



Material Safety Data Sheet

Product name: DOXOVES® (Liposomal Doxorubicin HCl)

Product code: F30204B-D2, F30204B-D

Revision date: 01/01/2023

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/ UNDERTAKING

Supplier:

FormuMax Scientific, Inc.

1230 Bordeaux Dr.

Sunnyvale, CA 94089, USA

Emergency telephone number: (408) 607-5788 (24 hours)
(408) 400-0108 (US daytime)

Product name: Liposomal Doxorubicin HCl
Synonyms: DOXOVES®
Product code: F30204B-D, F30204B-D2
Therapeutic class: none
Intended Use: Used in research only, not for human use

2. HAZARDS IDENTIFICATION

Emergency overview: WARNING! Cardiac toxicity Irritating to eyes and skin. This is a pharmacologically active compound.

This material is not a controlled product under WHMIS

Properties affecting health: Irritating to eyes and skin.

Principle routes of exposure:

Eye Contact: Irritating to eyes.
Skin contact: Irritating to skin.
Ingestion: May be harmful if swallowed.
Inhalation: May be harmful by inhalation.

Physico-chemical properties: No hazards resulting from material as supplied.

Hazard information:

Target organ effects: Reproductive
Reproductive effects: May cause adverse effects to the reproductive system.
Mutagenic effects: Active ingredient has been shown to have mutagenic properties when tested in animal models.
Sensitization: Unknown on product.

Carcinogenicity rating:

The below component(s) have been defined as a cancer-suspect agent (O) by a worldwide reputable agency. (in animals)

| Components | CAS Number | FSI |
|---------------------------|------------|-----|
| Doxorubicin hydrochloride | 25316-40-9 | O |

Signs and symptoms: Irritant

Medical conditions aggravated by exposure: Irritant

3. COMPOSITION/INFORMATION ON INGREDIENTS

| Components | CAS Number | Weight % |
|-------------------------------------|------------|----------|
| Sucrose | 57-50-1 | 10-15 |
| Doxorubicin hydrochloride | 25316-40-9 | <0.5 |
| Soy Phosphatidylcholines (lecithin) | 8002-43-5 | 0.5-1 |
| Cholesterol | 57-88-5 | 0.5-1 |

4. FIRST AID MEASURES

| | |
|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Eye contact: | In the case of contact with eyes, check for and remove any contact lenses, rinse immediately with plenty of water for 15 minutes and seek medical attention. |
| Skin contact: | Remove contaminated clothing immediately and wash skin generously with soap and water. In the case of skin irritation or allergic reactions see a physician. |
| Ingestion: | Do not induce vomiting. Call a physician immediately. |
| Inhalation: | Move to fresh air immediately. If experiencing difficulty breathing, seek medical attention. |
| Notes to physician: | Monitor a complete blood and platelet counts. |
| Protection of first aiders: | Follow bloodborne pathogen procedures in the event of accidental injection. |

5. FIRE-FIGHTING MEASURES

| | |
|-----------------------------------------------------------------------|--------------------------------------------------------------|
| Suitable extinguishing media: | Carbon dioxide, dry chemical powder, foam water spray. |
| Extinguishing media which must not be used for safety reasons: | None. |
| Special protective equipment for firefighters: | Wear self-contained breathing apparatus and protective suit. |
| Specific methods: | None. |

6. ACCIDENTAL RELEASE MEASURES

| | |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| Personal precautions: | Wear splash goggles and skin protection. Use suitable protective equipment. |
| Environmental precautions: | Collect and discard into appropriate container, then dispose of in accordance with all applicable federal, state and local regulations. |
| Methods for cleaning up: | Wipe up with absorbent material (e.g., cloth, fleece). |

7. HANDLING AND STORAGE

| | |
|--------------------------------------------------------|---------------------------------------------------------------------------|
| Handling: Technical measures/precautions: | No special technical protective measures required. |
| Safe handling advice: | Avoid contact with skin and eyes. Wash thoroughly after handling. |
| Storage: Technical measures/storage conditions: | Keep at temperatures between 2 and 8°C. Keep refrigerated. Do not freeze. |

Incompatible products: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| Components | ACGIH - OEL (TWA - 8 hr) | ACGIH - OEL (STEL) | OSHA - OEL (Ceiling) | OSHA - PBOEL | ASL |
|-----------------------------------------------|--------------------------|--------------------|----------------------|---------------------|------------------------|
| Doxorubicin hydrochloride (<1%) 25316-40-9 | 470 ng/m ³ | | | Category 4 Repro | 470 ng/cm ² |

Engineering controls: Handle, weigh or transfer in a chemical fume hood, vented enclosure or with effective local exhaust ventilation.
Avoid generation of aerosols outside of containment when priming syringes.

