

**Rapanofal™ (propofol injectable emulsion)**  
**Anesthetic Injection**  
**SAFETY DATA SHEET (SDS)**



**Section 1 – Identification**

TRADE NAME: Rapanofal™  
CHEMICAL NAME: Active Ingredient: 2, 6-diisopropylphenol  
CHEMICAL CLASS: Active Ingredient: Cumene Derivative  
THERAPEUTIC CLASS: Intravenous Anesthesia  
RELEVANT USE of the SUBSTANCE: Veterinary Pharmaceutical  
USES ADVISED AGAINST: Other than Relevant Use  
HOW SUPPLIED: NDC 86064-001-20, 20 ml vial, 10 mg/ml propofol

Company/Undertaking Identification

US Supplier/Manufacturer Name: iVAoes Animal Health  
Address: 80 SW 8<sup>th</sup> Street, Suite #2660, Miami, FL 33130  
Business Phone: 1-844-243-4968  
Emergency Phone: 1-888-621-0189  
Date of Preparation: 10/06/2016  
Revision Date: 10/7/2016

**Section 2 – Hazards Identification**

**EMERGENCY OVERVIEW:** **Product Description:** This product is a white-colored, oil in water emulsion. **Health Hazards:** In the workplace, may be harmful if swallowed. Adverse effects by other routes are not known to exist. In veterinary therapeutic uses, this product is administered by intravenous route. This product can cause adverse effects on the nervous system in mammals, may produce irregular heartbeat, reduced blood pressure, convulsions, swelling and sleepiness. Veterinary therapeutic uses have been associated with both fatal and life-threatening anaphylactic and anaphylactoid reactions. It is not known if these effects are possible as a result of workplace exposure. Refer to [Section 11 \(Toxicological Information\)](#) 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.

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**Section 3 – Composition/Information on Ingredients**

Chemical Name	CAS #	EINECS #	% w/v	Label Elements	EXPOSURE LIMITS IN AIR							
					ACGIH-TLVs		OSHA-PELs		NIOSH-RELS		NIOSH	OTHER
					TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	IDLH mg/m <sup>3</sup>	mg/m <sup>3</sup>
<b>ACTIVE INGREDIENT</b>												
Propofol 2, 6-diisopropylphenol	2078-54-8	218-206-8	Proprietary	SELF CLASSIFICATION EU 67/548 CLASSIFICATION: Harmful, Dangerous for the environment Risk Phrases: R22, R50/53 Symbols: Xn, N  EU/GHS 1272/2008  Classification: Acute Oral	NE	NE	NE	NE	NE	NE	NE	Teva OEL Range µg/m <sup>3</sup> ≥ 10 - < 100 (established March 5, 2012)
<b>EXCIPIENTS</b>												
Egg yolk Phospholipid	12346 5-35-0	Not Listed	Proprietary	EU 67/548 Hazard Classification: Not Applicable GHS and EU 1272/2008 Hazard Classification: Not Applicable								
Glycerol	56-81-5	200-289-5	Proprietary	EU 67/548 Hazard Classification: Not Applicable GHS and EU 1272/2008 Hazard Classification: Not Applicable	NE	NE	15 (total dust), 5 (resp. fraction)	NE	NE	NE	NE	DFG MAKs: TWA: 50 (inhalable fraction) PEAK: 2-MAK 15 min. average value, 1-hr interval, 4 per shift DFG MAK Pregnancy Risk Classification: C
Sodium metabisulfite	7681-57-4	231-673-0	Proprietary	EU 67/548 Classification: Harmful Risk Phrase Codes: R22, R31, R41 Hazard Symbols: Xn GHS & EU 1272/2008 Classification: Acute Oral Toxicity Cat. 4, Eye Damage Cat. 1 Hazard Codes: H302, H318 Hazard Symbol/Pictogram: GHS05, GHS07	5	NE	5 (vacated 1989 PEL)	NE	5	NE	NE	Carcinogen: IARC-3, TLV-A4
Soybean oil	8001-22-7	232-27-4	Proprietary	EU 67/548 Hazard Classification: Not Applicable GHS and EU 1272/2008 Hazard Classification: Not Applicable	NE	NE	NE	NE	NE	NE	NE	DFG MAK: Danger of Sensitization of the Airways
Water	7732-18-5	231-791-2	Proprietary	EU 67/548 Hazard Classification: Not Applicable GHS and EU 1272/2008 Hazard Classification: Not Applicable								

NOTE: This product contains sodium hydroxide for pH adjustment/buffering. This compound does not contribute and further hazard to this product and so is not addressed in this SDS. See Section 16 for full classification information of this product.

