

Revision Date 10-Feb-2011

Revision Number 2

1. PRODUCT AND COMPANY IDENTIFICATION

Product Identifier

Product Description: L-Thyroxine sodium salt hydrate Cat No. 138960000; 138960010; 138960050

Synonyms Sodium levothyroxine

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

Recommended Use Laboratory chemicals
Uses advised against No Information available

Details of the supplier of the safety data sheet

Company

Acros Organics BVBA

Janssen Pharmaceuticalaan 3a

2440 Geel, Belgium

E-mail address begel.sdsdesk@thermofisher.com

Emergency Telephone Number

For information in the US, call: 001-800-ACROS-01 For information in Europe, call: +32 14 57 52 11

Emergency Number, Europe: +32 14 57 52 99 Emergency Number, US: 001-201-796-7100

CHEMTREC Phone Number, US: 001-800-424-9300 CHEMTREC Phone Number, Europe: 001-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture REGULATION (EC) No 1272/2008

Not hazardous

Classification according to EU Directives 67/548/EEC or 1999/45/EC

For the full text of the R phrases mentioned in this Section, see Section 16

R -phrase(s) none

Label Elements

Signal Word None

Hazard Statements

Other Hazards

No information available.



L-Thyroxine sodium salt hydrate

Revision Date 10-Feb-2011

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	EC No.	Weight %	CAS-No	Classification	GHSCLAS	REACH Reg. No.
Levothyroxine		99	25416-65-3	=	=	=
25416-65-3						

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of first aid measures

Eye ContactRinse immediately with plenty of water, also under the eyelids, for at least 15 minutes Obtain

medical attention

Skin Contact Wash off immediately with soap and plenty of water removing all contaminated clothes and

shoes Obtain medical attention

Ingestion Clean mouth with water Get medical attention

Inhalation Remove from exposure, lie down Move to fresh air

Notes to Physician Treat symptomatically

5. FIRE-FIGHTING MEASURES

Extinguishing media
Suitable Extinguishing Media

Water spray Carbon dioxide (CO₂) Dry chemical chemical foam

Extinguishing media which must not be used for safety reasons

No information available.

Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors

Advice for fire-fighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation



L-Thyroxine sodium salt hydrate

Revision Date 10-Feb-2011

Environmental precautions

Prevent further leakage or spillage if safe to do so

Methods and material for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable and closed containers for disposal. Sweep up or vacuum up spillage and collect in suitable container for disposal.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid contact with skin and eyes Do not breathe dust Do not breathe vapors or spray mist

Conditions for safe storage, including any incompatibilities

Keep in a dry, cool and well-ventilated place Keep container tightly closed

Specific End Uses

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL)

Predicted No Effect Concentration

(PNEC)

Exposure controls Engineering Measures

Personal protective equipment

Eve Protection Hand Protection

Skin and body protection

Respiratory Protection

No information available. No information available.

Ensure adequate ventilation, especially in confined areas

Goggles

Protective gloves

Wear appropriate protective gloves and clothing to prevent skin exposure

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits

are exceeded or if irritation or other symptoms are experienced

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice

No information available. **Environmental exposure controls**

9. PHYSICAL AND CHEMICAL PROPERTIES

Powder, Solid **Physical State** Off-white **Appearance** odor odorless

Ηq 8.5-9.0 sat.aq.sol.(20°C)

Vapor Pressure negligible Vapor Density 30.6

Boiling Point/Range No information available.



L-Thyroxine sodium salt hydrate

Revision Date 10-Feb-2011

9. PHYSICAL AND CHEMICAL PROPERTIES

207 - 210°C / 404.6 - 410°F

No information available. 0.15 g/L (25°C)

2.381

C15 H10 I4 N Na O4 . x H2 O

798.86

10. STABILITY AND REACTIVITY

Reactivity

Chemical Stability

Melting Point/Range

Flash Point

Water Solubility

Specific Gravity

Molecular Formula

Molecular Weight

Stable under normal conditions

Possibility of Hazardous Reactions

Hazardous Polymerization No information available.
Hazardous Reactions . No information available.

Conditions to Avoid

Temperatures above .?1°C, Incompatible products.

Incompatible Materials

Strong oxidizing agents.

Hazardous Decomposition Products

Nitrogen oxides (NOx). Carbon monoxide (CO). Carbon dioxide (CO₂). Hydrogen iodide. Sodium oxides.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Acute Toxicity

Product InformationNo acute toxicity information is available for this product

Component Information

Chronic Toxicity

Carcinogenicity There are no known carcinogenic chemicals in this product

SensitizationNo information available.Mutagenic EffectsNo information availableReproductive EffectsNo information available.Developmental EffectsNo information available.Target OrgansNo information available.

Other Adverse Effects

The toxicological properties have not been fully investigated.



L-Thyroxine sodium salt hydrate

Revision Date 10-Feb-2011

11. TOXICOLOGICAL INFORMATION

Endocrine Disruptor Information None known

12. ECOLOGICAL INFORMATION

Toxicity

Ecotoxicity effectsContains no substances known to be hazardous to the environment or that are not degradable

in waste water treatment plants

Persistence and degradability

No information available

Bioaccumulative potential

No information available.

Mobility in soil

No information available.

Results of PBT and vPvB assessment

Other adverse effects

No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from Residues / Unused

Products

Dispose of in accordance with local regulations

Contaminated Packaging Empty containers should be taken for local recycling, recovery or waste disposal

14. TRANSPORT INFORMATION

IMDG/IMO

UN-No 2811 Hazard Class 6.1 Packing Group III

Proper Shipping Name TOXIC SOLID, ORGANIC, N.O.S.

<u>ADR</u>

UN-No 2811 Hazard Class 6.1 Packing Group III

Proper Shipping Name TOXIC SOLID, ORGANIC, N.O.S.



L-Thyroxine sodium salt hydrate

Revision Date 10-Feb-2011

14. TRANSPORT INFORMATION

IATA

UN-No 2811 Hazard Class 6.1 Packing Group III

Proper Shipping Name TOXIC SOLID, ORGANIC, N.O.S.*

15. REGULATORY INFORMATION

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

International Inventories

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory Lists

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

CHINA - China Inventory of Existing Chemical Substances

AICS - Inventory of Chemical Substances

KECL - Existing and Evaluated Chemical Substances

Chemical Safety Assessment

16. OTHER INFORMATION

Text of R phrases mentioned in Section 2-3

No information available.

Revision Date 10-Feb-2011 Revision Summary Not applicable

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text

End of Safety Data Sheet