYDRAMINE HYDROCHLORIDE: Prolonged or repeated contact with antihistamines may cause sensitization.

EYE CONTACT:

ACUTE EXPOSURE:

DIPHENHYDRAMINE HYDROCHLORIDE: Exposure to antihistamines may cause allergic and irritating conjunctival reactions in previously exposed persons.

CHRONIC EXPOSURE:

DIPHENHYDRAMINE HYDROCHLORIDE: Prolonged or repeated exposure to antihistamines may cause sensitization.

INGESTION:

ACUTE EXPOSURE:

DIPHENHYDRAMINE HYDROCHLORIDE: May cause thickening of bronchial secretions, epigastric distress, disturbed coordination, dizziness, sleepiness and sedation. Less common effects may include dryness of mouth, nose and throat, tightness of chest, wheezing, nasal stuffiness, urticaria, drug rash, photosensitivity, excessive perspiration, blurred vision, diplopia, tinnitus, acute labyrinthitis, nausea, vomiting, diarrhea, constipation, anorexia, urinary frequency, difficulty in urination, urinary retention, palpitations, tachycardia, extrasystoles, hypotension, hemolytic anemia, thrombocytopenia, agranulocytosis, excitation, nervousness, tremor, euphoria, neuritis, convulsions, tingling, weakness and heaviness of the hands, headache, fatigue, chills, diminished mental alertness, confusion, restlessness, irritability, insomnia and early menses. Anaphylactic shock is possible. A massive dose may cause impaired consciousness, fixed and dilated pupils, flushing, hallucinations, coma and death by cardiopulmonary arrest.

CHRONIC EXPOSURE:

DIPHENHYDRAMINE HYDROCHLORIDE: An increase in incidences of cleft palates has been reported in children whose mothers had taken diphenhydramine hydrochloride frequently during the first trimester of pregnancy. Animal test results report fetal malformations such as cleft palate, cryptorchid testes, hydronephrosis and deficient cranial ossification in cases of maternal exposure in early pregnancy. Exposed animals have developed moderate to severe chronic inflammatory foci in the lungs, congestion of the spleen, slight edema of the liver, mild congestion and scattered petechial hemorrhages of the intestinal mucosa. In the thyroid gland, mild depletion of colloid substance and mild follicular cell hypertrophy have been reported. Rats exposed to diphenhydramine hydrochloride did not exhibit any significant increase in tumor incidences. Simultaneous exposure to both diphenhydramine hydrochloride and sodium nitrite produced a significant increase in incidences of liver neoplasms in comparison with nitrite-dosed control animals.

SECTION 12 ECOLOGICAL INFORMATION

Not available

SECTION 13 DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations.

SECTION 14 TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: No classification assigned.

CANADIAN TRANSPORTATION OF DANGEROUS GOODS: 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:

CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4): Not regulated.

SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.30):
Not regulated.

SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.40):
Not regulated.

SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370.21):
ACUTE: Yes
CHRONIC: No
FIRE: No
REACTIVE: No
SUDDEN RELEASE: No

SARA TITLE III SECTION 313 (40 CFR 372.65): Not regulated.

OSHA PROCESS SAFETY (29CFR1910.119): Not regulated.

STATE REGULATIONS:

California Proposition 65: Not regulated.

CANADIAN REGULATIONS:

WHMIS CLASSIFICATION: Not determined.

EUROPEAN REGULATIONS:

EC CLASSIFICATION (CALCULATED): Not determined.

NATIONAL INVENTORY STATUS:

U.S. INVENTORY (TSCA): Exempt.

TSCA 12(b) EXPORT NOTIFICATION: Not listed.

SECTION 16 OTHER INFORMATION

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