

SAFETY DATA SHEET



1. Identification

Product identifier	PropoFlo 28
Other means of identification	
Synonyms	PropoFlo * PropoFlo Multidose Vial * Propofol ES * Propofol Injectable Emulsion 10 mg/mL * PropoFlo Plus
Recommended use	Veterinary anesthetic agent
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Anesthetic drug; may cause central nervous system and cardiovascular system effects. May cause drowsiness and dizziness.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Soybean oil		8001-22-7	10

Chemical name	Common name and synonyms	CAS number	%
Glycerol		56-81-5	2.25
Benzyl Alcohol		100-51-6	2
Propofol		2078-54-8	1

4. First-aid measures

Inhalation	Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. For breathing difficulties, oxygen may be necessary. If not breathing, give artificial respiration. and Get medical attention immediately.
Skin contact	In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.
Ingestion	Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Mild skin irritation. Exposure may cause temporary irritation, redness, or discomfort. Dermatitis. May cause respiratory irritation. Coughing. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Rash. (allergic skin rash); Difficulty in breathing. Central nervous system effects such as headache, dizziness, drowsiness, fatigue, and lack of muscular coordination can also occur. Nausea, vomiting. May cause decreases in blood pressure and other cardiac effects, decreased heart rate (bradycardia).
Indication of immediate medical attention and special treatment needed	Anesthetic drug: may cause central nervous system and cardiovascular system effects. Monitor respiratory, cardiac and central nervous system. Provide general supportive measures and treat symptomatically.
General information	IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Ensure adequate ventilation. Remove sources of ignition. Prevent product from entering drains. Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Restrict access to work area. Use with adequate ventilation. Wear appropriate personal protective equipment. Protect from heat and light. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities Keep locked up or in an area accessible only to qualified or authorized persons. Store in a well-ventilated place. @ ≤ 25C / 77F. Store in a tightly closed container. Protect from light. Protect from sunlight. Keep away from heat, sparks and open flame. Do not allow material to freeze. Keep out of the reach of children. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Glycerol (CAS 56-81-5)	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.
Soybean oil (CAS 8001-22-7)	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Soybean oil (CAS 8001-22-7)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Mist.

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value
Benzyl Alcohol (CAS 100-51-6)	TWA	44.2 mg/m ³
		10 ppm

Biological limit values No biological exposure limits noted for the ingredient(s).

Control banding approach Not available.

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas. Engineering controls should be used as the primary means to control exposures. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Thermal hazards Not applicable.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	Aqueous solution (Emulsion).
Physical state	Liquid.
Form	Liquid.
Color	White to off-white.
Odor	Odorless.
Odor threshold	Not available.
pH	6 - 9
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	0.996 g/ml
Solubility(ies)	
Solubility (water)	Slight
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	1.54 cP @ 25C/77F
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials. Heat, flames and sparks. Exposure to light. Sunlight. Protect from freezing.
Incompatible materials	Strong oxidizing agents. Bases. Acid chlorides. Acid anhydrides.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause hypersensitivity reactions in susceptible individuals. Vapors have a narcotic effect and may cause headache, fatigue, dizziness and nausea. Prolonged inhalation may be harmful.
Skin contact	Prolonged skin contact may cause temporary irritation. Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis. May cause hypersensitivity reactions in susceptible individuals.

Skin contact

Benzyl Alcohol	Species: Guinea Pig Severity: Moderate
Propofol	Species: Rabbit Severity: Irritant
Glycerol	Species: Rabbit Severity: Mild
Benzyl Alcohol	Species: Rabbit Severity: Minimal
Propofol	Species: Rat Severity: Severe Irritant

Eye contact

Propofol	Direct contact with eyes may cause temporary irritation. Species: Rabbit Severity: Irritant
Glycerol	Species: Rabbit Severity: Mild
Benzyl Alcohol	Species: Rabbit Severity: Severe

Ingestion

Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Mild skin irritation. Exposure may cause temporary irritation, redness, or discomfort. Dermatitis. May cause respiratory irritation. Coughing. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Rash. (allergic skin rash); Difficulty in breathing. Central nervous system effects such as headache, dizziness, drowsiness, fatigue, and lack of muscular coordination can also occur. Nausea, vomiting. May cause decreases in blood pressure and other cardiac effects, decreased heart rate (bradycardia).

