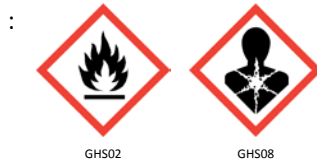


**SECTION 1: IDENTIFICATION****1.1. Product Identifier****Product Name:** Proctofoam® HC (topical aerosol)**1.2. Intended Use of the Product****Use of the substance/mixture:** Pharmaceutical. For the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses of the anal region.**1.3. Name, Address, and Telephone of the Responsible Party****Company**Meda Pharmaceuticals, Inc.  
265 Davidson Avenue  
Somerset, NJ 08873  
T 800-526-3840[www.meda.us](http://www.meda.us)**Manufacturer**Kremers Urban Pharmaceuticals, Inc.  
1101 "C" Ave West  
47274 Seymour, IN  
T 812-523-3457**1.4. Emergency Telephone Number****Emergency Number** : CHEMTREC 800-424-9300**SECTION 2: HAZARDS IDENTIFICATION**

Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

**2.1. Classification of the Substance or Mixture****Classification (GHS-US)**Flam. Aerosol 2 H223  
Repr. 1A H360  
Aquatic Acute 3 H402**2.2. Label Elements****GHS-US Labeling****Hazard Pictograms (GHS-US)****Signal Word (GHS-US)**

: Danger

**Hazard Statements (GHS-US)**: H223 - Flammable aerosol.  
H360 - May damage fertility or the unborn child.  
H402 - Harmful to aquatic life.**Precautionary Statements (GHS-US)**: 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 flames, hot surfaces. - No smoking.  
P211 - Do not spray on an open flame or other ignition source.  
P251 - Pressurized container: Do not pierce or burn, even after use.  
P273 - Avoid release to the environment.  
P280 - Wear protective clothing, protective gloves, eye protection.  
P308+P313 - If exposed or concerned: Get medical advice/attention.  
P405 - Store locked up.  
P410+P412 - Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.  
P501 - Dispose of contents/container according to 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

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## 3.2. Mixture

Name	Product Identifier	Classification (GHS-US)
Water	(CAS No) 7732-18-5	Not classified
1,2-Propylene glycol	(CAS No) 57-55-6	Aquatic Acute 3, H402
Isobutane	(CAS No) 75-28-5	Simple Asphy Flam. Gas 1, H220 Liquefied gas, H280
Alcohols, C16-18	(CAS No) 67762-27-0	Skin Irrit. 2, H315 Eye Irrit. 2A, H319
Polyoxyethylene sorbitan monostearate	(CAS No) 9005-67-8	Not classified
Propane	(CAS No) 74-98-6	Simple Asphy Flam. Gas 1, H220 Liquefied gas, H280
Pregn-4-ene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-, (11.beta.)-	(CAS No) 50-03-3	Repr. 1A, H360 STOT RE 2, H373
Pramocaine hydrochloride	(CAS No) 637-58-1	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2A, H319
Polyoxyethylene monooleyl ether	(CAS No) 9005-00-9	Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 2, H411
1-Hexadecanol	(CAS No) 36653-82-4	Not classified
Triethanolamine	(CAS No) 102-71-6	Not classified
Methyl p-hydroxybenzoate	(CAS No) 99-76-3	Comb. Dust Aquatic Acute 3, H402 Aquatic Chronic 3, H412
Propyl 4-hydroxybenzoate	(CAS No) 94-13-3	Comb. Dust, Aquatic Acute 2, H401

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.

**First-aid Measures After Inhalation:** When symptoms occur: go into open air and ventilate suspected area.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Drench affected area with water for at least 15 minutes.

**First-aid Measures After Eye Contact:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

**First-aid Measures After Ingestion:** Rinse mouth. Do not induce vomiting. Call a POISON CENTER/doctor/physician if you feel unwell.

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

**Symptoms/Injuries:** May damage fertility or the unborn child. Compressed gases may create low temperatures when they expand rapidly. Leaks and uses that allow rapid expansion may cause a frostbite hazard.

**Symptoms/Injuries After Inhalation:** May cause respiratory irritation.

**Symptoms/Injuries After Skin Contact:** May cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause eye irritation.

**Symptoms/Injuries After Ingestion:** Ingestion is likely to be harmful or have adverse effects.

**Chronic Symptoms:** May damage fertility or the unborn child.

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

If you feel unwell, seek medical advice (show the label where possible).

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

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

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

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## 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the Directions for Use on this label very carefully.

**Explosion Hazard:** Heat may build pressure, rupturing closed containers, spreading fire and increasing risk of burns and injuries.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

## 5.3. Advice for Firefighters

**Firefighting Instructions:** Fight fire from safe distance and protected location. Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection. Wear self-contained breathing apparatus when entering area unless atmosphere is proved to be safe.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid all contact with skin, eyes, or clothing. Avoid breathing vapor, mist, or spray.

#### 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. Eliminate ignition sources.

## 6.2. Environmental Precautions

Prevent entry to sewers and public waters. Contact competent authorities after a spill.

