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

Material: LANOXIN INJECTION

Company Name: GlaxoSmithKline, Corporate Environment, Health & Safety
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US General Information: +1-888-825-5249
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US number, available 24 hours
Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS RN</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIGOXIN</td>
<td>20830-75-5</td>
<td>0.02</td>
</tr>
<tr>
<td>ETHANOL</td>
<td>64-17-5</td>
<td>11</td>
</tr>
<tr>
<td>NON-HAZARDOUS INGREDIENTS</td>
<td>Unassigned</td>
<td>88.98</td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

Fire and Explosion: This product is classified as flammable.

Health: Caution - Potent pharmaceutical agent.
Exposure might occur via skin; ingestion; eyes.
Possible effects of overexposure in the workplace include: symptoms similar to alcohol intoxication; cardiovascular effects.
Health effects information is based on hazards of components.

Environment: No information is available about the potential of this product to produce adverse environmental effects.
4. FIRST-AID MEASURES

Ingestion
Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

Inhalation
Physical form suggests that risk of inhalation exposure is negligible.

Skin Contact
Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.

Eye Contact
Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment
Medical treatment in cases of overexposure should be treated as an overdose of a cardiac glycoside. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

Health Surveillance Procedures
Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

Antidotes
For medical treatment in cases of overexposure, a recommended antidote would be Digibind. The decision as to whether the severity of poisoning requires administration of any antidote and actual dose required should be made by qualified medical personnel. For the latest information, refer to the local poison control information centres.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards
This product is flammable. Fire and explosions might result if vapours are allowed to accumulate in the vicinity of a source of ignition.

Extinguishing Media
Carbon dioxide, dry powder or foam extinguishers are recommended. Do not use water extinguishers. Water jets may intensify the fire or be ineffective.

Special Firefighting Procedures
For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal. Move containers from the fire area if possible without increased personal risk.

Hazardous Combustion Products
Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions
Stop leak and eliminate all sources of ignition (no smoking, sparks or flames). Fence or cordon the affected area and do not allow individuals to touch or walk through the spilled material unless wearing appropriate protective clothing. Wear protective clothing and equipment consistent with the degree of hazard.

Environmental Precautions
Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.

Clean-up Methods
Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures

Water can be used for clean-up and decontamination operations.

7. HANDLING AND STORAGE

HANDLING

General Requirements
No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

STORAGE
No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT
DIGOXIN

GSK Occupational Hazard Category
4

GSK Occupational Exposure Limit
1 mcg/m³ (8 HR TWA)

ENGINEERING CONTROLS

Exposure Controls
An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them. Special considerations apply in the planning, design, review and implementation of controls - seek specialist assistance from local occupational hygienist or safety department.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection
Wear approved safety glasses with side shields if eye contact is possible.

Respirators
If respiratory protective equipment (RPE) is used, it should provide full face protection. Follow local regulations for respirator use in the workplace.

Other Equipment or Procedures
Wash hands and arms thoroughly after handling. Wear appropriate clothing to avoid skin contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
Clarity
Clear.

Colour
Colourless.

Physical Form
Solution.

Flash Point
50 °C (Estimation based on components).

pH of Aqueous Solutions
6.8 to 7.2

10. STABILITY AND REACTIVITY

Stability
DO NOT FREEZE - dispose of properly if frozen.

Conditions to Avoid
Avoid direct sunlight, conditions that might generate heat and sources of ignition.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity
Not expected to be toxic following ingestion.

Inhalation Toxicity
No studies have been conducted.
Skin Effects
Irritation is not expected following direct contact with intact skin.

Eye Effects
Minor irritation might occur following direct contact with eyes.

Target Organ Effects
Adverse effects might occur in the following organ(s) following overexposure: heart.

Sensitisation
Sensitisation (allergic skin reaction) is not expected.

Genetic Toxicity
Not expected to be genotoxic under occupational exposure conditions.

Carcinogenicity
No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

Reproductive Effects
Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Pharmacological Effects
This product contains active ingredient(s) with the following activity: a cardiac glycoside.

Other Adverse Effects
The following adverse effects have been noted with therapeutic use of this material: symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).

12. ECOLOGICAL INFORMATION

* Summary
This material contains an active pharmaceutical ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this mixture to the environment. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY
Aquatic

* Activated Sludge
This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.
IC50: > 100 mg/l, 3 Hours, Activated sludge
NOEC: 100 , 3 Hours, Activated sludge

* Algal
No toxicity to algae was observed for the active pharmaceutical ingredient in this mixture, but the upper range of the test was limited by the low water solubility of the compound.
IC50: > 10 mg/l, 72 Hours, Selenastrum capricornutum, green algae
NOEL: 10 mg/l, 72 Hours, Selenastrum capricornutum, green algae

* Daphnid
This material contains an active pharmaceutical ingredient that is harmful to daphnids.
EC50: 24.2 mg/l, 24 Hours, Daphnia magna, Static test

* Fish
This material contains an active pharmaceutical ingredient that is toxic to fish.
Adult Oncorhyncus mykiss, rainbow trout
EC50: 2.9 mg/l, 96 Hours, Static test
Adult Oncorhyncus mykiss, rainbow trout
NOEL: 0.56 mg/l, 96 Hours, Static test

MOBILITY
**Solubility**
This material contains an active pharmaceutical ingredient that for environmental fate predictions has limited solubility in water.

**Volutility**
This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance.

This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant $< 1.00\text{E}-16 \text{ atm m}^3/\text{mol}$, Estimated

**Adsorption**
This material contains an active pharmaceutical ingredient that is not likely to adsorb to soil or sediment if released directly to the environment. This material contains an active pharmaceutical ingredient that is not likely to adsorb to sludge or biomass if released directly to the environment.

Sludge Biomass 1.78 Measured Measured at pH 7

Distribution Coefficient (log Kd):

**Partitioning**
This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

**PERSISTENCE/DEGRADATION**

**Photolysis**
This mixture contains an active pharmaceutical ingredient that is likely to undergo photodegradation.

UV/Visible Spectrum: 220 nm

**Biodegradation**
This mixture contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.

Aerobic - Inherent
Percent Degradation: $> 99\%$, 14 days, Zahn-Wellens, Activated sludge

### 13. DISPOSAL CONSIDERATIONS

**Disposal Recommendations**
Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used. Wherever possible, disposal should be in an on-site licenced chemical incinerator, if allowed by the incinerator licence or permit. If no on-site incinerator is available, dispose of material in a licenced commercial chemical incinerator.

**Regulatory Requirements**
Observe all local and national regulations when disposing of this product.

### 14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

**UN Classification and Labelling**

**Transport Information**
This product is not regulated according to IATA, IMDG, US DOT or ADR/RID requirements.

### 15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.
EU Classification and Labelling
Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

Classification This product is classified as hazardous according to the OSHA Hazard Communication Standard.

Other US Regulations
TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination
Date Approved/Revised 15-Oct-2004 SDS Version Number 8

SDS Sections Updated
Sections Subsections
ECOLOGICAL INFORMATION
Activated Sludge Respiration
Adsorption
Algal
Algal Degradation
Bioaccumulation
Biodegradation
Daphnid
Distribution
Earthworm
Ecotoxicity
Fish
Hydrolysis
Microbial Growth Inhibition
Microtox
Mobility
Other Adverse Effects
Other Species - Aquatic
Other Species - Terrestrial
Partitioning
Persistence/Degradation
Photolysis
Solubility
Summary
Volutility

PHYSICAL AND CHEMICAL PROPERTIES
The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.