Information on toxicological effects

Acute toxicity Anesthetic drug: may cause central nervous system and cardiovascular system effects.

Product	Species	Test Results
PropoFlo 28		
Acute		
Oral		
ATE		> 10000 mg/kg
Components		
Benzyl Alcohol (CAS 100-51-6)		
Acute		
Dermal		
LD50	Rabbit	2000 mg/kg
Inhalation		
LC50	Rat	> 4.178 mg/L 1000 mg/l, 8 Hours
Oral		
LD50	Mouse	1580 mg/kg
	Rat	1230 mg/kg
Propofol (CAS 2078-54-8)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg

Components	Species	Test Results
Oral		
LD50	Mouse	1100 mg/kg
	Rat	500 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Corrosivity		
Propofol		Result: Irritant Severity: Moderate-Severe
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye Contact		
Propofol		Species: Rabbit Severity: Irritant
Glycerol		Species: Rabbit Severity: Mild
Benzyl Alcohol		Species: Rabbit Severity: Severe
Respiratory or skin sensitization		
Respiratory sensitization	Due to partial or complete lack of data the classification is not possible. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.	
Skin sensitization	Due to partial or complete lack of data the classification is not possible. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
Propofol		Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella
		In Vitro Chromosome Aberration Result: Negative Species: Human Lymphocytes
		In Vitro Cytogenetics Result: Negative Species: Chinese Hamster Ovary (CHO) cells
		In Vivo Micronucleus Result: Negative Species: Mouse
		Mitotic Gene Conversion Result: Negative Species: Saccharomyces cerevisiae
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
IARC Monographs. Overall Evaluation of Carcinogenicity	Not listed.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not regulated.	
US. National Toxicology Program (NTP) Report on Carcinogens	Not listed.	
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.	

Reproductivity

Propofol

15 mg/kg/day Reproductive & Fertility, No effects at maximum dose

Species: Rabbit

Organ: Intravenous

15 mg/kg/day Reproductive & Fertility, No effects at maximum dose

Species: Rat

Organ: Intravenous

Specific target organ toxicity - single exposure

Not classified.

Specific target organ toxicity - repeated exposure

Not classified.

Aspiration hazard

Not an aspiration hazard.

Chronic effects

Prolonged inhalation may be harmful.

Further information

Anesthetic drug: may cause central nervous system and cardiovascular system effects.

12. Ecological information

Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components	Species	Test Results
Benzyl Alcohol (CAS 100-51-6)	EC50	Daphnia magna (Water Flea)
		230 mg/L, 48 Hours 66 mg/L, 21 Day(s) Reproduction
		Pseudokirchneriella subcapitata (Green Alga)
	LC50	Pimephales promelas (Fathead Minnow)
		460 mg/L, 96 Hours
Aquatic		
Fish	LC50	Bluegill (Lepomis macrochirus)
		10 mg/l, 96 hours
Glycerol (CAS 56-81-5)		
	Aquatic	
Fish	LC50	Rainbow trout,donaldson trout (Oncorhynchus mykiss)
		51000 - 57000 mg/l, 96 hours

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available for this product.

Partition coefficient n-octanol / water (log Kow)

Propofol

3.8, [Log P]

Mobility in soil

No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions

Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

Glycerol (CAS 56-81-5)

Other Flavoring Substances with OSHA PEL's

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	06-29-2015
Revision date	05-31-2017
Version #	02
List of abbreviations	ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).
Disclaimer	Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.
Revision information	This document has undergone significant changes and should be reviewed in its entirety.