

Ropivacaine Hydrochloride Formulation (200 mg/100 mL Single Dose Infusion Bags and 400 mg/200 mL Single Dose Infusion Bags)

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Date of Issue: 12/09/2024

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Ropivacaine Hydrochloride Formulation (200 mg/100 mL Single Dose Infusion Bags and 400 mg/200 mL Single Dose Infusion Bags)

Chemical Name: (S)-(-)-1-Propylpiperidine-2-carboxylic acid (2,6- dimethylphenyl)-amide hydrochloride monohydrate

1.2. Intended Use of the Product

Pharmaceutical

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

Distributor

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

<http://www.fresenius-kabi.com/us/>

Co-Manufacturer

Caplin Steriles Limited Survey

No. 895 & 897

Guruvarajakandigai, Sirupuzhalpettai

Gummidipoondi (Taluk)

Thiruvallur 601201

Tamil Nadu

India

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS

(800)255-3924 (North America)

+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Serious eye damage/eye irritation Category 2

H319

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA)



Signal Word (GHS-US/CA)

: Warning

Hazard Statements (GHS-US/CA)

: H319 - Causes serious eye irritation.

Precautionary Statements (GHS-US/CA)

: P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P280 - Wear protective gloves, protective clothing, and eye protection.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.

2.3. Other Hazards

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

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

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3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Sodium chloride	Sodium salt of hydrochloric acid Salt SEA SALT SODIUM CHLORIDE Sodium chloride (NaCl) Sea salt	(CAS-No.) 7647-14-5	8.6	Not classified.
(2S)-N-(2,6-Dimethylphenyl)-1-propylpiperidine-2-carboxamide	Ropivacaine hydrochloride hydrate Ropivacaine hydrochloride	(CAS-No.) 132112-35-7	2	Eye Dam. 1, H318
Sodium hydroxide	Caustic soda Sodium hydroxide (Na(OH)) SODIUM HYDROXIDE LYE	(CAS-No.) 1310-73-2	< 0.1	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
Hydrochloric acid	Hydrogen chloride Muriatic acid HYDROCHLORIC ACID Hydrochloric acid, anhydrous	(CAS-No.) 7647-01-0	< 0.1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 1, H370 Aquatic Acute 2, H401
Water	AQUA	(CAS-No.) 7732-18-5	< 0.1	Not classified.

Full text of H-statements: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of 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).

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

Skin Contact: Remove contaminated clothing. Immediately drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

Eye Contact: Immediately rinse with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Causes serious eye irritation.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None known.

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, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

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.

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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.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Chlorides. Sodium oxides. Nitrogen oxides.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

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, spray).

6.1.1. For Non-Emergency Personnel

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

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: 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. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials 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. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Avoid contact with skin, eyes and clothing. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing vapors, mist, spray.

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 Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 20 – 25 °C (68 - 77 °F) [See USP Controlled Temperature]

7.3. Specific End Use(s)

Pharmaceutical

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), OSHA (PEL), or Canadian provincial governments.

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH OEL Ceiling	2 mg/m ³
USA OSHA	OSHA PEL TWA	2 mg/m ³
USA NIOSH	NIOSH REL (Ceiling)	2 mg/m ³

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USA IDLH	IDLH	10 mg/m ³
Alberta	OEL C	2 mg/m ³
British Columbia	OEL C	2 mg/m ³
Manitoba	OEL C	2 mg/m ³
New Brunswick	OEL C	2 mg/m ³
Newfoundland & Labrador	OEL C	2 mg/m ³
Nova Scotia	OEL C	2 mg/m ³
Nunavut	OEL C	2 mg/m ³
Northwest Territories	OEL C	2 mg/m ³
Ontario	OEL C	2 mg/m ³
Prince Edward Island	OEL C	2 mg/m ³
Québec	Plafond (OEL C)	2 mg/m ³
Saskatchewan	OEL C	2 mg/m ³
Yukon	OEL C	2 mg/m ³
Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH OEL Ceiling	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA OSHA	OSHA PEL (Ceiling)	7 mg/m ³
USA OSHA	OSHA PEL (Ceiling)	5 ppm
USA NIOSH	NIOSH REL (Ceiling)	7 mg/m ³
USA NIOSH	NIOSH REL (Ceiling)	5 ppm
USA IDLH	IDLH	50 ppm
Alberta	OEL C	3 mg/m ³
Alberta	OEL C	2 ppm
British Columbia	OEL C	2 ppm
Manitoba	OEL C	2 ppm
New Brunswick	OEL C	2 ppm
Newfoundland & Labrador	OEL C	2 ppm
Nova Scotia	OEL C	2 ppm
Nunavut	OEL C	2 ppm
Northwest Territories	OEL C	2 ppm
Ontario	OEL C	2 ppm
Prince Edward Island	OEL C	2 ppm
Québec	Plafond (OEL C)	2 ppm
Saskatchewan	OEL C	2 ppm
Yukon	OEL C	7 mg/m ³
Yukon	OEL C	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.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles or safety glasses with side shields.

Skin and Body Protection: Wear suitable protective clothing.

