

Dexium Injection 2mg (Dexamethasone Solution 2mg/mL)

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Revision Date: 11/12/2015 Date of issue: 11/12/2015

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Dexium Injection 2mg (Dexamethasone Solution 2mg/mL)

1.2. Intended Use of the Product

Use of the substance/mixture: Veterinary Anti-Inflammatory.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Bimeda Inc.

One Tower Lane

Oakbrook Terrace Tower

Oakbrook Terrace, IL 60181

T 630-928-0361

F 630-928 0362

www.bimedaus.com

1.4. Emergency Telephone Number

Emergency Number : 519-654-8055, 800-424-9300 CHEMTREC (in US); +1 703-527-3887 CHEMTREC (International and Maritime)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US classification

Resp. Sens. 1 H334

Skin Sens. 1 H317

Repr. 1B H360

STOT SE 3 H335

Full text of H-phrases: see section 16

2.2. Label Elements

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 allergy or asthma symptoms or breathing difficulties if inhaled.
 H335 - May cause respiratory irritation.
 H360 - May damage fertility or the unborn child.
 P201 - Obtain special instructions before use.
 P202 - Do not handle until all safety precautions have been read and understood.
 P261 - Avoid breathing vapors, mist, or spray.
 P271 - Use only outdoors or in a well-ventilated area.
 P272 - Contaminated work clothing must not be allowed out of the workplace.
 P280 - Wear protective gloves, protective clothing, and eye protection.
 P284 - [In case of inadequate ventilation] wear respiratory protection.
 P302+P352 - If on skin: Wash with plenty of water.
 P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.
 P308+P313 - If exposed or concerned: Get medical advice/attention.
 P312 - Call a poison center or doctor if you feel unwell.
 P321 - Specific treatment (see section 4 on this SDS).
 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.

Precautionary Statements (GHS-US)

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P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

P405 - Store locked up.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Polyethylene glycol	(CAS No) 25322-68-3	50	STOT SE 3, H335
Water	(CAS No) 7732-18-5	44.8	Not classified
Ethyl alcohol	(CAS No) 64-17-5	3.87	Flam. Liq. 2, H225 Eye Irrit. 2A, H319
Benzyl alcohol	(CAS No) 100-51-6	0.9	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:vapor), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401
Hydrochloric acid	(CAS No) 7647-01-0	For pH adjustment only	Met. Corr. 1, H290 Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
Dexamethasone	(CAS No) 50-02-2	0.2	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Resp. Sens. 1A, H334 Skin Sens. 1A, H317 Repr. 1B, H360 STOT SE 3, H335
Propyl 4-hydroxybenzoate	(CAS No) 94-13-3	0.02	Comb. Dust Aquatic Acute 2, H401
Benzoic acid, 4-hydroxy-, methyl ester	(CAS No) 99-76-3	0.18	Comb. Dust Aquatic Chronic 3, H412

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: May cause respiratory irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Skin sensitization. May damage fertility. May damage the unborn child.

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Symptoms/Injuries After Inhalation: Irritation of the respiratory tract and the other mucous membranes. Exposure may produce cough mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: May damage fertility or the unborn child.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

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

General Measures: Do not breathe vapor, mist or spray. Do not get in eyes, on skin, or on clothing.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. See Section 13, Disposal Considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid contact with eyes, skin and clothing. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe vapor, mist, spray. Avoid contact with skin, eyes and clothing.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Products: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Veterinary Anti-Inflammatory.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Polyethylene glycol (25322-68-3)		
USA AIHA	WEEL TWA (mg/m ³)	10 mg/m ³ (MW>200, aerosol)
Ethyl alcohol (64-17-5)		
USA ACGIH	ACGIH STEL (ppm)	1000 ppm
USA ACGIH	ACGIH chemical category	Confirmed Animal Carcinogen with Unknown Relevance to Humans
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	1900 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	1000 ppm
USA IDLH	US IDLH (ppm)	3300 ppm (10% LEL)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	1900 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	1000 ppm
Benzyl alcohol (100-51-6)		
USA AIHA	WEEL TWA (ppm)	10 ppm
Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	7 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

8.2. Exposure Controls

Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State

: Liquid

Appearance

: Clear, Colorless to pale yellow

Odor

: No data available

Odor Threshold

: No data available

pH

: ~ 4.9

Evaporation Rate

: No data available

Melting Point

: No data available

Freezing Point

: No data available

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Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: 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
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products:** Aldehydes, alcohols, ethers, carbon oxides, carboxylic acids, polymer fragments.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
LD50 Oral Rat	2100 mg/kg
Propyl 4-hydroxybenzoate (94-13-3)	
LD50 Oral Rat	> 5000 mg/kg
Polyethylene glycol (25322-68-3)	
LD50 Oral Rat	47000 mg/kg
LD50 Dermal Rabbit	> 20 ml/kg
Dexamethasone (50-02-2)	
LD50 Oral Rat	> 3 g/kg
Ethyl alcohol (64-17-5)	
LD50 Oral Rat	10470 mg/kg
LD50 Dermal Rat	20 ml/kg
LC50 Inhalation Rat	124.7 mg/l/4h
LC50 Inhalation Rat	124.7 mg/l/4h
Benzyl alcohol (100-51-6)	
LD50 Oral Rat	1230 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 4.178 mg/l/4h
LC50 Inhalation Rat	8.9 mg/l/4h
LC50 Inhalation Rat	> 5.4 mg/l/4h
Hydrochloric acid (7647-01-0)	
LD50 Dermal Rabbit	> 5010 mg/kg

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

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Ethyl alcohol (64-17-5)	
IARC group	1
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.
Hydrochloric acid (7647-01-0)	
IARC group	3

Reproductive Toxicity: May damage fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): May cause respiratory irritation.

