Section 1 – Identification

TRADE NAME: MorphaBond ER^{TM} CHEMICAL NAME: 7,8–didehydro-4,5 α -epoxy-17-methylmorphinan-3,6 α -diol sulfate (2:1) (salt) pentahydrate

MOLECULAR FORMULA: C₁₇H₂₁NO₇S

THERAPEUTIC CLASS: Full opioid agonist

RELEVANT USE of the SUBSTANCE: Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment

USES ADVISED AGAINST: Other than Relevant Use of the Substance

HOW SUPPLIED: Extended-release tablets - 15 mg, 30 mg, 60 mg, 100 mg

- MORPHABOND ER™ (morphine sulfate) extended-release tablets 15 mg are round, blue-colored, coated tablets ink-printed with IDS/M15 on one side; and plain on the other. They are supplied as opaque plastic bottles containing 100 tablets (NDC 69296-004-01)
- MORPHABOND ER[™] (morphine sulfate) extended-release tablets 30 mg are round, purple-colored, coated tablets ink-printed with IDS/M30 on one side; and plain on the other. They are supplied as opaque plastic bottles containing 100 tablets (NDC 69296-003-01)
- MORPHABOND ER[™] (morphine sulfate) extended-release tablets 60 mg are round, orange-colored, coated tablets ink-printed with IDS/M60 on one side; and plain on the other. They are supplied as opaque plastic bottles containing 100 tablets (NDC 69296-002-01)
- MORPHABOND ER™ (morphine sulfate) extended-release tablets 100 mg are round, gray-colored, coated tablets ink-printed with IDS/M100 on one side; and plain on the other. They are supplied as opaque plastic bottles containing 100 tablets (NDC 69296-001-01)

Companies/Undertaking Identification

US Manufacturer Name: Cerovene

Address:612 Corporate Way, Suite 10, Valley Cottage, NY 10989Business Phone:1-845-267-2055Emergency Phone:1-845-267-2055

US Distributor Name: Daiichi Sankyo, Inc.

Address:	2 Hilton Court, Parsippany, NJ 07054
Business Phone:	1-877-437-7763
Emergency Phone:	1-877-437-7763
Date of Preparation:	04/26/2017
Revision Date:	05/02/2017

Section 2 – Hazards Identification

CHEMICAL CLASS: Active Ingredient: Morphine sulfate

GHS06: Acute Toxicity GHS07: Irritant GHS08: Health Hazard, carcinogen, mutagenicity, reproductive toxicity, target organ toxicity, aspiration hazard



Signal Word: Danger

GHS Hazard Statements

Aggregated GHS information from 7 notifications provided by 29 companies to the ECHA C&L Inventory. Each notification may be associated with multiple companies.

H301 (13.79%): Toxic if swallowed [Danger Acute toxicity, oral - Category 3] H302 (86.21%): Harmful if swallowed [Warning Acute toxicity, oral - Category 4] H317 (13.79%): May cause an allergic skin reaction [Warning Sensitization, Skin - Category 1] H331 (10.34%): Toxic if inhaled [Danger Acute toxicity, inhalation - Category 3]

H334 (13.79%): May cause allergy or asthma symptoms or breathing difficulties if inhaled [Danger Sensitization, respiratory - Category 1]

H351 (79.31%): Suspected of causing cancer [Warning Carcinogenicity - Category 2] H361 (89.66%): Suspected of damaging fertility or the unborn child [Warning Reproductive toxicity - Category 2]

Information may vary between notifications depending on impurities, additives, and other factors. The percentage value in parenthesis indicates the notified classification ratio from all companies. Only Hazard Codes with percentage values above 10% are shown.

