

The information contained herein is based on the present state of our knowledge. It has been supplied for the purpose of protecting the health and safety of personnel handling the product under normal transport/warehouse conditions.

1. Identification of the substance/preparation and of the company/undertaking

Identification of the product: DigiFab[®] [Digoxin Immune Fab (Ovine)]


Manufacturer identification: Protherics Ltd (a BTG International Company)
5 Fleet Place
London
EC4M 7RD

2. Composition/information on ingredients

DigiFab[®] [Digoxin Immune Fab (Ovine)] is a sterile, nonpyrogenic, affinity purified, lyophilized preparation of ovine Fab immunoglobulin G fragments derived from the blood of sheep immunized with a digoxin dicarboxymethoxylamine derivative (DDMA) conjugated to the protein keyhole limpet hemocyanin.

3. Hazards identification

Main Hazard: Not generally hazardous in use but potential to be allergenic.

Classification	ACUTE ORAL TOXICITY – Category 4 (LD50 Predicted 1000 < 2000 mg/kg)
GHS Pictograms	
Signal Word	Warning
Hazard Statement	H302 Harmful if swallowed H332 Harmful if inhaled
Precautionary Statement	P261 Avoid breathing Dust P264 Wash hands thoroughly after handling P270 Do not eat, drink or smoke when using this product

4. First aid measures

Required only in the event of a vial breakage:

Eye contact: Irrigate thoroughly with water or saline solution, seek medical advice if necessary.

Inhalation: Remove from exposure, seek medical advice if necessary.

Skin contact: Wash affected area with water, seek medical advice if necessary.

Ingestion: Wash out mouth thoroughly with water, seek medical advice if necessary.

5. Fire-fighting measures

Extinguisher medium: Not applicable.

Unsuitable extinguisher medium: Not applicable.

Protective equipment for fire fighting: Not applicable.

6. Accidental release measures

In the event of a vial breakage, spray area with a water spray to dampen protein. Wear gloves and carefully remove all glass to designated containers. Wipe protein away with wet paper cloth and dispose of in clinical waste. Wash area thoroughly.

7. Handling and storage

Handling: Avoid vial breakage. Refer to point 6 above.

Storage: Store refrigerated at 2 to 8°C (36 to 46°F). Do not freeze.

8. Exposure controls/personal protection:

Exposure control limits: Not established.

Respiratory protection: Dust mask, work in extractor hood if exposing dust.

Eye protection: Safety glasses.

Hand protection: Rubber gloves.

Skin protection: Laboratory Coat, plastic apron

9. Physical and chemical properties

Physical properties

Form: Solid (friable cake)

Color: White or off-white

Odor: Odorless

Chemical properties: N/A

10. Stability and reactivity

Stability: Stable at stated storage conditions.

Conditions to be avoided: Elevated temperatures.

Hazardous decomposition products: Not applicable.

Substances to be avoided: Not applicable.

11. Toxicological information

This product is a pharmaceutical designed for intravenous human use. The data reproduced below indicates the safe levels of exposure via the intravenous route.

These products are proteins and although oral toxicity has not been determined expert medical opinion is that if these products are accidentally ingested they would be harmlessly digested in the human digestive system and therefore would not be toxic.

As a precautionary measure these products have been categorised as GHS category 4 for use.

The inhalation toxicity has not been fully developed but expert medical opinion is that if these products are accidentally inhaled they would not be toxic to humans. As these products are proteins however it can be expected that allergenic reactions may be expected in some sensitive individuals for repeated exposure. If these products are used within the limits of product information leaflet the probability of exposure to dust within occupational or transport setting is minimal.

Single Dose Toxicity: No toxic effects were observed when DigiFab[®] was administered to healthy male Sprague Dawley rats in equimolar doses sufficient to neutralize a 1 mg/kg dose of digoxin.

Repeated Dose Toxicity: Not Available

Carcinogenicity: Not Available

Reproductive Toxicity, teratogenicity and embryotoxicity: Not Available

Mutagenicity: Not Available

12. Ecological information

Ecotoxicity: Not available.

Persistence: Not available.

Appraisal: Not available.

Mobility: Not available.

Bioaccumulation: Not available.

13. Disposal conditions

Disposal: Disposal of product and items that have come into contact with the product as Biological Waste.

Packaging: Disposal in accordance with local regulations.

14. Transport information

Special precautions: Transport at 2 to 8 °C.

Not Considered Hazardous For Transport

UN no: Not applicable.

Packing group: Not applicable.

ADR/RID: Not applicable.

IMO – IMG code: Not applicable.

15. Regulatory information

Labelling information: See section 3.

16. Other information

Not Applicable

17. Revision History

Section 3&11 New Toxicity Information

Revision Date: May 2015

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