

Product Code: 10-020100

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Product Name: Amphotericin B Concentrate

1. Information on the Substance/Preparation and Company

1.1	<u>Catalog #</u>	<u>Product name</u>
	10-020100	Amphotericin B Concentrate (250 µg/mL)
1.2	<u>Company</u>	Diagnostic HYBRIDS, Inc. 1055 East State Street, Suite 100 Athens, OH 45701, USA (740) 589-3300 or (866) 344-3477
1.3	<u>In emergencies</u>	Call your local emergency center

2. Components and Hazardous Ingredients

<u>Hazardous Ingredients</u>	<u>Classification Substance</u>	<u>EINECS Nr.</u>
Amphotericin B	Xi, R:22-36/37/38; S26	215-742-2
Sodium desoxycholate	Xn, R:22, 37; Acute Tox. 4	206-132-7

Classification key: Toxic (T); Very toxic (T+); Harmful (Xn); Irritant (Xi); Dangerous for the environment (N); Oxidizing agent (O); Explosive (E); Flammable (F)

3. Hazards Identification

- Contains non-hazardous quantities of proprietary ingredients [OSHA Regulations (Standards-29CFR) Hazard Communication-1910.1200(i)(1)].
- Amphotericin B may cause severe allergic reaction with potentially lethal side effects.

4. First Aid Measures

- Eye contact:* ▪ Rinse immediately with water for 15 minutes, occasionally lifting the upper and lower eyelids
- Consult a doctor/medical service
- Skin contact:* ▪ Rinse with plenty of water
- Remove clothing before washing
- Consult a doctor/medical service
- After inhalation:* ▪ Remove the victim into fresh air
- Consult a doctor/medical service
- After ingestion:* ▪ Consult a doctor/medical service

5. Fire Fighting Measures

- Suitable extinguishing media:* ▪ All non combustible extinguishing media allowed
- Unsuitable extinguishing media:* ▪ No data available
- Special exposure hazards:* ▪ No data available
- Instructions:* ▪ Take account of contaminated fire fighting water
- Use fire fighting water moderately and contain it
- Special protective equipment for firefighters:* ▪ No data available

6. Accidental Release Measures

- Personal protection:* ▪ See 8.2, below
- Environmental precautions:* ▪ Discharge according to local regulations
- Clean-up:* ▪ Take up liquid spill into absorbent material
- Discharge absorbed material according to local regulations
- Wash clothing and equipment after handling

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7. Handling and Storage

- Handling:*
- *If solution is spilled:* take up with an absorbent material; if contact is possible, wear gloves as protection.
 - Discharge according to local regulations
 - Remove and clean contaminated clothing
 - Handle and open the container with care
- Storage:*
- -20°C
 - Keep away from: heat sources

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Chemical/Component	TLV/NIOSH REL	OSHA PEL	CAS No.
Amphotericin B	Not listed	Not listed	1397-89-3
Sodium deoxycholate	Not listed	Not listed	302-95-4

Note: Information in above table from NIOSH Pocket Guide to Chemical Hazards, 2005.

8.2 Control of Exposure

- Eye protection:*
- Safety glasses or Face shield
- Hand protection:*
- Gloves should be waterproof
 - Suitable materials: Butyl rubber, natural rubber, neoprene, nitrile rubber, polyethylene, PVC
 - Hands should be washed after working with this product.
- Skin protection:*
- Protective clothing
- Respiratory protection:*
- Area ventilation is generally adequate; avoid generation of dusts, mists or other airborne forms when working with the product
 - Insufficient ventilation: wear respiratory protection

9. Physical and Chemical Properties

Light straw/yellow in color, clear, aqueous liquid; odorless

Note: Boiling and Freezing Points for all aqueous components are near those of pure water.

10. Stability and Reactivity

- *Stability:* Stable if stored in specified conditions (see labeling).
- *Reactivity/Hazardous decomposition products:* No hazardous decomposition products are formed in high quantities.
- *Conditions/Materials to avoid:* see Section 3. Hazards Identification

11. Toxicological Information

Acute toxicity:

<i>Amphotericin B</i>	LD ₅₀ oral, rat	>5000 mg/kg
<i>Sodium deoxycholate</i>	LD ₅₀ oral, rat	1370 mg/kg

Chronic toxicity:

<i>Amphotericin B</i>	Target Organ(s): kidneys
<i>Sodium deoxycholate</i>	Target Organ(s): No data available

Note: Toxicity levels listed in the table above are for the ingredients when in their pure state.

Routes of exposure

- Ingestion, inhalation, eyes and skin
- Caution! Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals. Causes photosensitivity. Exposure to light can result in allergic reactions resulting in dermatologic lesions, which can vary from sunburn-like response to edematous, vesiculated lesions or bullae.

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Acute effects/symptoms

Amphotericin B: Known to have severe and potentially lethal side effects consisting of high fever, shaking chills, hypotension, anorexia, nausea, vomiting, headache, dyspnea, and tachypnea.

Chronic effects

Amphotericin B: Multiple organ damage associated with therapeutic doses with significant nephrotoxicity and/or hepatotoxicity. Several forms of anemia and other blood dyscrasias have been reported.

12. Ecological Information

Aquatic toxicity:

Sodium deoxycholate LC₅₀ (48 h): 115 mg/L (*Oryzias latipes*; Japanese killifish)

Other Information:

- *Effect on the ozone layer:* Not dangerous for the ozone layer (1999/45/EC)
- *Greenhouse effect:* No data available
- *Effect on waste water purification:* No data available

13. Waste Disposal Considerations

Disposal methods:

- Dispose of material according to local regulations.

14. Transport Information



USA: No restrictions.

Canada: No restrictions.

EU: No restrictions.

15. Regulatory Information

Classification according to directives 67/548/EEC and 1999/45/EC

Symbol	Risk and Safety Precaution
	R22: Harmful if swallowed R36/37/38: Irritating to eyes, respiratory system and skin R42/43: May cause sensitization by inhalation and skin contact R52: Harmful to aquatic organisms
Xn – harmful Xi – irritant	S24/25: Avoid contact with skin and eyes S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S29: Do not empty into drains
	S36/37/39: Wear suitable protective clothing, gloves and eye/face protection S45: In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)
N	

16. Other Information

- Based on: US 29 CFR 1910:1200(g); Canadian Hazardous Product Act, Part II; Directive 91/155/EEC et seq.
- This product is designed for use by professionals.
- The above information is believed to be accurate and represents the information available to date, but Diagnostic Hybrids does not purport it to be all-inclusive; this should be used only as a guide.
- Refer to the Product Insert for this Product for additional details on the proper storage, handling, use, and disposal of the reagents included in this Product.
- Contact Diagnostic Hybrids, Inc. if additional information is required.

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