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<b>Section 4 – First Aid Measures</b>
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**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.

**INHALATION:** If aerosols are inhaled, remove victim to fresh air. The contaminated individual must seek medical attention if any adverse effects occur

**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. If alert, victim should drink up to three glasses of water. Do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain emergency medical attention.

**INJECTION:** If this product is accidentally injected, flush injection site with water. Seek medical attention. Refer to Section 11 Toxicological Information.

**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 Section 11 (Toxicological Information) may experience aggravation upon exposure.

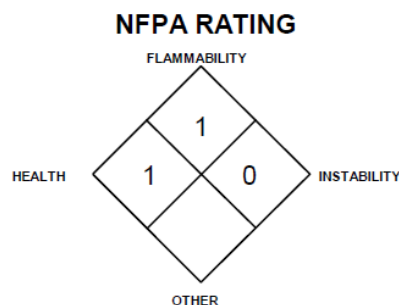
**INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED:** Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention. Respiratory depression should be treated by artificial ventilation with

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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**



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

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.

SPECIAL HAZARDS ARISING FROM THE PRODUCT: This solution is not flammable or combustible. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides).

EXPLOSION SENSITIVITY TO MECHANICAL IMPACT: Not applicable.

EXPLOSION SENSITIVITY 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.

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**Section 6 – Accidental Release Measures**

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12" x 12") of absorbent material, 250 mL and 1 L spill control pillows and a small scoop to collect glass fragments (if applicable). Absorbents should be able to be incinerated. Finally, the kit should contain two large waste-disposal bags. Avoid generating aerosols from this product.

**PROTECTIVE EQUIPMENT:**

Small Spills/Spills in Hoods: Personnel wearing nitrile or other appropriate gloves, lab coats or other protective clothing and eye protection should immediately clean spills of less than 5 mL.

Large Spills: Use proper protective equipment, including double nitrile or appropriate gloves, protective clothing (i.e., Tyvek coveralls), and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.

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.

Spills in hoods: Decontamination of all interior hood surfaces may be required after the above procedures have been followed. If the HEPA filter of the hood is contaminated, label the unit "Do not use-contaminated" and have trained personnel wearing appropriate protective equipment change and dispose of the filter properly as soon as possible.

Large spills: Restrict access to the spill areas. For spills of amounts larger than 5 mL, limit the spread by gently covering with absorbent sheets, or spill control pads or pillows. Be sure not to generate aerosols. The dispersion of aerosols into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.

All spills: Use procedures described above and then place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State and local hazardous waste disposal regulations (see Section 13, Disposal Considerations).

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For spills on water, contain, minimize dispersion and collect. Dispose of recovered product and report spill per regulatory requirements.

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.

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

<b>Section 7 – Handling &amp; Storage</b>
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NOTE: Consistent with the OSHA Blood-borne Pathogen regulation (29 CFR 1910.1030), observe Universal Precautions while using this product. Place used or product-contaminated hypodermic needles and syringes in a rigid “Sharps” container. Do not recap or clip used or product-contaminated hypodermic needles.

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. 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. Avoid generation of aerosols. 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: 4° to 25°C (40° to 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 veterinary pharmaceutical, indicated for use in cats and dogs

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.

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**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: Liquid.

COLOR: White.

ODOR: Odorless.

ODOR THRESHOLD: Not applicable.

MOLECULAR WEIGHT: Mixture.

MOLECULAR FORMULA: Mixture.

pH: 4.5 to 6.6

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

The following information is specifically for the active ingredient:

FORM: Powdered, crystalline solid.