Personal protective equipment

Eye protection: Safety glasses with side-shields, goggles, or face shield required.
Hand protection: Protective gloves recommended when manufacturing product.
Skin and body protection: Lab coats are recommended to be worn to minimize the potential for skin exposure.
Respiratory protection: None required.
Other/general protection: Prepare syringes in a bio-safety cabinet or fume hood.

9. PHYSICAL AND CHEMICAL PROPERTIES

General Information

Appearance: Liquid translucent
Color: Red
Odor: none

Important Health Safety and Environmental Information

Flash point: Not determined
Specific gravity: 1.04
pH: 6.0-7.0
Water solubility: Soluble

Other information

Explosivity: None.

10. STABILITY AND REACTIVITY

Chemical stability: Stable at normal conditions
Materials to avoid: Unknown on product.
Conditions to avoid: Unknown on product.
Hazardous polymerization: Hazardous polymerization does not occur.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Eye contact: Irritating to the eyes.

11. TOXICOLOGICAL INFORMATION

Skin contact: Irritating to the skin.
Ingestion: May be harmful if swallowed.
Inhalation: May be harmful by inhalation.
LD50 Oral Mouse (m) (mg/kg): 698 (as of doxorubicin HCl)

Subchronic toxicity

No data available.

Chronic toxicity

No data available.

Specific effects

Corrosive effects: Unknown on product.
Sensitization: Unknown on product.
Target organ effects: Reproductive
Mutagenic effects: Active ingredient has been shown to have mutagenic properties when tested in animal models.
Reproductive effects: Can cause fetal harm when administered to a pregnant women. Embryotoxic at doses of 1 mg/kg/day (as of doxorubicin HCl) in rats. Embryotoxic and abortifacient at 0.5 mg/kg/day (as of doxorubicin HCl) in rabbits.
Carcinogenic effects: Classified as a suspected human carcinogen.

General notes

The information included in this section pertains to the active pharmaceutical ingredient(s) of this material and not to the formulated product.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: This product has no known eco-toxicological effects.
Aquatic toxicity effects: This product has no known aquatic toxicological effects.

13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products:

Waste disposal must be in accordance with appropriate US, Federal, State and International regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority.

Contaminated packaging:

None.

14. TRANSPORT INFORMATION

Product not regulated by DOT, IATA/ICAO, IMO/IMDG, ADR/RID, or TDG.

15. REGULATORY INFORMATION

| Components | CAS Number | SARA 313 | SARA 302 | CERCLA | CEPA |
|------------------|------------|----------|----------|--------|---------|
| Sucrose (10-15%) | 57-50-1 | | | | Listed. |

SARA (311, 312) hazard class

| | |
|-------------------------------------------|-------|
| Immediate health: | None. |
| Delayed health: | None. |
| Fire: | None. |
| Sudden Release of Pressure Hazard: | None. |
| Reactivity: | None. |

State Regulations

| Components | CAS Number | NJRTK | PARTK | MARTK | RIRTK |
|---------------------------------|------------|-------|---------|---------|---------|
| Sucrose (10-30%) | 57-50-1 | | Listed. | Listed. | Listed. |
| Doxorubicin hydrochloride (<1%) | 25316-40-9 | | Listed. | | |

International Inventories

| Components | TSCA | DSL | NDSL |
|------------------|---------|---------|------|
| Sucrose (10-30%) | Listed. | Listed. | |

WHMIS:

| | |
|----------------------------|-------|
| WHMIS trade secret: | None. |
| WHMIS hazard class: | None. |

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensations and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substance Control Act.
5. WHMIS = Canadian Workplace Hazardous Materials Information System.
6. This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):

None.

MSDS format:

North American Format - U.S. and Canada
This Material Safety Data Sheet was prepared in accordance with ANSI Z400.1-2004.

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End of Safety Data Sheet