Precautionary Statements

P201–Obtain special instructions before use P202-Do not handle until all safety precautions have been read and understood P261-Avoid breathing dust/fume/gas/mist/vapors/spray P264-Wash thoroughly after handling P270-Do not eat, drink or smoke when using this product P271-Use only outdoors or in a well-ventilated area P272-Contaminated work clothing should not be allowed out of the workplace P280-Wear protective gloves/protective clothing/eye protection/face protection P281-Use personal protective equipment as required P285-In case of inadequate ventilation wear respiratory protection P301+P310-IF SWALLOWED: Immediately call a POISON CENTER/doctor/ P301+P312-IF SWALLOWED: call a POISON CENTER/doctor/IF you feel unwell P302+P352-IF ON SKIN: wash with plenty of water P304+P340-IF INHALED: Remove person to fresh air and keep comfortable for breathing P304+P341-IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing P308+P313-IF exposed or concerned: Get medical advice/attention P311-Call a POISON CENTER or doctor/ P321-Specific treatment (see FIRST-AID MEASURES on this label) P330-Rinse mouth P333+P313-IF SKIN irritation or rash occurs: Get medical advice/attention P342+P311-IF experiencing respiratory symptoms: Call a POISON CENTER/doctor/ P363- Wash contaminated clothing before reuse P403+P233- Store in a well-ventilated place. Keep container tightly closed P405-Store locked up P501-Dispose of contents/container in accordance with all local and national regulations

EMERGENCY OVERVIEW: **Product Description**: This product comes as 100 tablet, extended release in 1 bottle, plastic **Health Hazards**: In the workplace, may be harmful if swallowed. Properties include induction of ANALGESIA or NARCOSIS. This product can cause adverse effects on the nervous system in mammals, may produce irregular heartbeat, reduced blood pressure, convulsions, swelling and sleepiness. Refer to <u>Section 11 (Toxicological Information)</u> for additional information on adverse effects. **Flammability Hazards**: This product is expected to be combustible. If heated to high temperatures for a prolonged period, the material may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds, including carbon and nitrogen oxides. **Reactivity Hazards**: This product is not chemically reactive. **Environmental Hazards**: Release of large quantity may cause harm to animals and aquatic organisms if accidentally released to the environment.

Emergency Recommendations: Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

Section 3 – Composition/Information on Ingredients

Each tablet contains the following:

Inactive Ingredients	CAS Number
hypromellose	9050-31-1
xanthan gum	11138-66-2
cellulose	9004-34-6
sodium alginate	9005-38-3
alginic acid	9005-32-7
mannitol	87-78-5
colloidal silicon dioxide	7631-86-9
magnesium stearate	557-04-0
ethyl acrylate	140-88-5
methyl methacrylate	80-62-6
lactose monohydrate	64044-51-5
polysorbate 80	9005-65-6
titanium dioxide	13463-67-7
polyethylene glycol	25322-68-3
shellac in ethanol	9000-59-3
isopropyl alcohol	67-63-0
iron oxide black	12227-89-3
n-butyl alcohol	71-36-3
propylene glycol	57-55-6
ammonium hydroxide	1336-21-6

The tablet strengths describe the amount of morphine per tablet as the pentahydrated sulfate salt (morphine sulfate).

- The 15 mg tablets also contain: FD&C Blue No. 1, FD&C Red No. 40 and FD&C Yellow No.
 6
- The 30 mg tablets also contain: FD&C Blue No. 2 and FD&C Red No. 40
- The 60 mg tablets also contain: FD&C Yellow No. 6 and FD&C Red No. 40
- The 100 mg tablets also contain: FD&C Blue No. 2, FD&C Yellow No. 6 and FD&C Red No. 40

Morphine sulfate is an odorless, white, crystalline powder with a bitter taste. It has a solubility of 1 in 21 parts of water and 1 in 1000 parts of alcohol, but is practically insoluble in chloroform

or ether. The octanol: water partition coefficient of morphine is 1.42 at physiologic pH and the pKb is 7.9 for the tertiary nitrogen (mostly ionized at pH 7.4).

In accordance with 29 CFR 1910.1200, the exact percentage composition of the mixture has been withheld as a trade secret.

Section 4 – First Aid Measures

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must be taken for medical attention if any adverse effects are observed. Contaminated clothing and shoes must be removed. Take a copy of this SDS to health professional with victim(s) exposed to this substance. Wash clothing and thoroughly clean shoes before reuse.

SKIN EXPOSURE: If skin contact with this material occurs, flush affected area with water. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effects occur after flushing.

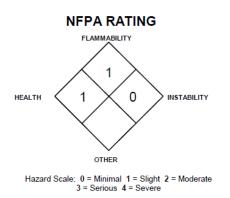
EYE EXPOSURE: If this material enters the eyes, open contaminated individual's eyes while under gently running water. Use sufficient force to open eyelids. Have contaminated individual "roll" eyes. Minimum flushing is for 20 minutes. Contaminated individual must seek medical attention if adverse effect occurs or continues after flushing.