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Irritation of the respiratory tract and the other mucous membranes. Exposure may produce cough mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: May damage fertility or the unborn child.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
LC50 Fish 1	59.5 mg/l (Exposure time: 96 h - Species: <i>Oryzias latipes</i>)
EC50 Daphnia 1	11.2 mg/l
ErC50 (algae)	91 mg/l
NOEC chronic crustacea	0.2 mg/l (Species: <i>Daphnia magna</i>)
NOEC chronic algae	20 mg/l

Propyl 4-hydroxybenzoate (94-13-3)	
LC50 Fish 1	4.1 (4.1 - 8.8) mg/l (Exposure time: 96 h - Species: <i>Danio rerio</i>)
EC50 Daphnia 1	7.97 (7.97 - 32.3) mg/l
NOEC chronic algae	2.1 mg/l

Ethyl alcohol (64-17-5)	
EC50 Daphnia 1	9268 - 14221 mg/l (Exposure time: 48 h - Species: <i>Daphnia magna</i>)
LC 50 Fish 2	> 100 mg/l (Exposure time: 96 h - Species: <i>Pimephales promelas</i> [static])
ErC50 (algae)	1000 mg/l

Benzyl alcohol (100-51-6)	
LC50 Fish 1	460 mg/l (Exposure time: 96 h - Species: <i>Pimephales promelas</i> [static])
EC50 Daphnia 1	23 mg/l (Exposure time: 48 h - Species: water flea)
LC 50 Fish 2	10 mg/l (Exposure time: 96 h - Species: <i>Lepomis macrochirus</i> [static])
ErC50 (algae)	770 mg/l

Hydrochloric acid (7647-01-0)	
LC50 Fish 1	3.25 - 3.5 mg/l (Exposure time: 96 h - Species: <i>Lepomis macrochirus</i>)
EC50 Daphnia 1	4.92 mg/l (Exposure time: 48 h - Species: <i>Daphnia magna</i>)

12.2. Persistence and Degradability

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Persistence and Degradability	Not established.

Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
Persistence and Degradability	Readily biodegradable, according to appropriate OECD test.

Ethyl alcohol (64-17-5)	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Dexium Injection 2mg (Dexamethasone Solution 2mg/mL)	
Bioaccumulative Potential	Not established.

Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
Bioconcentration factor (BCF REACH)	6.4
Log Pow	1.98

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Ethyl alcohol (64-17-5)	
Log Pow	-0.32
Bioaccumulative Potential	Not established.
Benzyl alcohol (100-51-6)	
Log Pow	1.1

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

Dexium Injection 2mg (Dexamethasone Solution 2mg/mL)	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard Delayed (chronic) health hazard
Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Propyl 4-hydroxybenzoate (94-13-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Polyethylene glycol (25322-68-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Dexamethasone (50-02-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Ethyl alcohol (64-17-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Benzyl alcohol (100-51-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
SARA Section 302 Threshold Planning Quantity (TPQ)	500 (gas only)
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
SARA Section 313 - Emission Reporting	1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

15.2 US State Regulations

Ethyl alcohol (64-17-5)	
U.S. - California - Proposition 65 - Carcinogens List	WARNING: This product contains chemicals known to the State of California to cause cancer. Ethyl Alcohol is included on the Proposition 65 list when it is used in alcoholic beverages.
U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects. Ethyl Alcohol is included on the Proposition 65 list when it is used in alcoholic beverages.

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Ethyl alcohol (64-17-5)

U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Benzyl alcohol (100-51-6)

U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) List

Hydrochloric acid (7647-01-0)

U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 11/12/2015
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 4 (Inhalation:vapor)	Acute toxicity (inhalation:vapor) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 2	Flammable liquids Category 2
Flam. Liq. 4	Flammable liquids Category 4
Met. Corr. 1	Corrosive to metals Category 1
Repr. 1B	Reproductive toxicity Category 1B
Resp. Sens. 1	Respiratory sensitisation Category 1
Resp. Sens. 1A	Respiratory sensitisation Category 1A
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
Skin Sens. 1A	Skin sensitization Category 1A
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H225	Highly flammable liquid and vapor
H227	Combustible liquid
Comb. Dust	May form combustible dust concentrations in air
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation
H360	May damage fertility or the unborn child
H401	Toxic to aquatic life

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H412	Harmful to aquatic life with long lasting effects
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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.

SDS US (GHS HazCom)