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# DOXORUBICIN HYDROCHLORIDE LIPOSOME INJECTION [FORMULATION]

MERCK

Revised: 11/4/2013

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**MSDS**

Material Safety Data Sheet

# SAFETY DATA SHEET

## 1 PRODUCT AND COMPANY IDENTIFICATION

**Product name:** Doxorubicin Hydrochloride Liposome Injection [Formulation]

**SDS No:** P0000021652

**Synonyms, Trade Names:**

CAELYX (pegylated liposomal doxorubicin hydrochloride),  
Doxil, Doxorubicin Hydrochloride (SCH 200746),  
SP000109

**Manufacturer:**

Merck  
One Merck Drive P.O. Box 100  
Whitehouse Station, NJ, USA 08889-0100

**Telephone:** 908-423-1000 (General Information Only)

**Fax:** 908-735-1496

**Contact Person:** EHS Data Steward

**e-mail:** MSDS@merck.com

**Emergency telephone:** 1-908-423-6000  
(24/7/365) English Only

**Intended Use:** Finished pharmaceutical product.

## 2 HAZARDS IDENTIFICATION

**Emergency Overview:**

**Appearance:**

**Color:** Red  
**Physical State :** Liquid  
**Odor:** Unknown

**Signal words** WARNING!

**Potential Health Effects:**

**General**

Finished pharmaceutical product. Suspected of causing genetic defects. Suspected of causing cancer. Wash thoroughly after handling. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. IF exposed or concerned: Get medical advice/attention.

**Inhalation:** No data available.

**skin:** No data available.

**eye:** No data available.

**Ingestion:** No data available.

**OSHA Regulatory Status** This product is hazardous according to OSHA 29CFR 1910.1200.

**Environment:** The environmental hazards and fate of this material have not been

characterized.

### 3 COMPOSITION / INFORMATION ON INGREDIENTS

**General information:** The formulations for these products are proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the composition table. Active ingredients in any concentration are listed.

**Hazardous Component(s):**

| Chemical name             | CAS-No.    | Concentration |
|---------------------------|------------|---------------|
| Sucrose                   | 57-50-1    | 10.0%         |
| Doxorubicin hydrochloride | 25316-40-9 | 0.2%          |

\* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

### 4 FIRST AID MEASURES

**Inhalation:** Move into fresh air and keep at rest. For breathing difficulties, oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

**Skin contact:** Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

**Eye contact:** Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

**Ingestion:** Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

**Notes to the physician:**

**Hazards:** See Sections 2 and 11.

**Treatment:** Treat supportively and symptomatically.

### 5 FIRE-FIGHTING MEASURES

**Extinguishing media:** Water spray, fog, CO<sub>2</sub>, dry chemical, or alcohol resistant foam.

**Unsuitable extinguishing media:** None known.

**Unusual Fire & Explosion Hazards:** Emits toxic fumes under fire conditions.

**Special Fire Fighting Procedures:** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Protective Measures:** Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

### 6 ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Use personal protective equipment. Immediately contact emergency personnel.

Keep unnecessary personnel away. Follow all fire fighting procedures.

**Environmental precautions:** Do not release into the environment.

**Spill Cleanup Methods:** Small Liquid Spills: Absorb up with sand or other non-combustible absorbent material. Large quantities should not be discharged into the drain but removed with absorbing material. For waste disposal, see section 13 of the MSDS. Prevent runoff from entering drains, sewers, or streams.

## 7 HANDLING AND STORAGE

**Handling:** Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. Do not get in eyes, on skin, on clothing. Wash thoroughly after handling.

**Storage:** Keep container tightly closed in a cool, well-ventilated place.

## 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure limits:

| Chemical name                  | Type | Exposure Limit values        | Source  |
|--------------------------------|------|------------------------------|---|
| Sucrose                        | TWA  | 10 mg/m <sup>3</sup>         | US. ACGIH Threshold Limit Values (2009)                                     |
| Sucrose - Respirable fraction. | PEL  | 5 mg/m <sup>3</sup>          | US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006) |
| Sucrose - Total dust.          | PEL  | 15 mg/m <sup>3</sup>         | US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006) |
| Doxorubicin hydrochloride      | TWA  | (<1ug/m <sup>3</sup> ) OEB 5 | Merck   |

OEB (Occupational Exposure Band) is an internal Merck control band.

**Protective Measures:** Observe occupational exposure limits and minimize the risk of inhalation of vapors and mist. No open handling permitted. Closed systems are required to control at source (e.g., glove boxes/isolators). Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

**Respiratory Protection:** Use an appropriate approved air-purifying respirator equipped with HEPA cartridges/canisters where there is the potential for exceeding established occupational exposure limits or occupational exposure bands. When handling a compound in solution, a cartridge/canister appropriate for the solution may also be needed. Use redundant respiratory protection as a prudent practice for adjunct protection in addition to effective engineering controls. Powered air filter respirator. Use a positive pressure, air-supplied, pressure demand tight fitting respirator (e.g., SCBA or airline equipped with emergency escape bottle) where there is a potential for uncontrolled releases in excess of the respirator's capabilities, where exposure levels are unknown or where air-purifying respirators may not provide adequate protection.