## 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:** Clear up spills immediately and dispose of waste safely.

## 6.4. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Do not spray on an open flame or other ignition source. Do not expose to heat, or ignition sources as this could cause an explosion.

**Precautions for Safe Handling:** Do not handle until all safety precautions have been read and understood.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work. Wash contaminated clothing before reuse.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Keep cool. Protect from sunlight.

**Storage Conditions:** Store in a dry, cool and well-ventilated place. Keep container closed when not in use.

**Incompatible Products:** Strong acids. Strong bases. Strong oxidizers.

**Storage Temperature:** < 50 °C (< 122 °F)

**7.3. Specific End Use(s)** Pharmaceutical. For the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses of the anal region.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

Triethanolamine (102-71-6)		
USA ACGIH	ACGIH TWA (mg/m <sup>3</sup> )	5 mg/m <sup>3</sup>
Isobutane (75-28-5)		
USA ACGIH	ACGIH STEL (ppm)	1000 ppm
USA NIOSH	NIOSH REL (TWA) (mg/m <sup>3</sup> )	1900 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (TWA) (ppm)	800 ppm
Propane (74-98-6)		
USA ACGIH	ACGIH TWA (ppm)	1000 ppm
USA NIOSH	NIOSH REL (TWA) (mg/m <sup>3</sup> )	1800 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (TWA) (ppm)	1000 ppm
USA IDLH	US IDLH (ppm)	2100 ppm (10% LEL)
USA OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	1800 mg/m <sup>3</sup>

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USA OSHA	OSHA PEL (TWA) (ppm)	1000 ppm
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## 8.2. Exposure Controls

### Appropriate Engineering Controls

: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

### Personal Protective Equipment

: Protective clothing. Gloves.



### Materials for Protective Clothing

: Chemically resistant materials and fabrics.

### Hand Protection

: Wear chemically resistant protective gloves.

### Eye Protection

: Chemical goggles or safety glasses.

### Skin and Body Protection

: Wash contaminated clothing before reuse.

### Respiratory Protection

: Use NIOSH-approved air-purifying or supplied-air respirator where airborne concentrations of dust are expected to exceed exposure limits.

### 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	: A fluffy white foam
Odor	: Mild propellant odor
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
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. Sparks, heat, open flame and other sources of ignition.
- 10.5. **Incompatible Materials:** Strong acids. Strong bases. Strong oxidizers.
- 10.6. **Hazardous Decomposition Products:** None known.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

<b>1,2-Propylene glycol (57-55-6)</b>	
LD50 Oral Rat	20000 mg/kg
LD50 Dermal Rabbit	20800 mg/kg
<b>1-Hexadecanol (36653-82-4)</b>	
LD50 Oral Rat	5 g/kg

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<b>Methyl p-hydroxybenzoate (99-76-3)</b>	
LD50 Oral Rat	> 2100 mg/kg
<b>Propyl 4-hydroxybenzoate (94-13-3)</b>	
LD50 Oral Rat	> 5000 mg/kg
<b>Triethanolamine (102-71-6)</b>	
LD50 Oral Rat	6400 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
<b>Isobutane (75-28-5)</b>	
LC50 Inhalation Rat	658 mg/l/4h
<b>Propane (74-98-6)</b>	
LC50 Inhalation Rat	658 mg/l/4h
<b>Pramocaine hydrochloride (637-58-1)</b>	
ATE (Oral)	500.00 mg/kg body weight
<b>Polyoxyethylene monooleyl ether (9005-00-9)</b>	
LD50 Oral Rat	> 21 g/kg
LD50 Dermal Rabbit	> 2000 mg/kg
<b>Alcohols, C16-18 (67762-27-0)</b>	
LD50 Oral Rat	> 10000 mg/kg
LD50 Dermal Rabbit	> 8000 mg/kg

**Skin Corrosion/Irritation:** Not classified

**Serious Eye Damage/Irritation:** Not classified

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

<b>Triethanolamine (102-71-6)</b>	
IARC group	3
National Toxicity Program (NTP) Status	Evidence of Carcinogenicity.

**Reproductive Toxicity:** May damage fertility or the unborn child.

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

<b>Polyoxyethylene monooleyl ether (9005-00-9)</b>	
LOAEL (oral,rat,90 days)	500 mg/kg bodyweight/day

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** May cause respiratory irritation.

**Symptoms/Injuries After Skin Contact:** May cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause eye irritation.

**Symptoms/Injuries After Ingestion:** Ingestion is likely to be harmful or have adverse effects.

**Chronic Symptoms:** May damage fertility or the unborn child.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

Ecology - General : Harmful to aquatic life.

