SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Levothyroxine Formulation

Version            Revision Date:    SDS Number:     Date of last issue:     Date of first issue:
3.4                10.10.2020     1130735-00011     23.03.2020             30.11.2016

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

1.1 Product identifier
Trade name : Levothyroxine Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
Company : MSD
          Shotton Lane
          NE23 3JU  Cramlington NU - Great Britain
Telephone : 44 1 670 59 30 00
Telefax : 908-735-1496
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Flammable liquids, Category 3  H226: Flammable liquid and vapour.
Reproductive toxicity, Category 2  H361: Suspected of damaging fertility or the unborn child.
Specific target organ toxicity - repeated exposure, Category 1  H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms : 
Signal word : Danger
Hazard statements : H226  Flammable liquid and vapour.
                   H361  Suspected of damaging fertility or the unborn child.
                   H372  Causes damage to organs through prolonged or repeated exposure.
Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Hazardous components which must be listed on the label:
levothyroxine sodium

2.3 Other hazards
Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol#</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>603-002-00-5</td>
<td>Flam. Liq. 2; H225 Eye Irrit. 2; H319</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>levothyroxine sodium</td>
<td>55-03-8</td>
<td>200-221-4</td>
<td></td>
<td>Acute Tox. 2; H300 Repr. 2; H361 STOT RE 1; H372 (Thyroid, Cardiovascular system, Central nervous system)</td>
<td>&gt;= 0,1 - &lt; 1</td>
</tr>
</tbody>
</table>

#: Voluntarily-disclosed non-hazardous substance
For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice:
In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders:
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment.
When the potential for exposure exists (see section 8).

**If inhaled**
- If inhaled, remove to fresh air.
- Get medical attention.

**In case of skin contact**
- In case of contact, immediately flush skin with soap and plenty of water.
- Remove contaminated clothing and shoes.
- Get medical attention.
- Wash clothing before reuse.
- Thoroughly clean shoes before reuse.

**In case of eye contact**
- Flush eyes with water as a precaution.
- Get medical attention if irritation develops and persists.

**If swallowed**
- If swallowed, DO NOT induce vomiting.
- Get medical attention.
- Rinse mouth thoroughly with water.

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

**Risks**
- Suspected of damaging fertility or the unborn child.
- Causes damage to organs through prolonged or repeated exposure.

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

**Treatment**
- Treat symptomatically and supportively.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

**Suitable extinguishing media**
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

**Unsuitable extinguishing media**
- High volume water jet

#### 5.2 Special hazards arising from the substance or mixture

**Specific hazards during firefighting**
- Do not use a solid water stream as it may scatter and spread fire.
- Flash back possible over considerable distance.
- Vapours may form explosive mixtures with air.
- Exposure to combustion products may be a hazard to health.

**Hazardous combustion products**
- Carbon oxides
5.3 Advice for firefighters

**Special protective equipment for firefighters**: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

**Specific extinguishing methods**: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

**Personal precautions**: Remove all sources of ignition. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

**Environmental precautions**: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

#### 6.3 Methods and material for containment and cleaning up

**Methods for cleaning up**: Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapours/mists with a water spray jet. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.
SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling : Do not breathe mist or vapours.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures, which in contact with water, emit flammable gases
Explosives
Gases
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according to Regulation (EC) No. 1907/2006

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Version: 3.4
Revision Date: 10.10.2020
SDS Number: 1130735-00011
Date of last issue: 23.03.2020
Date of first issue: 30.11.2016

7.3 Specific end use(s)
Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Occupational Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
</tr>
<tr>
<td>Ethanol</td>
</tr>
<tr>
<td>levothyroxine sodium</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>343 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>950 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>950 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>206 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>114 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>87 mg/kg bw/day</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>Fresh water</td>
<td>0.96 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.79 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>2.75 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>580 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>3.6 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>2.9 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.63 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>720 mg/kg food</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures
Use explosion-proof electrical, ventilating and lighting equipment.
Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
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No open handling permitted. Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

**Personal protective equipment**

**Eye protection**: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Hand protection**

**Material**: Chemical-resistant gloves

**Remarks**: Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

**Skin and body protection**: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387

**Filter type**: Combined particulates and organic vapour type (A-P)

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>colourless</td>
</tr>
<tr>
<td>Odour</td>
<td>slight</td>
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<tr>
<td>Odour Threshold</td>
<td>No data available</td>
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<tr>
<td>pH</td>
<td>9,7 - 10,7</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>44 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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<tr>
<td>3.4</td>
<td>10.10.2020</td>
<td>1130735-00011</td>
<td>23.03.2020</td>
<td>30.11.2016</td>
</tr>
</tbody>
</table>

flammability limit
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : 1,05 g/cm³

Solubility(ies)
Water solubility : soluble
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
Flammability (liquids) : Not applicable
Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents Acids
10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:

Ethanol:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity: LC50 (Rat): 124.7 mg/l
Exposure time: 4 h
Test atmosphere: vapour

Levothyroxine sodium:
Acute oral toxicity: TDLo (Humans): 10 mg/kg
TDLo (Dog): 10 mg/kg
LD50 (Rat): > 1,000 mg/kg

Acute dermal toxicity: LD50 (Rat): > 50 mg/kg

Acute toxicity (other routes of administration):
LD50 (Rat): 20 mg/kg
Application Route: Intraperitoneal
LD50 (Rat): 50 mg/kg
Application Route: Subcutaneous

Skin corrosion/irritation
Not classified based on available information.