INGESTION: If this material is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, seek immediate medical attention. Do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is <u>unconscious</u>, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and <u>obtain emergency medical attention</u>.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: In therapeutic use, pre-existing compromised cardiovascular function and hypotensive disorders, zinc deficiency, epilepsy, impaired cerebral circulation or increased intracranial pressure, bronchospasm, elevated serum triglycerides, and drug or alcohol dependency may be seriously aggravated. Workplace exposure may also aggravate these conditions. Persons who have hypersensitivity reactions to this material or other disorders described in <u>Section 11 (Toxicological Information)</u> may experience aggravation upon exposure.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention. Respiratory depression should be treated by artificial ventilation with oxygen. Cardiovascular depression may require repositioning of the patient by raising the patient's legs, increasing the flow rate of IV fluids, and administering pressor agents and/or anti-cholinergic agents.

Section 5 – Fire Fighting Measures



FLASH POINT: Not available. AUTOIGNITION TEMPERATURE: Not available. FLAMMABLE LIMITS (in air by volume, %): Not available.

FIRE EXTINGUISHING MEDIA: Unless incompatibilities exist for surrounding materials, carbon dioxide, water spray, 'ABC' type chemical extinguishers, foam, dry chemical and halon extinguishers can be used to fight fires involving this product.

UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

EXPLOSION SENSITVITY TO MECHANICAL IMPACT: Not applicable.

EXPLOSION SENSISTIVITY TO STATIC DISCHARGE: Not applicable.

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. All personal protective gear and contaminated fire-response equipment should be decontaminated with soapy water and thoroughly rinsed before being returned to service. Move fire-exposed containers if it can be done without risk to firefighters. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

SPECIAL HAZARDS: Emits toxic fumes of carbon monoxide,, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur containing compounds.

Section 6 – Accidental Release Measures

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Personnel involved in clean-up should wear appropriate protective equipment – minimize exposure.

ENVIRONMENTAL PRECAUTIONS: Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

METHODS FOR CLEAN-UP AND CONTAINMENT: Cleanup of Small Spills: The spilled product should be gently covered with absorbent pads. Clean spill with pad and dispose of properly. Decontaminate the spill area **(three** times) using a bleach and detergent solution and then rinse with clean water.

REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. See Section 13, Disposal Considerations for more information.

Section 7 – Handling & Storage

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be thoroughly trained to handle it safely. Do not eat or drink while handling this product. After handling this product, wash face and hands thoroughly prior to eating, drinking, smoking or applying cosmetics. Ensure this product is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection). Minimize all exposures to this product..

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 25°C (77°F). Do not allow product to freeze. Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Empty containers may contain residual material; therefore, empty containers should be handled with **care and disposed of properly.**

SPECIFIC END USE(S): This is a human-use only clinical product, indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat or other protective clothing. Prevent dispersion of particulates by wetting or dampening surfaces prior to clean up of equipment. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water.

Section 8 - Exposure Controls/ Personal Protection

VENTILATION AND ENGINEERING CONTROLS: General: use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used. Wear appropriate personal protect equipment consistent with the recommendations of this SDS. Prevent accumulation of product on work surfaces by routinely cleaning areas appropriately.

WORKPLACE EXPOSURE LIMITS/CONTROL PARAMETERS: Note: exposure limits for sodium hydroxide are not necessarily applicable as this compound is added for pH balancing and once reacted with other ingredients, no sodium hydroxide remains. No exposure limits for this compound are given in this SDS.

Section 9 – Physical and Chemical Properties

The following information is for the veterinary pharmaceutical product:

PHYSICAL FORM: Solid COLOR: Various ODOR: Odorless ODOR THRESHOLD: Not applicable MOLECULAR WEIGHT:

- Average: 668.754
- Monoisotopic: 668.2403662

MOLECULAR FORMULA: C₁₇H₂₁NO₇S pH: 1.2 at physiological conditions

HOW TO DETECT THIS SUBSTANCE (identification/warning properties): There are no distinguishing characteristics for identification in event of accidental release.