<b>1,2-Propylene glycol (57-55-6)</b>	
LC50 Fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
LC 50 Fish 2	41 (41 - 47) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 2	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
<b>Methyl p-hydroxybenzoate (99-76-3)</b>	
LC50 Fish 1	59.5 mg/l
EC50 Daphnia 1	11.2 mg/l
ErC50 (algae)	91 mg/l
NOEC chronic crustacea	0.2 mg/l
NOEC chronic algae	20 mg/l
<b>Propyl 4-hydroxybenzoate (94-13-3)</b>	
LC50 Fish 1	4.1 (4.1 - 8.8) mg/l

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EC50 Daphnia 1	7.97 (7.97 - 32.3) mg/l
NOEC chronic algae	2.1 mg/l
<b>Triethanolamine (102-71-6)</b>	
LC50 Fish 1	10600 - 13000 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
LC 50 Fish 2	1000 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
<b>Polyoxyethylene monooleyl ether (9005-00-9)</b>	
LC50 Fish 1	> 100 mg/l Species not indicated
LC50 other aquatic organisms 1	100 - 20 mg/l Daphnia, Test Duration not indicated
EC50 Daphnia 1	0.72 mg/l
NOEC (acute)	1 mg/l
NOEC chronic fish	0.16 mg/l
NOEC chronic crustacea	0.77 mg/l
<b>Alcohols, C16-18 (67762-27-0)</b>	
EC50 Daphnia 1	1666 mg/l (Exposure time: 48 h - Species: Daphnia magna)
<b>12.2. Persistence and Degradability</b>	
<b>Proctofoam® HC (topical aerosol)</b>	
Persistence and Degradability	Not established.
<b>Methyl p-hydroxybenzoate (99-76-3)</b>	
Persistence and Degradability	Readily biodegradable, according to appropriate OECD test.
<b>12.3. Bioaccumulative Potential</b>	
<b>Proctofoam® HC (topical aerosol)</b>	
Bioaccumulative Potential	Not established.
<b>1,2-Propylene glycol (57-55-6)</b>	
BCF fish 1	< 1
<b>1-Hexadecanol (36653-82-4)</b>	
Log Pow	6.65
<b>Methyl p-hydroxybenzoate (99-76-3)</b>	
Bioconcentration factor (BCF REACH)	6.4
Log Pow	1.98
<b>Triethanolamine (102-71-6)</b>	
BCF fish 1	3.9
Log Pow	-2.53
<b>Isobutane (75-28-5)</b>	
BCF fish 1	1.57 - 1.97
Log Pow	2.88 (at 20 °C)
<b>Propane (74-98-6)</b>	
Log Pow	2.3
<b>Polyoxyethylene monooleyl ether (9005-00-9)</b>	
BCF fish 1	387.5 l/kg
Log Kow	8.37 Calculated
Bioaccumulative Potential	Not expected to bioaccumulate.
<b>Alcohols, C16-18 (67762-27-0)</b>	
BCF fish 1	1300 (activated sludge)
Log Pow	6.65
<b>12.4. Mobility in Soil</b>	
<b>Polyoxyethylene monooleyl ether (9005-00-9)</b>	
Log Koc	5.69 Calculated

## 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 waste material in accordance with all local, regional, national, and international regulations.

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**Ecology – Waste Materials:** Avoid release to the environment.

## SECTION 14: TRANSPORT INFORMATION

### 14.1. In Accordance with DOT

Proper Shipping Name : CONSUMER COMMODITY  
Hazard Class : 9  
Identification Number : ID8000  
Limited Quantity  
ERG Number : 171

### 14.2. In Accordance with IMDG

Proper Shipping Name : Consumer Commodity  
Hazard Class : 9

### 14.3. In Accordance with IATA

Proper Shipping Name : CONSUMER COMMODITY  
Identification Number : UN8000  
Hazard Class : 9  
Limited Quantity  
ERG Code (IATA) : 9L

## SECTION 15: REGULATORY INFORMATION

### 15.1 US Federal Regulations

<b>Proctofoam<sup>®</sup> HC (topical aerosol)</b>	
<b>SARA Section 311/312 Hazard Classes</b>	Delayed (chronic) health hazard Sudden release of pressure hazard
<b>1,2-Propylene glycol (57-55-6)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>EPA TSCA Regulatory Flag</b>	Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.
<b>1-Hexadecanol (36653-82-4)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Methyl p-hydroxybenzoate (99-76-3)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Propyl 4-hydroxybenzoate (94-13-3)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Water (7732-18-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Triethanolamine (102-71-6)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Isobutane (75-28-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Propane (74-98-6)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Polyoxyethylene monoctadecyl ether (9005-00-9)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Polyoxyethylene sorbitan monostearate (9005-67-8)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Alcohols, C16-18 (67762-27-0)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>15.2 US State Regulations</b>	
<b>1,2-Propylene glycol (57-55-6)</b>	
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List	
<b>Triethanolamine (102-71-6)</b>	
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List	

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

## Isobutane (75-28-5)

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

## Propane (74-98-6)

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

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

**Revision Date** : 11/03/2014

**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 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic 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. Aerosol 2	Flammable aerosol Category 2
Flam. Gas 1	Flammable gases Category 1
Liquefied gas	Gases under pressure Liquefied gas
Repr. 1A	Reproductive toxicity Category 1A
Simple Asphy	Simple Asphyxiant
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
H220	Extremely flammable gas
H223	Flammable aerosol
Comb. Dust	May form combustible dust concentrations in air
H280	Contains gas under pressure; may explode if heated
H302	Harmful if swallowed
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H360	May damage fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H411	Toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

*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)