Components:

Ethanol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Serious eye damage/eye irritation
Not classified based on available information.

Components:
Ethanol:
Species: Rabbit
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Ethanol:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:
Ethanol:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Genotoxicity in vivo: Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: equivocal

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Suspected of damaging fertility or the unborn child.

Components:
Ethanol:
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<thead>
<tr>
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<td>30.11.2016</td>
</tr>
</tbody>
</table>

Effects on fertility
: Test Type: Two-generation reproduction toxicity study
  Species: Mouse
  Application Route: Ingestion
  Result: negative

### levothyroxine sodium:

Effects on foetal development
: Test Type: Development
  Species: Rat
  Application Route: Oral
  Developmental Toxicity: LOAEL: 0.25 mg/kg body weight

Test Type: Development
  Species: Mouse
  Application Route: Oral
  Developmental Toxicity: NOAEL: 3 mg/kg body weight

Test Type: Development
  Species: Rabbit
  Result: No teratogenic effects

Test Type: Development
  Species: Guinea pig
  Result: No teratogenic effects

Reproductive toxicity - Assessment
: Suspected of damaging the unborn child.

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
Causes damage to organs through prolonged or repeated exposure.

**Components:**

### levothyroxine sodium:

Target Organs
: Thyroid, Cardio-vascular system, Central nervous system

Assessment
: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

### Ethanol:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>1.280 mg/kg</td>
<td>3.156 mg/kg</td>
</tr>
</tbody>
</table>

Application Route: Ingestion
Exposure time: 90 Days

**Aspiration toxicity**
Not classified based on available information.
Experience with human exposure

**Components:**

**levothyroxine sodium:**

**Ingestion:**

- **Target Organs:** Thyroid
- **Target Organs:** Cardio-vascular system
- **Target Organs:** Central nervous system
- **Symptoms:** Palpitation, hypotension, Tremors, Headache, increase in appetite, Sweating, Vomiting, Diarrhoea, Fever, nervousness, weight loss

### SECTION 12: Ecological information

#### 12.1 Toxicity

**Components:**

**Ethanol:**

- **Toxicity to fish:** LC50 (Pimephales promelas (fathead minnow)): > 1.000 mg/l
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Ceriodaphnia (water flea)): > 1.000 mg/l
  Exposure time: 48 h
- **Toxicity to algae/aquatic plants:** ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
  Exposure time: 72 h
- **EC10 (Chlorella vulgaris (Fresh water algae)):** 11.5 mg/l
  Exposure time: 72 h
- **Toxicity to microorganisms:** EC50 (Pseudomonas putida): 6.500 mg/l
  Exposure time: 16 h
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** NOEC: 9.6 mg/l
  Exposure time: 9 d
  Species: Daphnia magna (Water flea)

#### 12.2 Persistence and degradability

**Components:**

**Ethanol:**

- **Biodegradability:** Result: Readily biodegradable.
  Biodegradation: 84 %
  Exposure time: 20 d

#### 12.3 Bioaccumulative potential

**Components:**

**Ethanol:**

- **Partition coefficient:** n- log Pow: -0.35
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12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number
ADN: UN 1170
ADR: UN 1170
RID: UN 1170
IMDG: UN 1170
IATA: UN 1170

14.2 UN proper shipping name
ADN: ETHANOL SOLUTION
ADR: ETHANOL SOLUTION
RID: ETHANOL SOLUTION
IMDG: ETHANOL SOLUTION
IATA: Ethanol solution

14.3 Transport hazard class(es)
ADN: 3
ADR: 3
RID: 3
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14.4 Packing group

**ADN**
Packing group: III
Classification Code: F1
Hazard Identification Number: 30
Labels: 3

**ADR**
Packing group: III
Classification Code: F1
Hazard Identification Number: 30
Labels: 3
Tunnel restriction code: (D/E)

**RID**
Packing group: III
Classification Code: F1
Hazard Identification Number: 30
Labels: 3

**IMDG**
Packing group: III
Labels: 3
EmS Code: F-E, S-D

**IATA (Cargo)**
Packing instruction (cargo aircraft): 366
Packing instruction (LQ): Y344
Packing group: III
Labels: Flammable Liquids

**IATA (Passenger)**
Packing instruction (passenger aircraft): 355
Packing instruction (LQ): Y344
Packing group: III
Labels: Flammable Liquids

14.5 Environmental hazards

**ADN**
Environmentally hazardous: no

**ADR**
Environmentally hazardous: no

**RID**
Environmentally hazardous: no

**IMDG**
Marine pollutant: no
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14.6 Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).
REACH - List of substances subject to authorisation (Annex XIV)
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

P5c FLAMMABLE LIQUIDS Quantity 1: 5.000 t Quantity 2: 50.000 t

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version
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according to Regulation (EC) No. 1907/2006

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Version 3.4 Revision Date: 10.10.2020 SDS Number: 1130735-00011 Date of last issue: 23.03.2020 Date of first issue: 30.11.2016

Full text of H-Statements

H225 : Highly flammable liquid and vapour.
H300 : Fatal if swallowed.
H319 : Causes serious eye irritation.
H361 : Suspected of damaging fertility or the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA : Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative
Levothyroxine Formulation

Further information

Sources of key data used to compile the Safety Data Sheet:
- Internal technical data
- Data from raw material SDSs
- OECD eChem Portal search results

Classification of the mixture:

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