Section 10. STABILITY and REACTIVITY

CHEMICAL STABILITY: Normally stable

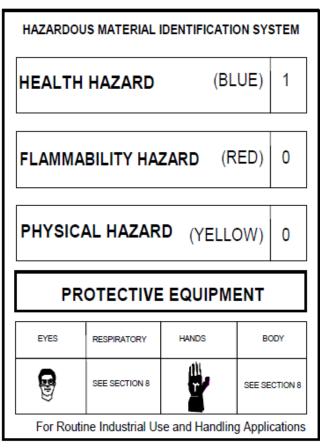
DECOMPOSITION PRODUCTS: Combustion: Products of thermal decomposition may include carbon and sulfur containing oxides. Hydrolysis: None known.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Strong acids and bases. Avoid materials that are incompatible with water.

POSSIBILITY OF HAZARDOUS REACTION/POLYMERIZATION: None known.

CONDITIONS TO AVOID: Exposure to or contact with extreme temperatures, incompatible chemicals.

Section 11 – Toxicological Information



Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The main expected routes of occupational exposure to this product are via eye and skin contact. The anticipated symptoms of exposure, by route of exposure are described further in this section.

CONTACT WITH SKIN or EYES: Skin contact may be irritating, especially if prolonged. Chronic skin exposure may cause dermatitis. Eye contact may cause irritation.

SKIN ABSORPTION: No data is available on potential absorption of this product through intact skin.

INGESTION: Ingestion of this product is not anticipated to be a significant route of occupational exposure. Ingestion of this product (i.e., through poor hygiene practices) may be harmful. Accidental dosage with MORPHABOND ER can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and, in some cases, pulmonary edema, bradycardia, hypotension, partial or complete airway obstruction, atypical snoring, and death. Marked mydriasis rather than miosis may be seen with hypoxia in overdose situations.

In case of accidental ingestion, priorities are the re-establishment of a patent and protected airway and institution of assisted or controlled ventilation, if needed. Employ other supportive measures (including oxygen, vasopressors) in the management of circulatory shock and pulmonary edema as indicated. Cardiac arrest or arrhythmias will require advanced life support techniques. The opioid antagonists, naloxone or nalmefene, are specific antidotes to respiratory depression resulting from opioid overdose. For clinically significant respiratory or circulatory depression secondary to morphine overdose, administer an opioid antagonist. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to morphine overdose. Because the duration of reversal would be expected to be less than the duration of action of morphine in MORPHABOND ER, carefully monitor the patient until spontaneous respiration is reliably reestablished. MORPHABOND ER will continue to release morphine and add to the morphine load for 24 to 48 hours or longer following ingestion, necessitating prolonged monitoring. If the response to an opioid antagonist is suboptimal or only brief in nature, administer additional antagonist as directed by the product's prescribing information. In an individual physically dependent on opioids, administration of the recommended usual dosage of the antagonist will precipitate an acute withdrawal syndrome. The severity of the withdrawal symptoms experienced will depend on the degree of physical dependence and the dose of the antagonist administered. If a decision is made to treat serious respiratory depression in the physically dependent patient, administration of the antagonist should be initiated with care and by titration with smaller than usual doses of the antagonist.

OTHER POTENTIAL HEALTH EFFECTS: Body systems affected by therapeutic use are listed below. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known.

- Body as a Whole
- Cardiovascular System
- Central Nervous System
- Ears
- Eyes

- Digestive System
- Liver
- Hypersensitivity Reactions
- Injection Site
- Metabolic/Nutritional System
- Musculoskeletal System
- Respiratory System
- Skin
- Urogenital System

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

Acute: May cause irritation by skin or eye contact or inhalation. Ingestion may be harmful.

Chronic: Repeated skin contact may cause dermatitis (dry, red skin). No other chronic effects have been reported from workplace exposure. Chronic exposure to this product may cause adverse effects as described under 'Other Potential Health Effects'.

TARGET ORGANS: It is anticipated that for Occupational Exposure the target organs are: Acute: Skin, eyes, respiratory system. Chronic: None known from workplace exposure. In therapeutic use this product may have an impact on the body systems described under 'Other Potential Health Effects'.

TOXICITY DATA: The following toxicity data are available for the active ingredient. Additional toxicity data are currently available for active ingredient of this product. Data are available for the excipient ingredient, but are not presented in this SDS.

