



# Azithromycin (<sup>13</sup>C, 99%; D<sub>3</sub>, 98%) CP 95%

## Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations  
Issue date: 3/14/2024 Version: 1.0

### SECTION 1: Identification

#### 1.1. Identification

Product form	: Substance
Substance name	: Azithromycin ( <sup>13</sup> C, 99%; D <sub>3</sub> , 98%) CP 95%
CAS-No.	: 83905-01-5
Product code	: C1768
Formula	: C37*CH69D3N2O12
Other means of identification	: Also applicable to: C1768-SF

#### 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](mailto:cilsales@isotope.com) - [www.isotope.com](http://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

Respiratory sensitization, Category 1	H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled
Skin sensitization, Category 1	H317	May cause an allergic skin reaction
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) : H317 - May cause an allergic skin reaction  
H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled  
H410 - Very toxic to aquatic life with long lasting effects  
Precautionary statements (GHS US) : P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.  
P272 - Contaminated work clothing must not be allowed out of the workplace.  
P273 - Avoid release to the environment.

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P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P284 - [In case of inadequate ventilation] wear respiratory protection.  
P302+P352 - If on skin: Wash with plenty of water.  
P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.  
P321 - Specific treatment (see supplemental first aid instruction on this label).  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.  
P363 - Wash contaminated clothing before reuse.  
P391 - Collect spillage.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

### 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
Azithromycin ( <sup>13</sup> C, 99%; D <sub>3</sub> , 98%) CP 95% (Main constituent)	CAS-No.: 83905-01-5	100	Resp. Sens. 1, H334 Skin Sens. 1, H317 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 : If you feel unwell, seek medical advice (show the label where possible). Evacuate danger area.  
First-aid measures after inhalation : When symptoms occur: go into open air and ventilate suspected area. If not breathing give artificial respiration. Get medical advice/attention.  
First-aid measures after skin contact : Wash with plenty of soap and water. and soap. Get immediate medical advice/attention.  
First-aid measures after eye contact : Rinse cautiously with water for several minutes.  
First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Rinse mouth out with water. Get medical advice/attention.

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

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.  
Symptoms/effects after inhalation : May cause an allergy or asthma symptoms or breathing difficulties if inhaled.  
Symptoms/effects after skin contact : May cause an allergic skin reaction.  
Symptoms/effects after eye contact : May cause eye irritation.  
Symptoms/effects after ingestion : May be 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 : Suitable extinguishing agents: Carbon dioxide, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

### 5.2. Specific hazards arising from the chemical

Fire hazard : Combustible. Development of hazardous combustion gases or vapours possible in the event of fire.  
Hazardous decomposition products in case of fire : Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides (NO<sub>x</sub>).

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

Firefighting instructions : Fight fire with normal precautions from a reasonable distance. Wear a self contained breathing apparatus. Do not enter fire area without proper protective equipment, including respiratory protection.  
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection. Wear recommended personal protective equipment.

## SECTION 6: Accidental release measures

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

#### 6.1.1. For non-emergency personnel

Emergency procedures : Avoid breathing vapors, mist, gas. Avoid dust formation. Ensure adequate air ventilation. Evacuate unnecessary personnel. Evacuate danger area.

#### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Do not allow to enter drains or water courses. Avoid release to the environment.

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

For containment : Take up mechanically (sweeping, shoveling) and collect in suitable container for disposal.  
Methods for cleaning up : This material and its container must be disposed of in a safe way, and as per local legislation.

### 6.4. Reference to other sections

For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Provide adequate ventilation to minimize dust and/or vapor concentrations.  
Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Handle in accordance with good industrial hygiene and safety practice.

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

Technical measures : Store in a well-ventilated place. Keep container tightly closed.  
Storage conditions : Store in freezer (-20°C). Protect from light, air and moisture.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

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No additional information available

### 8.2. Appropriate engineering controls

Appropriate engineering controls : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.  
Environmental exposure controls : Avoid release to the environment.

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

#### Personal protective equipment:

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

#### Materials for protective clothing:

Wear suitable protective clothing and gloves

#### Hand protection:

Wear suitable protective clothing and gloves

#### Eye protection:

Wear eye protection. Chemical goggles or face shield with safety glasses

#### Skin and body protection:

Wear suitable protective clothing, gloves and eye/face protection

#### Respiratory protection:

In case of inadequate ventilation wear respiratory protection. Approved supplied air 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 : Powder.  
Color : White  
Odor : No data available  
Odor threshold : No data available  
pH : 10.1

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Melting point	: 113 – 115 °C (235 - 239 °F)
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
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Molecular mass	: 753 g/mol (Labeled)
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
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: Product is not explosive.
Oxidizing properties	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

### 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, nitrogen oxides (NO<sub>x</sub>).

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

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LD50 oral rat	> 2000 mg/kg Remarks: Behavioral:Somnolence (general depressed activity). Respiratory disorder Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
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Skin corrosion/irritation	: Not classified pH: 10.1
Serious eye damage/irritation	: Not classified pH: 10.1
Respiratory or skin sensitization	: May cause an allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
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.
Symptoms/effects after inhalation	: May cause an allergy or asthma symptoms or breathing difficulties if inhaled.
Symptoms/effects after skin contact	: May cause an allergic skin reaction.
Symptoms/effects after eye contact	: May cause eye irritation.
Symptoms/effects after ingestion	: May be harmful if swallowed.

## SECTION 12: Ecological information

### 12.1. Toxicity

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

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ErC50 algae	0.0018 mg/l ErC50 - Cyanobacteria. NOEC - Microcystis aeruginosa (blue-green algae) - 0.0001900 mg/l
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### 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 : Environmental precautions. Avoid release to the environment. Disposal must be done according to official regulations.

## 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.

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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

#### 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)

##### DOT

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



##### TDG

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



##### IMDG

Transport hazard class(es) (IMDG) : 9  
Hazard labels (IMDG) : 9



##### IATA

Transport hazard class(es) (IATA) : 9  
Hazard labels (IATA) : 9



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### 14.4. Packing group

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

### 14.5. Environmental hazards

Dangerous for the environment : Yes  
Marine pollutant : Yes



Other information : No supplementary information available.

### 14.6. Special precautions for user

**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 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 CFR 173.27)	: No Limit

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DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) : No Limit

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

### TDG

UN-No. (TDG) : UN3077

TDG Special Provisions : 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) : '

### 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

#### Azithromycin (<sup>13</sup>C, 99%; D<sub>3</sub>, 98%) CP 95% (83905-01-5)

SARA Section 302 Threshold Planning Quantity (TPQ)	Not subject to reporting requirements of the United States SARA Section 302.
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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
Azithromycin ( <sup>13</sup> C, 99%; D <sub>3</sub> , 98%) CP 95%	83905-01-5	Not present	-	

### 15.2. International regulations

#### CANADA

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Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

#### EU-Regulations

No additional information available

#### National regulations

No additional information available

### 15.3. US State regulations

No additional information available

## SECTION 16: Other information

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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.

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Full text of H-phrases	
H317	May cause an allergic skin reaction
H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled
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.