

SAFETY DATA SHEET



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

Material	LANOXIN ELIXIR PEDIATRIC
Synonym(s)	LANOXIN ELIXIR PEDIATRIC 50 MCG/ML * LANOXIN PG ELIXIR 50 MCG/ML * LENOXIN LIQUIDUM * DIGOXIN, FORMULATED PRODUCT
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response</p> <p>GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

2. HAZARDS IDENTIFICATION

Fire and Explosion	This product is classified as flammable.
Health	<p>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.</p>
Environment	No information is available about the potential of this product to produce adverse environmental effects.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
DIGOXIN	20830-75-5	0.01	244-068-1
ETHANOL	64-17-5	10.39	200-578-6
Other components below reportable levels		89.6	

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.

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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	5
GSK Occupational Exposure Limit	1 mcg/m ³ (8 HR TWA)
ENGINEERING CONTROLS	
Exposure Controls	The active ingredient was formerly assigned to OHC 4 with the Highly Potent notation. 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.
Containment	Open handling may result in overexposure. It is strongly advised that dedicated areas and containment, such as glove boxes, isolators, and enclosed material transfer systems be used to prevent personnel exposure and spread of contamination.
Ventilation	Local exhaust ventilation (LEV) is not appropriate at this level, since total containment should usually be used.
Administrative	Strict control of access to the working area is essential. Only trained personnel should enter the area during operations. Adopt procedures to prevent contamination of working materials and adjacent areas.
PERSONAL PROTECTIVE EQUIPMENT	
Eye Protection	When isolation is not possible, chemical splash goggles or equivalent eye protection must be used with other applicable protective equipment.
Gloves	Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Glove selection must take into account any solvents and other hazards present. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided.
Respirators	When isolation is not possible, respiratory protective equipment (RPE) should be combined with applicable protective equipment.
Other Equipment or Procedures	Follow all local regulations if personal protective equipment (PPE) is used in the workplace. When isolation is not possible in production areas, applicable protective equipment must be used. Consider additional control procedures for maintenance, cleaning and emergencies.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	
Clarity	Clear.
Colour	Yellow.
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. TOXICOLOGY INFORMATION

Pharmacological Effects	This product contains active ingredient(s) with the following activity: a cardiac glycoside.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: heart.

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Routes of Exposure

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.
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.
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 Respiration**

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

NOEC: 10 mg/l, 72 Hours, Selenastrum capricornutum, green algae

Daphnid

This material contains an active pharmaceutical ingredient that is harmful to daphnids. This material contains an active pharmaceutical ingredient that is not toxic to daphnids in chronic toxicity studies.

EC50: 24.2 mg/l, 24 Hours, Daphnia magna, Static test

Chronic LOEC: > 10 mg/l, 7 Days, Ceriodaphnia dubia, Static renewal test

Chronic NOEC: 10 mg/l

Fish

This material contains an active pharmaceutical ingredient that is toxic to fish.

Adult Oncorhynchus mykiss, rainbow trout

EC50: 2.9 mg/l, 96 Hours, Static test

Adult Oncorhynchus mykiss, rainbow trout

NOEC: 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.

Mobility**Volatility**

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 < 1.00E-16 atm m³/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 at pH 7

Distribution Coefficient (log K_d):

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

Persistence/Degradation**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.

US OSHA Standard (29 CFR Part 1910.1200)**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

SDS Version Number

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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.