COLOR: White to off-white.

MOLECULAR FORMULA:  $C_{12}H_{18}O$ .

MOLECULAR WEIGHT: 178.27.

ODOR: Odorless.

ODOR THRESHOLD: Not applicable.

VAPOR DENSITY: Not applicable.

VAPOR PRESSURE @ 25°C: 0.0099999 mmHg [predict.]

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BOILING POINT: 242°C (467.6°F)  
EVAPORATION RATE (nBuAc = 1): Not applicable.  
MELTING POINT: 18°C (64.4°F)  
DENSITY @ 20°C: 1.54 g/cm<sup>3</sup>  
FLASH POINT: 107.5°C (225.5°F) [predict.]  
FLAMMABILITY: Combustible.  
SOLUBILITY IN WATER: Insoluble in water.  
pH: Not available.  
OTHER SOLUBILITIES: Soluble in alcohol and toluene.  
PARTITION COEFFICIENT: Log K<sub>ow</sub> = 3.79; Log P(oct) = 3.662 (predict.)

**Section 10. STABILITY and REACTIVITY**

**CHEMICAL STABILITY:** Normally stable. The propofol component is air sensitive. This product can decompose in the presence of air and is therefore supplied with a blanket of nitrogen in each vial.

**DECOMPOSITION PRODUCTS:** Combustion: Products of thermal decomposition may include carbon and nitrogen 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.



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**Section 11 – Toxicological Information**

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM			
HEALTH HAZARD		(BLUE)	1
FLAMMABILITY HAZARD		(RED)	0
PHYSICAL HAZARD		(YELLOW)	0
PROTECTIVE EQUIPMENT			
EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8
For Routine Industrial Use and Handling Applications			

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 inhalation of aerosols, eye and skin contact. The anticipated symptoms of exposure, by route of exposure are described further in this section.

**INHALATION:** Inhalation of aerosols may irritate the mucous membranes and upper respiratory tract. No specific information is available on possible inhalation effects.

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

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**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. No specific information is available on possible ingestion effects.

**INJECTION:** Accidental injection of this product, by a contaminated needle or via laceration or puncture wound from a contaminated object may cause pain and irritation, in addition to the wound and effects described under 'Other Potential Health Effects'. Accidental injection may cause severe allergic reactions, based on information on therapeutic use.

**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'.

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**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 Propofol. 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.

**SENSITIZATION TO THE MATERIAL:** Use of Propofol as an injectable emulsion has been associated with both fatal and life-threatening anaphylactic and anaphylactoid reactions, this is likely to be from the sodium metabisulfite excipient. This product contains Sodium Metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than non-asthmatic people.

**REPRODUCTIVE TOXICITY INFORMATION:** There are no adequate and well-controlled studies of Propofol 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 B (refer to Definition of Terms for full category definitions).

**Mutagenicity:** Propofol was not mutagenic in the in vitro bacterial reverse mutation assay (Ames test) using Salmonella typhimurium strains TA98, TA100, TA1535, TA1537 and TA1538.

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Propofol was not mutagenic in either the gene mutation/gene conversion test using *Saccharomyces cerevisiae*, or in vitro cytogenetic studies in Chinese hamsters. In the in vivo mouse micronucleus assay with Chinese Hamsters Propofol administration did not produce chromosome aberrations.

**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/m<sup>2</sup> basis) and have revealed no evidence of impaired fertility or harm to the fetus due to Propofol. Propofol, 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/m<sup>2</sup> basis). The pharmacological activity (anesthesia) of the drug on the mother is probably responsible for the adverse effects seen in the offspring.

**Reproductive Toxicity:** Propofol Injectable emulsion has been reported to be excreted in human milk and the effects of oral absorption of small amounts of Propofol 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.

<b>Section 16 – Other Information</b>
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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.

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IN CASE OF FIRE: Use water fog, dry chemical or CO<sub>2</sub>, 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:

Propofol: This is a self-classification.

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 long-lasting 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:

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Propofol: This is a self-classification.

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.

Sodium Metabisulfite: This is a published classification.

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 supplier for information.