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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.
Odor	: No odor
Odor Threshold	: No data available
pH	: 4 – 6
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)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: 1.002 – 1.005 at 25 °C (77 °F) (water =1)
Specific Gravity	: No data available
Solubility	: Water: 53.8 mg/l in water at 25 °C (77 °F). Solubility is limited at pH above 6
Partition Coefficient: N-Octanol/Water	: 14:1 between n-octanol and phosphate buffer
Viscosity	: No data 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:

Thermal decomposition may produce: Carbon oxides, Nitrogen oxides. Chlorides. Sodium oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified.

Acute Toxicity (Dermal): Not classified.

Acute Toxicity (Inhalation): Not classified.

LD50 and LC50 Data:

No additional information available

Skin Corrosion/Irritation: Not classified.

Eye Damage/Irritation: Causes serious eye irritation.

pH: 4 – 6

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Respiratory or Skin Sensitization: Not classified.

Germ Cell Mutagenicity: Not classified.

Carcinogenicity: Not classified.

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

Reproductive Toxicity: Not classified.

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

Aspiration Hazard: Not classified.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

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

Chronic Symptoms: None known.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Sodium chloride (7647-14-5)	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 mg/l (Exposure time: 1 h Source: ECHA_API)
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	325 mg/kg
LD50 Dermal Rabbit	1350 mg/kg (Source: NLM_HSDB)
Hydrochloric acid (7647-01-0)	
LD50 Oral Rat	238 – 277 mg/kg (Source: JAPAN_GHS)
LD50 Dermal Rabbit	> 5010 mg/kg (Source: JAPAN_GHS)
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h Source: JAPAN_GHS)
Water (7732-18-5)	
LD50 Oral Rat	> 90 ml/kg (Source: FOOD_JOURN)
Hydrochloric acid (7647-01-0)	
IARC Group	3

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static] Source: EPA)
EC50 - Crustacea [2]	340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)
Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	40 mg/l
Hydrochloric acid (7647-01-0)	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)

12.2. Persistence and Degradability

Ropivacaine Hydrochloride Formulation (200 mg/100 mL Single Dose Infusion Bags and 400 mg/200 mL Single Dose Infusion Bags)	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

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Bioaccumulative Potential	Not established.
Sodium chloride (7647-14-5)	
BCF Fish 1	(no bioaccumulation)

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, territorial, provincial, and international regulations.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

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

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Ropivacaine Hydrochloride Formulation (200 mg/100 mL Single Dose Infusion Bags and 400 mg/200 mL Single Dose Infusion Bags)	
SARA Section 311/312 Hazard Classes	Health hazard - Serious eye damage or eye irritation
Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
CERCLA RQ	1000 lb
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	

15.2. US State Regulations

Sodium hydroxide (1310-73-2)	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
U.S. - Massachusetts - Right To Know List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
Hydrochloric acid (7647-01-0)	

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

15.3. Canadian Regulations

Sodium chloride (7647-14-5)

Listed on the Canadian DSL (Domestic Substances List)

Sodium hydroxide (1310-73-2)

Listed on the Canadian DSL (Domestic Substances List)

Hydrochloric acid (7647-01-0)

Listed on the Canadian DSL (Domestic Substances List)

Water (7732-18-5)

Listed on the Canadian DSL (Domestic Substances List)

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

Date of Preparation or Latest : 12/09/2024

Revision

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

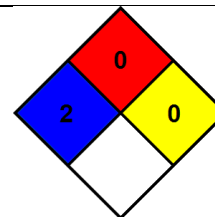
GHS Full Text Phrases:

H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H319	Causes serious eye irritation
H370	Causes damage to organs
H401	Toxic to aquatic life
H402	Harmful to aquatic life

NFPA Health Hazard : 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.

NFPA Fire Hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health : 2 Moderate Hazard - Temporary or minor injury may occur

Flammability : 0 Minimal Hazard

Physical : 0 Minimal Hazard

Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)

AU_WES: Australia WES

CHEMVIEW: ChemView (U.S. Environmental Protection Agency)

EC_RAR: European Commission Renewal Assessment Report

EC_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits

ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports

ECHA_API: European Chemicals Agency API

ECHA_RAC: ECHA Committee for Risk Assessment

FOOD_JOURN: Food Research Journal (1956)

IARC: The International Agency for Research on Cancer

IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles

IUCLID: International Uniform Chemical Information Database

JAPAN_GHS: Japan GHS Basis for Classification Data

JP_J-CHECK: Japan J-Check

KR_NIER: South Korea National Institute of Environmental Research Evaluations

NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme

NIOSH: National Institute for Occupational Health and Safety (U.S. Department

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EFSA: European Food Safety Authority	of Health and Human Services)
EPA: U.S. Environmental Protection Agency	NLM_CIP: National Library of Medicine ChemID plus database
EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)	NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank
EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)	NLM_PUBMED: National Library of Medicine PubMed database
EPA_HPV: High Production Volume Chemicals (U.S. Environmental Protection Agency)	NTP: National Toxicology Program
EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)	NZ_CCID: New Zealand Chemical Classification and Information Database
EU_CLH: European Union Harmonised Classification and Labelling Proposal	OECD_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)
EU_RAR: European Union Risk Assessment Report	OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)
	WHO: World Health Organization

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.

NA GHS SDS 2015 (Can, US)