

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/05/2023
4.12	09/28/2024	1130650-00019	Date of first issue: 11/30/2016

SECTION 1. IDENTIFICATION

Product name : Levothyroxine Formulation
Other means of identification : Leventa (A010426)

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Flammable liquids : Category 3
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 1 (Thyroid, Cardio-vascular system, Central nervous system)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H226 Flammable liquid and vapor.
H361 Suspected of damaging fertility or the unborn child.
H372 Causes damage to organs (Thyroid, Cardio-vascular system, Central nervous system) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version 4.12 Revision Date: 09/28/2024 SDS Number: 1130650-00019 Date of last issue: 12/05/2023
Date of first issue: 11/30/2016

P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Ethanol#	Ethyl alcohol	64-17-5	$\geq 10 - < 30$
levothyroxine sodium	L-Tyrosine, O-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-, monosodium salt	55-03-8	$\geq 0.1 - < 1^*$

Voluntarily-disclosed substance

* Actual concentration or concentration range is withheld as a trade secret

SECTION 4. 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.

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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/05/2023
4.12	09/28/2024	1130650-00019	Date of first issue: 11/30/2016

Most important symptoms and effects, both acute and delayed	:	Get medical attention. Rinse mouth thoroughly with water. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.
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).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
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.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/05/2023
4.12	09/28/2024	1130650-00019	Date of first issue: 11/30/2016

Methods and materials for containment and cleaning up : Non-sparking tools should be used.
Soak up with inert absorbent material.
Suppress (knock down) gases/vapors/mists with a water spray jet.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

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 vapors.
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.

Conditions for safe storage : Keep in properly labeled 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.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version 4.12 Revision Date: 09/28/2024 SDS Number: 1130650-00019 Date of last issue: 12/05/2023
Date of first issue: 11/30/2016

Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures which in contact with water emit flammable gases
Explosives
Gases
Very acutely toxic substances and mixtures

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	TWA	1,000 ppm 1,880 mg/m ³	CA AB OEL
		STEL	1,000 ppm	CA BC OEL
		STEV	1,000 ppm	CA QC OEL
		STEL	1,000 ppm	ACGIH
levothyroxine sodium	55-03-8	TWA	0.1 µg/m ³ (OEB 5)	Internal
		Wipe limit	1 µg/100 cm ²	Internal

Engineering measures : 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. 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. Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapor type

Hand protection

Material : Chemical-resistant gloves

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version 4.12	Revision Date: 09/28/2024	SDS Number: 1130650-00019	Date of last issue: 12/05/2023 Date of first issue: 11/30/2016
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- Eye protection : 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.
- 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.
- 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : Aqueous solution
- Color : colorless
- Odor : slight
- Odor Threshold : No data available
- pH : 9.7 - 10.7
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : 44 °C
- Evaporation rate : No data available
- Flammability (solid, gas) : Not applicable
- Flammability (liquids) : Not applicable
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower : No data available

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/05/2023
4.12	09/28/2024	1130650-00019	Date of first issue: 11/30/2016

flammability limit

Vapor pressure : No data available

Relative vapor 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

Autoignition 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.

Particle characteristics

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Flammable liquid and vapor.
Vapors may form explosive mixture with air.
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : Oxidizing agents
Acids

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation

Skin contact

Ingestion

Eye contact

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/05/2023
4.12	09/28/2024	1130650-00019	Date of first issue: 11/30/2016

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): 10,470 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat, male): 116.9 mg/l
Exposure time: 4 h
Test atmosphere: vapor

Acute dermal toxicity : LD50 (Rabbit): > 15,800 mg/kg

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
Result : Irritation to eyes, reversing within 21 days

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/05/2023
4.12	09/28/2024	1130650-00019	Date of first issue: 11/30/2016

Method : OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Ethanol:

Test Type	: Mouse ear swelling test (MEST)
Routes of exposure	: Skin contact
Species	: Mouse
Result	: negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Ethanol:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
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Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Application Route: Ingestion Result: negative
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Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Components:

Ethanol:

Effects on fertility	: Test Type: Two-generation reproduction toxicity study Species: Mouse Application Route: Ingestion
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SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/05/2023
4.12	09/28/2024	1130650-00019	Date of first issue: 11/30/2016

Result: negative

levothyroxine sodium:

Effects on fetal 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 (Thyroid, Cardio-vascular system, Central nervous system) 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:

Species : Rat
NOAEL : 1,730 mg/kg
LOAEL : 3,200 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Aspiration toxicity

Not classified based on available information.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/05/2023
4.12	09/28/2024	1130650-00019	Date of first issue: 11/30/2016

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, Diarrhea, Fever, nervousness, weight loss

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l
aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
plants Exposure time: 72 h

EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic tox- : NOEC (Oryzias latipes (Japanese medaka)): >= 79 mg/l
icity) Exposure time: 100 d

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 9.6 mg/l
aquatic invertebrates (Chron- Exposure time: 9 d
ic toxicity)

Toxicity to microorganisms : EC50 (Protozoa): 5,800 mg/l
Exposure time: 4 h

Persistence and degradability

Components:

Ethanol:

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

Bioaccumulative potential

Components:

Ethanol:

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/05/2023
4.12	09/28/2024	1130650-00019	Date of first issue: 11/30/2016

Partition coefficient: n-octanol/water : log Pow: -0.35

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	: Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
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

International Regulations

UNRTDG

UN number	: UN 1170
Proper shipping name	: ETHANOL SOLUTION
Class	: 3
Packing group	: III
Labels	: 3
Environmentally hazardous	: no

IATA-DGR

UN/ID No.	: UN 1170
Proper shipping name	: Ethanol solution
Class	: 3
Packing group	: III
Labels	: Flammable Liquids
Packing instruction (cargo aircraft)	: 366
Packing instruction (passenger aircraft)	: 355

IMDG-Code

UN number	: UN 1170
Proper shipping name	: ETHANOL SOLUTION
Class	: 3
Packing group	: III
Labels	: 3
EmS Code	: F-E, S-D
Marine pollutant	: no

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/05/2023
4.12	09/28/2024	1130650-00019	Date of first issue: 11/30/2016

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

TDG

UN number	:	UN 1170
Proper shipping name	:	ETHANOL SOLUTION
Class	:	3
Packing group	:	III
Labels	:	3
ERG Code	:	127
Marine pollutant	:	no

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.

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / STEL	:	Short-term exposure limit
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / STEL	:	short-term exposure limit
CA QC OEL / STEV	:	Short-term exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/05/2023
4.12	09/28/2024	1130650-00019	Date of first issue: 11/30/2016

tem; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 09/28/2024
Date format : mm/dd/yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8