

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Teslascan®

**Synonyms:** Teslascan® (mangafodipir) Infusion

**Applications:** An intravenous contrast agent for Magnetic Resonance Imaging (MRI)

**Emergency Number:** In an emergency, call 1-800-654-0118

**Manufacturer:** Amersham Health  
101 Carnegie Center  
Princeton, NJ 08540  
609-514-6000 or 1-800-654-0118

## 2. COMPOSITION, INFORMATION ON INGREDIENTS

| <u><b>Ingredient Name</b></u> | <u><b>CAS No.</b></u> | <u><b>Percent by Weight</b></u> |
|-------------------------------|-----------------------|---------------------------------|
| Mangafodipir Trisodium        | 140678-14-4           | 1- 5%                           |
| Fodipir                       | --                    | <0.1%                           |
| Water                         | 7732-18-5             | 95%                             |

## 3. HAZARDS IDENTIFICATION

### \*\*\*\*\*EMERGENCY OVERVIEW\*\*\*\*\*

A clear yellow aqueous solution. Presents little or no hazard if spilled or in a fire.

Risk Phrase: R61 - May cause harm to unborn child

Hazard Symbol: T - Toxic

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### **Potential Health**

**Effects:** If entering the blood stream of a pregnant woman, it may harm the unborn child.

**Eyes:** May cause slight irritation.

**Skin:** Not an irritant.

**Ingestion:** No data available.

**Inhalation:** No data available.

## 4. FIRST AID MEASURES

**Eyes:** Flush eyes with water for up to 15 minutes. If irritation persists, seek medical attention.

**Skin:** Wash skin with soap and water.

**Ingestion:** Determine amount ingested and consult a physician.

**Inhalation:** Move person to fresh air and consult a physician.

## **5. FIRE FIGHTING MEASURES**

**Flammable Properties:** Nonflammable. This is an aqueous-based formulation.

**Extinguishing Media:** Use any extinguishing media appropriate for the surrounding fire.

**Fire Fighting Procedures:** As for any fire, fire fighters should wear self-contained breathing apparatus (SCBA) and full protective gear.

**Unusual Fire and Explosion Hazards:** None.

## **6. ACCIDENTAL RELEASE MEASURES**

**Personal Precautions:** Avoid contact with skin, eye, and clothing. Wear gloves. Wash after cleaning spill.

**Spills:** Wipe up a spill with cloth or absorb on paper towels. Wash area with soap and water. Take appropriate precautions when broken glass is present.

## **7. HANDLING AND STORAGE**

**Handling:** Avoid contact with skin, eyes, and clothing. Wash after handling.

**Storage:** Store vial on side in original carton between 15°C and 30°C (59°F and 86°F). Do not store vial upright. Upright storage may cause oxidation or discoloration. Do not freeze. Freezing may compromise the package integrity.

## **8. EXPOSURE CONTROLS, PERSONAL PROTECTION**

**Ventilation:** General ventilation is adequate.

**Protective Equipment:** Wear gloves (e.g., latex, PVC, polyethylene) which will prevent contact.

## **9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance:** Clear liquid

**Color:** Yellow

**Solubility:** Very soluble in water

**Specific Gravity:** 1.03

**pH:** 8.4 to 9.2

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal and anticipated storage and handling conditions.

**Conditions to Avoid:** None.

**Materials to Avoid:** Avoid contact with strong oxidizing agents.

## 11. TOXICOLOGICAL INFORMATION

**Eye Effects:** Slightly irritating based on a rabbit eye irritation test. Slight conjunctival redness was observed and cleared in 24 hours.

**Skin Effects:** Not a skin irritant based on rabbit irritation tests. No delayed contact hypersensitivity was observed in Guinea pigs.

**Acute Effects:** Minimum lethal intravenous dose was greater than 2000 mg/kg in rats and mice.

**Subchronic Effects:** Repeated intravenous administration at a daily dose of 219 mg/kg resulted in kidney and liver toxicity in rats and monkeys. The no observed effect level was 80 mg/kg for rats and 20 mg/kg for monkeys. The NOEL for repeat dose (21 day) dog study was 10  $\mu$ mol/kg. Target organs at higher doses (30 and 100  $\mu$ mol/kg) were liver and kidney.

**Mutagenicity:** Not a mutagen based on negative results from a series of genotoxicity studies (Ames test, chromosomal aberration in vitro, mammalian cell mutagenesis in vitro, transformation in vitro, and mouse micronucleus).

**Teratogenicity:** Rats: Repeated intravenous administration to pregnant rats resulted in bone malformations in fetuses. NOEL was 4 mg/kg.

Rabbits: Repeated intravenous administration to pregnant rabbits did not result in fetal malformations. Postimplantation losses were increased with daily administration of 45 mg/kg. NOEL was 30 mg/kg.

**Fertility:** No adverse effects on the fertility of male or female rats after repeated intravenous administration.

## 12. ECOLOGICAL INFORMATION

**Summary:** The product is readily soluble in water. The active ingredient is rated as not toxic to Daphnia or fish, but is toxic to algae. The no observed effect concentration for algae is 1.0 mg/l. The active ingredient does not readily degrade and has a low potential for bioaccumulation.

### Ecotoxicological Data:

|                |                  |          |         |            |
|----------------|------------------|----------|---------|------------|
| Acute toxicity | LC <sub>50</sub> | 24 hours | Daphnia | >2500 mg/l |
|                | LD <sub>50</sub> | 96 hours | fish    | >1000 mg/l |

|                  |                         |                     |       |               |
|------------------|-------------------------|---------------------|-------|---------------|
| Biodegradability | EC <sub>50</sub><br>BOD | 72 hours<br>28 days | algae | 21 mg/l<br>3% |
|------------------|-------------------------|---------------------|-------|---------------|

### 13. DISPOSAL CONSIDERATIONS

**Disposal Methods:** As with any waste, discharge, treatment, or disposal is subject to national, state, and local laws and regulations. As of the MSDS revision date, this product does not meet the United States EPA definition of a hazardous waste.

### 14. TRANSPORT INFORMATION

**General:** Transportation of this product is not subject to the United States Department of Transportation Hazardous Materials Regulations.

### 15. REGULATORY INFORMATION

**US Federal Regulations:** Section 313: This product does **not** contain any toxic chemical subject to the release reporting requirements of Section 313 of EPCRA and 40 CFR Part 372.

### 16. OTHER INFORMATION

**Revision Date:** April 2003 (company name, emergency number and regulatory information)

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