according to the OSHA Hazard Communication Standard



Levothyroxine Formulation

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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 OSHA Hazard Communication Standard (29 CFR 1910.1200)

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, sparks, open flame and hot surfac-

es. No smoking.

P233 Keep container tightly closed.

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P241 Use explosion-proof electrical, ventilating and lighting

equipment.

P242 Use only non-sparking tools.

P243 Take precautionary measures against static discharge.

P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling.

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:

P403 + P235 Store in a well-ventilated place. Keep cool.

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	CAS-No.	Concentration (% w/w)
Ethanol#	64-17-5	>= 10 - < 20
levothyroxine sodium	55-03-8	>= 0.1 - < 1

[#] Voluntarily-disclosed substance

Actual concentration 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.

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If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

and effects, both at

and

delayed

Protection of first-aiders :

Notes to physician

Suspected of damaging fertility or the unborn child.

Causes damage to organs through prolonged or repeated exposure.

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).

Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

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 prod-

icts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 emer-

gency 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

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cannot be contained.

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 equip-

ment.

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

according to the OSHA Hazard Communication Standard



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> 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

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	STEL	1,000 ppm	ACGIH
		TWA	1,000 ppm 1,900 mg/m ³	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m³	OSHA Z-1
levothyroxine sodium	55-03-8	TWA	0.1 μg/m3 (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

General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any

hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled

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release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

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.

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.

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 : 111 °F / 44 °C

Evaporation rate : No data available

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Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

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 reac-

tions

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.

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SECTION 11. TOXICOLOGICAL INFORMATION

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: > 5,000 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

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Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ethanol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

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

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

Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

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identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

No ingredient of this product present at levels greater than or equal to 0.1% is **NTP**

identified as a known or anticipated carcinogen by NTP.

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

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 - As-

sessment

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.

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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.

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 :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 5,012 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 fish (Chronic tox-

icity)

NOEC (Oryzias latipes (Japanese medaka)): >= 79 mg/l

Exposure time: 100 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 9.6 mg/l

Exposure time: 9 d

according to the OSHA Hazard Communication Standard



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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:

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 : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

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

according to the OSHA Hazard Communication Standard



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UN/ID No. : UN 1170
Proper shipping name : Ethanol solution

Class : 3 Packing group : III

Labels : Flammable Liquids

Packing instruction (cargo : 366

aircraft)

Packing instruction (passen: 355

ger aircraft)

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

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

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number : UN 1170

Proper shipping name : Ethanol solutions

Class : 3 Packing group : III

Labels : FLAMMABLE LIQUID

ERG Code : 127 Marine pollutant : no

Remarks : Above applies only to containers over 119 gallons or 450

liters. Not regulated if shipped in packages less than or equal to 119 gallons (450 liters). If transporting by vessel or aircraft, unless other means of transportation is impracticable, then the

product must be shipped as a flammable liquid.

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

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Flammable (gases, aerosols, liquids, or solids)

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Reproductive toxicity

Specific target organ toxicity (single or repeated exposure)

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Water 7732-18-5 Hydroxypropyl-beta-cyclodextrin 128446-35-5 Ethanol 64-17-5

California List of Hazardous Substances

Ethanol 64-17-5

California Permissible Exposure Limits for Chemical Contaminants

Ethanol 64-17-5

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

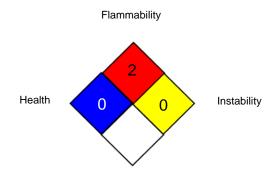
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NFPA 704:



Special hazard

HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its for Air Contaminants

ACGIH / STEL : Short-term exposure limit

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour

workday during a 40-hour workweek

OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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 System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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 sub-

according to the OSHA Hazard Communication Standard



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stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - 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

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 Agen-

cy, http://echa.europa.eu/

Revision Date : 09/28/2024

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.

US / Z8