SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name. : Lanoxin Injection

Other means of identification : LANOXIN INJECTION PEDIATRIC 0.1 MG/ML * LANOXIN INJECTION ADULT 0.5MG/2ML * DIGOXIN, FORMULATED PRODUCT

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/preparation : Pharmaceutical Agent (No additional information available)

1.3. Details of the supplier of the safety data sheet

Covis Pharma B.V.
Baarn, Zug Branch
Grafenauweg 12
CH-6300 Zug, Switzerland

CH General Information:
Office : 0041 (0) 41 748 04 04 / Fax : 0041 (0) 41 748 04 09
Note : Zug Area code is 041. In Switzerland this area code must be used before the 7 digit tel. number
Medical Emergency : see U.S. information below
Information and Advice: US number, available 24 hours
Multi-language response

1.4. Emergency telephone number

Transport Emergency: For Chemical Emergency, Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
Outside USA and Canada: +1 703-527-3887 (collect calls accepted)
Medical Emergency +1-866-488-4423
US number, available 24 hours
Multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification
Flam. Liq. 2 H225

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US) :



Signal word (GHS-US) : Danger

Hazard statements (GHS-US) : H225 - Highly flammable liquid and vapour

Precautionary statements (GHS-US) : P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P233 - Keep container tightly closed
P240 - Ground/bond container and receiving equipment
P241 - Use explosion-proof electrical/ventilating/lighting/… equipment
P242 - Use only non-sparking tools
P243 - Take precautionary measures against static discharge
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P303+P361+P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
P308+P313 - IF exposed or concerned: Get medical advice/attention
P370+P378 - In case of fire: Use ... for extinction
P403+P235 - Store in a well-ventilated place. Keep cool
P405 - Store locked up
P501 - Dispose of contents/container to ...

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS-US classification
Ethyl alcohol	(CAS No.) 64-17-5	11	Flam. Liq. 2, H225 Carc. 1A, H350
Digoxin	(CAS No.) 20830-75-5	0.01	Acute Tox. 2 (Oral), H300

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : If not breathing, give artificial respiration.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact : Flush with plenty of water for at least 15 minutes. Seek medical advice if irritation develops or persists.

First-aid measures after ingestion : Do not induce vomiting. Give water to victim to drink. Seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

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 center.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam, dry chemical, carbon dioxide.

Unsuitable extinguishing media : Do not use extinguishing media containing water.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Highly flammable liquid and vapor.

Explosion hazard : Above flash point, vapor-air mixtures are explosive within flammable limits.

Reactivity : Stable at ambient temperature and under normal conditions of use.

5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid breathing vapors. Avoid skin and eye contact and wear appropriate personal protective equipment. Eliminate every possible source of ignition.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : If possible, stop flow of product.

Methods for cleaning up : Confine spill and soak up with absorbent. Place in an approved container and dispose in accordance with local, state and federal regulations.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : No special storage conditions required.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ethyl alcohol (64-17-5)		
USA ACGIH	ACGIH STEL (ppm)	1000 ppm
USA IDLH	US IDLH (ppm)	3300 ppm (10% LEL)
USA NIOSH	NIOSH REL (TWA) (mg/m3)	1900 mg/m³
USA NIOSH	NIOSH REL (TWA) (ppm)	1000 ppm
USA OSHA	OSHA PEL (TWA) (mg/m3)	1900 mg/m³
USA OSHA	OSHA PEL (TWA) (ppm)	1000 ppm

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : Wear impervious gloves to minimize skin contact.

Eye protection : Chemical goggles or face shield.

Skin and body protection : Wear suitable working clothes.

Respiratory protection : In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : colorless.

Odour : alcohol-like.

Odour threshold : No data available

pH : No data available

pH solution : 6.8 - 7.2

Relative evaporation rate (butylacetate=1) : No data available

Melting point : No data available

Freezing point : No data available

Boiling point : No data available

Flash point : 50 °C

Self ignition temperature : No data available

Decomposition temperature : No data available

Flammability (solid, gas) : No data available

Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable at ambient temperature and under normal conditions of use.

10.2. Chemical stability

The product is stable at normal handling- and storage conditions.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Heat, flames, and other ignition sources.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Digoxin (20830-75-5)	
LD50 oral rat	28.27 mg/kg
ATE (oral)	28.27 mg/kg

Ethyl alcohol (64-17-5)	
LD50 oral rat	7060 mg/kg
LC50 inhalation rat (mg/l)	124.7 mg/l (Exposure time: 4 h)

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Ethyl alcohol (64-17-5)	
IARC group	1
National Toxicity Program (NTP) Status	1

Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - water : 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 Oncorhyncus mykiss, rainbow trout
EC50: 2.9 mg/l, 96 Hours, Static test
Adult Oncorhyncus mykiss, rainbow trout
NOEC: 0.56 mg/l, 96 Hours, Static test

Ethyl alcohol (64-17-5)	
LC50 fish 1	12.0 - 16.0 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	9268 - 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 2	10800 mg/l (Exposure time: 24 h - Species: Daphnia magna)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Ethyl alcohol (64-17-5)	
Log Pow	-0.32

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

In accordance with DOT / ADR / RID / ADNR / IMDG / ICAO / IATA

14.1. UN number

Not a dangerous good in sense of transport regulations.

14.2. UN proper shipping name

Not applicable

14.2 Additional information

Other information : No supplementary information available.

Overland transport

No additional information available

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

Digoxin (20830-75-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on SARA Section 302 (Specific toxic chemical listings)	
SARA Section 302 Threshold Planning Quantity (TPQ)	≤ 10000

Ethyl alcohol (64-17-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

Ethyl alcohol (64-17-5)				
U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No significance risk level (NSRL)
Yes	Yes			

Digoxin (20830-75-5)
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List

Ethyl alcohol (64-17-5)
U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Full text of R-, H- and EUH-phrases:

Acute Tox. 2 (Oral)	Acute toxicity (oral) Category 2
Flam. Liq. 2	Flammable liquids Category 2
H225	Highly flammable liquid and vapour
H300	Fatal if swallowed

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.