CARCINOGENIC POTENTIAL OF MATERIAL: Long-term studies in animals have not been performed to evaluate the carcinogenic potential of MorphaBond ER. Components of the product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

SODIUM METABISULFITE: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

The remaining components are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be a cancer-causing agent by these agencies.

IRRITANCY OF PRODUCT: May cause respiratory, skin or eye irritation.

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of MorphaBond ER in pregnant women. In the workplace, the risk to the fetus should be communicated and the appropriate action should be taken to prevent exposure in accordance with company policy and regulatory requirements. In formulated products this material is rated by the FDA for therapeutic risk as Pregnancy Risk Category X (refer to Definition of Terms for full category definitions).

Embryotoxicity/Teratogenicity: Reproduction studies have been performed in rats and rabbits at intravenous doses of 15 mg/kg/day (approximately equivalent to the recommended human induction dose on a mg/m2 basis) and have revealed no evidence of impaired fertility or harm to the fetus due to MorphaBond ER. MorphaBond ER, however, has been shown to cause maternal deaths in rats and rabbits and decreased pup survival during the lactating period in dams treated with 15 mg/kg/day (approximately equivalent to the recommended human induction dose on a mg/m2 basis). The pharmacological activity (anesthesia) of the drug on the mother is probably responsible for the adverse effects seen in the offspring.

Reproductive Toxicity: MorphaBond ER has been reported to be excreted in human milk and the effects of oral absorption of small amounts of MorphaBond ER are not known. Because there is potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

BIOLOGICAL EXPOSURE INDICES: Currently, there are no Biological Exposure Indices (BEIs) determined for the components of this product.

Section 16 – Other Information

ANSI LABELING (Z129.1, Provided to Summarize Occupational Hazard Information): WARNING! MAY BE HARMFUL IF SWALLOWED. ACCIDENTAL INJECTION MAY CAUSE ADVERSE EFFECTS. COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES. CAN CAUSE HARM TO AQUATIC ORGANISMS. MAY CAUSE ALLERGIC REACTIONS INCLUDING ANAPHYLATIC AND ANAPHYLACTOID REACTIONS.

ANSI LABELING (continued): Do not taste or swallow. Avoid contact with skin, eyes, and clothing. Keep container closed. Use gloves, safety glasses, and appropriate respiratory and body protection.

FIRST-AID: If exposed, seek immediate medical attention. If swallowed, do not induce vomiting. If alert, give victim up to three glasses of water. Never give anything by mouth to an unconscious person. In case of contact, immediately flush skin with copious amounts of warm

water for 20 minutes. Remove contaminated clothing and shoes. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. IN CASE OF FIRE: Use water fog, dry chemical or CO₂, or alcohol foam.

IN CASE OF SPILL: Refer to Safety Data Sheet for complete spill response procedures. Spill response should be performed by persons properly trained to do so. Decontaminate area with bleach and detergent solution and triple rinse area. Place spill debris in a suitable container. Refer to SDS for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

67/548/EEC EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION FOR COMPONENTS:

FULL TEXT GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008:

Classification: Acute Oral Toxicity Category 4, Aquatic Acute Toxicity Category 1, Aquatic Chronic Toxicity Category 1

Hazard Statements: H302: Harmful if swallowed. H410: Very toxic to aquatic life with longlasting effects.

Sodium Metabisulfite: This is a published classification:

Classification: Acute Oral Toxicity Category 4, Eye Damage Cat. 1

Hazard Statement Codes: H302: Harmful if swallowed. H318: Causes serious eye damage.

All Other Components: An official classification for these substances has not been published in the CLP 1272: 2008 and is not applicable for self-classification.

FULL TEXT EU 67/548/EEC:

Classification: Harmful, Dangerous for the Environment

Hazard Statements: R22: Harmful if swallowed. R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Classification: Harmful.

Risk Phrases: R22: Harmful if swallowed. R31: Contact with acids liberates toxic gas. R41: Risk of serious damage to eyes.

All Components: An official classification for these substances has not been published in Commission Directives 93/72/EEC, 94/69 EC, 96/54/EC or subsequent directives and is not applicable for self-classification.

REFERENCES AND DATA SOURCES: Contact the manufacturer for information.