**Hand protection:** Chemical resistant gloves. Consider double gloving.

**Eye protection:** Wear safety glasses with side shields (or goggles). Wear appropriate splash goggles if there is a potential for direct contact with liquid splash, mists or aerosols. Wear a faceshield or other full face protection if there is a potential for

direct contact to the face with dusts, mists, or aerosols.

**Skin and Body Protection:** Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Hygiene measures:** Wash skin thoroughly with soap and water.

## 9 PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

**Appearance:**

|                             |         |
|-----------------------------|---------|
| <b>Physical State:</b>      | Liquid  |
| <b>Color:</b>               | Red     |
| <b>Odor:</b>                | Unknown |
| <b>pH:</b>                  | 6.5     |
| <b>Relative density:</b>    | 1.03    |
| <b>Solubility(ies):</b>     |         |
| <b>Solubility in Water:</b> | Soluble |

## 10 STABILITY AND REACTIVITY

|  |   |
|--|---|
| <b>Stability:</b>                          | Stable  |
| <b>Possibility of hazardous reactions:</b> | Stable  |
| <b>Conditions to avoid:</b>                | None at ambient temperatures.   |
| <b>Incompatible materials:</b>             | No data available.  |
| <b>Hazardous decomposition products:</b>   | Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors. |

## 11 TOXICOLOGICAL INFORMATION

**General information:** The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

**Product:**

|                                     |                    |
|-------------------------------------|--------------------|
| <b>Acute Toxicity (Dermal):</b>     | No data available. |
| <b>Acute Toxicity (Inhalation):</b> | No data available. |

**Specified substance(s):****Acute Toxicity (Oral);****Name**

Sucrose

Doxorubicin hydrochloride

**Test results**

LD50 (Rat): 29.7 g/kg Female

LD50 (Rat): 35.4 g/kg Male

LD50 (Mouse): &gt; 570 mg/kg

LD50 (Rat): &gt; 698 mg/kg

**Repeated dose toxicity:****Name**

Sucrose

Doxorubicin hydrochloride

**Test results**

No data available.

In repeat-dose toxicity studies in animals serious or significant adverse effects were observed in the following organs: Cardiovascular System , blood , liver .

**Inhalation:**

No data available.

**Ingestion:**

No data available.

**Skin corrosion/irritation:**

No data available.

**Serious eye damage/eye irritation:**

No data available.

**Respiratory sensitizer/Skin sensitizer:**

No data available.

**Carcinogenicity:**

Suspected of causing cancer.

**Mutagenesis:**

Suspected of causing genetic defects.

**Reproductive toxicity:**

Active pharmaceutical ingredient: Adverse developmental and reproduction effects were observed in rats.

**Other Effects:**

No additional information

**12 ECOLOGICAL INFORMATION****General information:**

The ecotoxicological properties have not been fully investigated. The environmental hazards and fate of this material have not been characterized.

**Ecotoxicity:****Product:****Acute toxicity(Fish):**

No data available.

**Chronic Toxicity(Fish):**

No data available.

**Acute toxicity(Aquatic invertebrates):**

No data available.

**Chronic Toxicity(Aquatic invertebrates):**

No data available.

**Acute toxicity(Aquatic plants):**

No data available.

**Persistence and degradability:**

No data available.

**Bioaccumulative potential:** No data available.

**Mobility:** No data available.

### 13 DISPOSAL CONSIDERATIONS

**Disposal Methods:** Disposal must be in accordance with applicable national, state/provincial, and/or local regulations.

**Measures for Avoidance and Recovery:** Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

### 14 TRANSPORT INFORMATION

**DOT**

Not regulated.

**IMDG - International Maritime Dangerous Goods Code**

Not regulated.

**IATA - International Air Transport Association**

Not regulated.

### 15 REGULATORY INFORMATION

**US Regulations**

- **CERCLA Hazardous Substance List (40 CFR 302.4):**  
None
- **Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):**  
None
- **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):**  
None

**SARA Title III**

- **Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):**  
None
- **Section 313 Toxic Release Inventory (40 CFR 372):**  
None present or none present in regulated quantities.

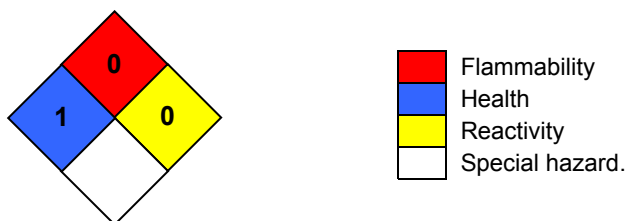
**State Regulations**

- **California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):**  
No ingredient regulated by CA Prop 65 present.
- **Massachusetts Right-To-Know List:**  
Sucrose Listed
- **New Jersey Right-To-Know List:**  
No ingredient regulated by NJ Right-to-Know Law present.

- Pennsylvania Right-To-Know List:**  
 Sucrose Listed

**16 OTHER INFORMATION**
**OTHER INFORMATION**

This SDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

**NFPA Hazard ID**


Hazard rating: 0 - Minimal; 1 - Slight; 2 - Moderate; 3 - Serious; 4 - Severe

**Revision Information:** Not relevant.  
**Issue Date:** 04.11.2013  
**Disclaimer:** This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment.