

# Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Issue date: 1/6/2011 Revision date: 3/26/2024 Supersedes: 8/22/2016 Version: 3.0

# **SECTION 1: Identification**

#### 1.1. Identification

Product form : Substance

Substance name : 17-α-Ethynylestradiol (2,4,16,16-D<sub>4</sub>, 97-98%)

CAS-No. : 57-63-6
Product code : DLM-4691
Formula : C20H24O2

Synonyms : (8R,9S,13S,14S,17R)-17-Ethynyl-13-methyl-7,8,9,11,12,14,15,16-octahydro-6H-

cyclopenta[a]phenanthrene-3,17-diol; 17α-19-Norpregna-1,3,5(10)-trien-20-yne-3,17-diol; 17-

Ethinyl-3,17-estradiol

#### 1.2. Recommended use and restrictions on use

No additional information available

# 1.3. Supplier

Cambridge Isotope Laboratories, Inc.

50 Frontage Rd

01810

ANDOVER, MA, 01810

USA

T 1-800-322-1174

cilsales@isotope.com - www.isotope.com

#### 1.4. Emergency telephone number

Emergency number : 1-703-741-5970

Chemtrec 1-800-424-9300 24 hours

# **SECTION 2: Hazard(s) identification**

# 2.1. Classification of the substance or mixture

#### **GHS US classification**

Acute toxicity (oral) Category 4 H302 Harmful if swallowed

Carcinogenicity Category 1A H350 May cause cancer (Dermal, Inhalation, oral)
Hazardous to the aquatic environment – Chronic Hazard Category 1 H410 Very toxic to aquatic life with long lasting effects

Full text of H statements : see section 16

#### 2.2. GHS Label elements, including precautionary statements

#### **GHS US labeling**

Hazard pictograms (GHS US)







Signal word (GHS US) : Danger

Hazard statements (GHS US) : H302 - Harmful if swallowed

H350 - May cause cancer (Dermal, Inhalation, oral) H410 - Very toxic to aquatic life with long lasting effects

Precautionary statements (GHS US) : P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P264 - Wash Both hands thoroughly after handling.

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P270 - Do not eat, drink or smoke when using this product.

P273 - Avoid release to the environment.

P280 - Wear protective clothing, protective gloves.

P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.

P308+P313 - If exposed or concerned: Get medical advice/attention.

P330 - Rinse mouth.

P391 - Collect spillage.

P405 - Store locked up.

P501 - Dispose of contents/container to Comply with applicable regulations.

#### 2.3. Other hazards which do not result in classification

No additional information available

# 2.4. Unknown acute toxicity (GHS US)

Not applicable

# **SECTION 3: Composition/Information on ingredients**

#### 3.1. Substances

Name	Product identifier	%	GHS US classification
17-α-Ethynylestradiol (2,4,16,16-D <sub>4</sub> , 97-98%) (Main constituent)	CAS-No.: 57-63-6		Acute Tox. 4 (Oral), H302 Carc. 1A, H350 Aquatic Chronic 1, H410

Full text of hazard classes and H-statements : see section 16

### 3.2. Mixtures

Not applicable

# **SECTION 4: First-aid measures**

# 4.1. Description of first aid measures

First-aid measures general : Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

First-aid measures after inhalation : If breathed in, move person to fresh air. If not breathing, give artificial respiration. Consult a

physician.

First-aid measures after skin contact : Wash with soap and plenty of water. Consult a physician.

First-aid measures after eye contact : Flush eyes with water as a precaution.

First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

#### 4.2. Most important symptoms and effects (acute and delayed)

Potential Adverse human health effects and : This information is base symptoms the purposes of health,

: 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. Stomach - Irregularities - Based on Human Evidence.

Symptoms/effects : May cause cancer (in contact with skin, if inhaled, if swallowed).

Symptoms/effects after inhalation : May be harmful if inhaled. May cause respiratory tract irritation. Symptoms/effects after skin contact : May be harmful if absorbed through skin. May cause skin irritation.

Symptoms/effects after eye contact : May cause eye irritation.
Symptoms/effects after ingestion : Harmful if swallowed.

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#### 4.3. Immediate medical attention and special treatment, if necessary

No additional information available

# **SECTION 5: Fire-fighting measures**

#### 5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Use water spray, alcohol-resistant foam, dry chemical, or carbon dioxide.

#### 5.2. Specific hazards arising from the chemical

Hazardous decomposition products in case of fire : Carbon oxides (CO, CO2).

#### 5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions : Wear self contained breathing apparatus for fire fighting if necessary.

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

#### 6.1.1. For non-emergency personnel

Emergency procedures

: Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

#### 6.1.2. For emergency responders

No additional information available

#### 6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

# 6.3. Methods and material for containment and cleaning up

For containment : Take up mechanically (sweeping, shoveling) and collect in suitable container for disposal.

#### 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 : Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate

exhaust ventilation at places where dust is formed. Normal measures for preventive fire

protection.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Wash hands before

breaks and at the end of workday.

#### 7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Keep container tightly closed in a cool, dry and well-ventilated place.

Storage conditions : Store at room temperature away from light and moisture.

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#### **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

#### 17-α-Ethynylestradiol (2,4,16,16-D<sub>4</sub>, 97-98%) (57-63-6)

#### **USA - ACGIH - Occupational Exposure Limits**

ACGIH chemical category

No component of this product present at levels greater than or equal to 0.1% is identifiable as a carcinogen or potential carcinogen by ACGIH.

#### 8.2. Appropriate engineering controls

Appropriate engineering controls

: Handle in accordance with good industrial hygiene and safety practice. Wash hands before

breaks and at the end of workday.

Environmental exposure controls

: Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

#### 8.3. Individual protection measures/Personal protective equipment

#### Personal protective equipment:

Gloves. Protective clothing. Protective goggles. Self-contained breathing apparatus.

#### Eye protection:

Wear safety glasses with side shields (or goggles) and a face shield.

#### Skin and body protection:

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

#### Respiratory protection:

When appropriate, use NIOSH/CEN approved respirator.

#### Personal protective equipment symbol(s):









#### **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

Physical state : Solid Appearance : Solid. Color : White

Odor : No data available
Odor threshold : No data available
pH : No data available
i : No data available

Melting point : 182 – 183 °C (360 - 361 °F) - lit.

Freezing point : No data available Boiling point : No data available Flash point : No data available Relative evaporation rate (butyl acetate=1) : No data available Flammability (solid, gas) : No data available No data available Vapor pressure No data available Relative vapor density at 20°C Relative density No data available : 300.43 g/mol (Labeled) Molecular mass

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Solubility : No data available Partition coefficient n-octanol/water (Log Pow) : No data available Auto-ignition temperature : No data available Decomposition temperature : No data available : No data available Viscosity, kinematic Viscosity, dynamic No data available **Explosion limits** No data available Explosive properties No data available Oxidizing properties : No data available

#### 9.2. Other information

No additional information available

# **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

No additional information available

#### 10.2. Chemical stability

Stable if stored under recommended conditions.

#### 10.3. Possibility of hazardous reactions

No additional information available

#### 10.4. Conditions to avoid

No additional information available

#### 10.5. Incompatible materials

Strong oxidizing agents.

#### 10.6. Hazardous decomposition products

Carbon oxides (CO, CO2).

LD50 oral rat

# **SECTION 11: Toxicological information**

#### 11.1. Information on toxicological effects

Acute toxicity (oral) : Harmful if swallowed.

Acute toxicity (dermal) : Not classified

Acute toxicity (inhalation) : Not classified

# 17-α-Ethynylestradiol (2,4,16,16-D<sub>4</sub>, 97-98%) (57-63-6)

ATE US (oral) 960 mg/kg body weight

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified

Respiratory or skin sensitization : Not classified Germ cell mutagenicity : Not classified

Carcinogenicity : May cause cancer (Dermal, Inhalation, oral).

960 mg/kg

#### 17-α-Ethynylestradiol (2,4,16,16-D<sub>4</sub>, 97-98%) (57-63-6)

National Toxicology Program (NTP) Status Known Human Carcinogens

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Reproductive toxicity : Not classified STOT-single exposure : Not classified STOT-repeated exposure : Not classified Aspiration hazard : Not classified Viscosity, kinematic : No data available

Potential Adverse human health effects and

symptoms

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. Stomach - Irregularities - Based on Human Evidence.

Symptoms/effects : May cause cancer (in contact with skin, if inhaled, if swallowed).

Symptoms/effects after inhalation : May be harmful if inhaled. May cause respiratory tract irritation.

Symptoms/effects after skin contact : May be harmful if absorbed through skin. May cause skin irritation.

Symptoms/effects after eye contact : May cause eye irritation. Symptoms/effects after ingestion : Harmful if swallowed.

# **SECTION 12: Ecological information**

# 12.1. Toxicity

Ecology - general : Very toxic to aquatic life with long lasting effects.

#### 12.2. Persistence and degradability

No additional information available

#### 12.3. Bioaccumulative potential

No additional information available

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Other adverse effects

Other adverse effects

: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Very toxic to aquatic life with long lasting effects.

### **SECTION 13: Disposal considerations**

#### 13.1. Disposal methods

Regional legislation (waste) : Waste materials should be disposed of under conditions which meet Federal, State, and local

environmental control regulations.

Product/Packaging disposal recommendations : Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed

professional waste disposal service to dispose of this material.

Ecology - waste materials : Dispose of as unused product.

# **SECTION 14: Transport information**

In accordance with DOT / TDG / IMDG / IATA

# 14.1. UN number

DOT NA No : UN3077 UN-No. (TDG) : UN3077 UN-No. (IMDG) : 3077 UN-No. (IATA) : 3077

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# 14.2. UN proper shipping name

Proper Shipping Name (DOT) : Environmentally hazardous substances, solid, n.o.s.

Proper Shipping Name (TDG) : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. Proper Shipping Name (IMDG) : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Proper Shipping Name (IATA) : Environmentally hazardous substance, solid, n.o.s.

# 14.3. Transport hazard class(es)

: 9 Transport hazard class(es) (DOT) : 9

Hazard labels (DOT)



#### **TDG**

Transport hazard class(es) (TDG) : 9 9

Hazard labels (TDG)



#### **IMDG**

Transport hazard class(es) (IMDG)

Hazard labels (IMDG)



#### IATA

Transport hazard class(es) (IATA) : 9

9 Hazard labels (IATA)



#### 14.4. Packing group

Packing group (DOT) : III Packing group (TDG) : III : III Packing group (IMDG) : 111 Packing group (IATA)

# 14.5. Environmental hazards

Dangerous for the environment : Yes : Yes

Marine pollutant



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Other information : No supplementary information available.

# 14.6. Special precautions for user

Special transport precautions : Not dangerous goods.

DOT

UN-No.(DOT) : UN3077

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DOT Special Provisions (49 CFR 172.102)

- : 8 A hazardous substance that is not a hazardous waste may be shipped under the shipping description "Other regulated substances, liquid or solid, n.o.s.", as appropriate. In addition, for solid materials, special provision B54 applies.
  - 146 This description may be used for a material that poses a hazard to the environment but does not meet the definition for a hazardous waste or a hazardous substance, as defined in 171.8 of this subchapter, or any hazard class as defined in Part 173 of this subchapter, if it is designated as environmentally hazardous by the Competent Authority of the country of origin, transit or destination.
  - 335 Mixtures of solids that are not subject to this subchapter and environmentally hazardous liquids or solids may be classified as "Environmentally hazardous substances, solid, n.o.s," UN3077 and may be transported under this entry, provided there is no free liquid visible at the time the material is loaded or at the time the packaging or transport unit is closed. Each transport unit must be leak-proof when used as bulk packaging.
  - 384 For transportation by motor vehicle, substances meeting the conditions for high viscosity flammable liquids as prescribed in §173.121(b)(1)(i), (b)(1)(ii), and (b)(1)(iv) of this subchapter, may be reassigned to Packing Group III under the following conditions:
  - A112 Notwithstanding the quantity limits shown in Column (9A) and (9B) for this entry, the following IBCs are authorized for transportation aboard passenger and cargo-only aircraft. Each IBC may not exceed a maximum net quantity of 1,000 kg:
  - a. Metal: 11A, 11B, 11N, 21A, 21B and 21N
  - b. Rigid plastics: 11H1, 11H2, 21H1 and 21H2
  - c. Composite with plastic inner receptacle: 11HZ1, 11HZ2, 21HZ1 and 21HZ2
  - d. Fiberboard: 11G
  - e. Wooden: 11C, 11D and 11F (with inner liners)
  - f. Flexible: 13H2, 13H3, 13H4, 13H5, 13L2, 13L3, 13L4, 13M1 and 13M2 (flexible IBCs must be sift-proof and water resistant or must be fitted with a sift-proof and water resistant liner).
  - B54 Open-top, sift-proof rail cars are also authorized.
  - B120 The use of flexible bulk containers conforming to the requirements in subpart R and subpart S of part 178 of this subchapter is permitted.
  - IB8 Authorized IBCs: Metal (11A, 11B, 11N, 21A, 21B, 21N, 31A, 31B and 31N); Rigid plastics (11H1, 11H2, 21H1, 21H2, 31H1 and 31H2); Composite (11HZ1, 11HZ2, 21HZ1, 21HZ2, 31HZ1 and 31HZ2); Fiberboard (11G); Wooden (11C, 11D and 11F); Flexible (13H1, 13H2, 13H3, 13H4, 13H5, 13L1, 13L2, 13L3, 13L4, 13M1 or 13M2).
  - IP3 Flexible IBCs must be sift-proof and water-resistant or must be fitted with a sift-proof and water-resistant liner.
  - N20 A 5M1 multi-wall paper bag is authorized if transported in a closed transport vehicle.
  - N91 The use of a non specification sift-proof, non-bulk, metal can with or without lid, or a non specification sift-proof, non-bulk fiber drum, with or without lid is authorized when transporting coal tar pitch compounds by motor vehicle or rail freight. The fiber drum must to be fabricated with a three ply wall, as a minimum. The coal tar pitch compound must be in a solid mass during transportation.
  - T1 1.5 178.274(d)(2) Normal...... 178.275(d)(2)

TP33 - The portable tank instruction assigned for this substance applies for granular and powdered solids and for solids which are filled and discharged at temperatures above their melting point which are cooled and transported as a solid mass. Solid substances transported or offered for transport above their melting point are authorized for transportation in portable tanks conforming to the provisions of portable tank instruction T4 for solid substances of packing group III or T7 for solid substances of packing group II, unless a tank with more stringent requirements for minimum shell thickness, maximum allowable working pressure, pressure-relief devices or bottom outlets are assigned in which case the more stringent tank instruction and special provisions shall apply. Filling limits must be in accordance with portable tank special provision TP3. Solids meeting the definition of an elevated temperature material must be transported in accordance with the applicable requirements of this subchapter.

DOT Packaging Exceptions (49 CFR 173.xxx) : 155
DOT Packaging Non Bulk (49 CFR 173.xxx) : 213
DOT Packaging Bulk (49 CFR 173.xxx) : 240
DOT Quantity Limitations Passenger aircraft/rail (49 : No Limit

CFR 173.27)

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DOT Quantity Limitations Cargo aircraft only (49

CFR 175.75)

DOT Vessel Stowage Location

: No Limit

: A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel.

#### **TDG**

UN-No. (TDG)

**TDG Special Provisions** 

: UN3077

: 16 - (1) The technical name of at least one of the most dangerous substances that predominantly contributes to the hazard or hazards posed by the dangerous goods must be shown, in parentheses, on the shipping document following the shipping name in accordance with clause 3.5(1)(c)(ii)(A) of Part 3 (Documentation). The technical name must also be shown, in parentheses, on a small means of containment or on a tag following the shipping name in accordance with subsections 4.11(2) and (3) of Part 4 (Dangerous Goods Safety Marks).
(2) Despite subsection (1), the technical name for the following dangerous goods is not required to be shown on a shipping document or on a small means of containment when Canadian law for domestic transport or an international convention for international transport prohibits the disclosure of the technical name:

- (a) UN1544, ALKALOID SALTS, SOLID, N.O.S. or ALKALOIDS, SOLID, N.O.S:
- (b) UN1851, MEDICINE, LIQUID, TOXIC, N.O.S;
- (c) UN3140, ALKALOID SALTS, LIQUID, N.O.S. or ALKALOIDS, LIQUID, N.O.S;
- (d) UN3248, MEDICINE, LIQUID, FLAMMABLE, TOXIC, N.O.S; or
- (e) UN3249, MEDICINE, SOLID, TOXIC, N.O.S.
- (3) Despite subsection (1), the technical name for the following dangerous goods is not required to be shown on a small means of containment:
- (a) UN2814, INFECTIOUS SUBSTANCE, AFFECTING HUMANS; or
- (b) UN2900, INFECTIOUS SUBSTANCE, AFFECTING ANIMALS,99 (1) Mixtures of solids that are not dangerous goods and liquids or solids that are UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S, or UN3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S, may be handled, offered for transport or transported as UN3077 if there is no visible liquid when the dangerous goods are loaded into a means containment and during transport.
- (2) These Regulations, except for Part 1 (Coming into Force, Repeal, Interpretation, General Provisions and Special Cases) and Part 2 (Classification), do not apply to the handling, offering for transport or transporting of less than 450 kg of UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S, or less than 450 L of UN3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S, on a road vehicle or a railway vehicle. The dangerous goods must be contained in one or more small means of containment designed, constructed, filled, closed, secured and maintained so that under normal conditions of transport, including handling, there will be no accidental release of the dangerous goods that could endanger public safety.

Explosive Limit and Limited Quantity Index : 5 kg

Excepted quantities (TDG) : E1
Emergency Response Guide (ERG) Number : 171

#### **IMDG**

Special provision (IMDG) : 274, 335, 966, 967, 969

Limited quantities (IMDG) : 5 kg
Excepted quantities (IMDG) : E1
Packing instructions (IMDG) : LP02, P002
Packing provisions (IMDG) : PP12
IBC packing instructions (IMDG) : IBC08
IBC special provisions (IMDG) : B3

Tank instructions (IMDG) : BK1, BK2, BK3, T1

Tank special provisions (IMDG) : TP33

EmS-No. (Fire) : F-A - FIRE SCHEDULE Alfa - GENERAL FIRE SCHEDULE

EmS-No. (Spillage) : S-F - SPILLAGE SCHEDULE Foxtrot - WATER-SOLUBLE MARINE POLLUTANTS

Stowage category (IMDG) : A
Stowage and handling (IMDG) : SW23

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Flash point (IMDG) : '
Properties and observations (IMDG) : '
MFAG-No : 171

**IATA** 

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y956
PCA limited quantity max net quantity (IATA) : 30kgG
PCA packing instructions (IATA) : 956
PCA max net quantity (IATA) : 400kg
CAO packing instructions (IATA) : 956
CAO max net quantity (IATA) : 400kg

Special provision (IATA) : A97, A158, A179, A197, A215

ERG code (IATA) : 9L

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

Not applicable

# **SECTION 15: Regulatory information**

#### 15.1. US Federal regulations

17-α-Ethynylestradiol (2,4,16,16-D <sub>4</sub> , 97-98%) (57-63-6)	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
	Delayed (chronic) health hazard

Commercial status of components according to the United States Environmental Protection Agency's Toxic Substances Control Act (TSCA):

Name	CAS-No.	Listing	Commercial status	Flags
17-α-Ethynylestradiol (2,4,16,16-D <sub>4</sub> , 97-98%)	57-63-6	Not present	-	

# 15.2. International regulations

#### CANADA

#### 17-α-Ethynylestradiol (2,4,16,16-D<sub>4</sub>, 97-98%) (57-63-6)

Listed on the Canadian NDSL (Non-Domestic Substances List)

#### **EU-Regulations**

No additional information available

#### **National regulations**

# 17-α-Ethynylestradiol (2,4,16,16-D<sub>4</sub>, 97-98%) (57-63-6)

Listed as carcinogen on NTP (National Toxicology Program)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

# 15.3. US State regulations

17-α-Ethynylestradiol (2,4,16,16-D <sub>4</sub> , 97-98%) (57-63-6)	
U.S California - Proposition 65 - Carcinogens List	Yes
U.S California - Proposition 65 - Developmental Toxicity	Yes
U.S California - Proposition 65 - Reproductive Toxicity - Female	No

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17-α-Ethynylestradiol (2,4,16,16-D <sub>4</sub> , 97-98%) (57-63-6)	
U.S California - Proposition 65 - Reproductive Toxicity - Male	No
State or local regulations	U.S Massachusetts - Right To Know List U.S Pennsylvania - RTK (Right to Know) List

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Other information : This product is not radioactive. The data given for this product are those of the corresponding

unlabeled compound, unless specifically indicated otherwise. Health and safety data for labeled compounds are generally not available, but are assumed to be similar or identical to the

corresponding unlabeled compound.

Full text of H-phrases	
H302	Harmful if swallowed
H350	May cause cancer
H410	Very toxic to aquatic life with long lasting effects

Safety Data Sheet (SDS), USA

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.