
SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Contact information

General

Distributor:
Parnell Technologies Pty Ltd
Unit 4, Century Estate
476 Gardeners Road, NSW 2015
Australia

Distributor:
Parnell U.S.1, Inc.
7015 College Blvd, Level 6
Overland Park, KS 66211
USA

Emergency telephone number

+61 2 9667 4411 (business hours)

+1-800-887-2763 (24 hours)

Product identifier

PropfolVet Multi Dose

Relevant identified uses of the substance or mixture and uses advised against

Active pharmaceutical ingredient: Propofol drug used for induction and maintenance of anesthesia in veterinary medicine.

Note

The pharmacological, toxicological, and ecological properties of this material and/ or its ingredients have not been fully characterized and it should only be handled by technically qualified individuals. Exposure by any route should be minimized. Exercise due care: wear suitable protective clothing, gloves, and eye/face protections.

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification according to GHS Regulation

Acute Toxicity Oral- Category 4 – H302

Acute Toxicity Inhalation- Category 4 – H332

Skin Corrosion/irritation - Category 2 – H315

Serious Eye damage/eye irritation - Category 2 – H319

Specific target organ toxicity -Single Exposure – Category 3 – H335

Label elements

Hazard Pictogram



Signal word

Warning

SECTION 2 - HAZARDS IDENTIFICATION Continued...
Hazard statements

H302	Toxic if swallowed
H332	Fatal if inhaled
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation

Precautionary statements

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P301+P316	If swallowed: Get emergency medical help immediately
P304+P340	If Inhaled: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	If IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P501	Dispose of contents/container according to applicable national regulations.

Other Hazards

No data available.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Chemical name	CAS-No.	Concentration (% w/w)
Propofol	2078-54-8	≥ 0.5 - < 1.5
Benzyl alcohol	100-51-6	≥ 1.5 - ≤ 3
Oleic acid	112-80-1	≥ 0.05 - < 0.1
Egg lecithin	93685-90-6	≥ 1 - < 1.5
Soybean oil	8001-22-7	≥ 9 - < 11
Glycerin	56-81-5	≥ 1.5 - ≤ 3
Sodium hydroxide	1310-73-2	N/A
Water for injection	2078-54-8	QS to 100

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed	If you feel unwell, seek medical advice.
Eye Contact	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Skin Contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is laboured, administer oxygen. Immediately notify medical personnel and supervisor.
Ingestion	Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
Protection of first aid responders	Avoid contact with skin, eyes, and clothing. See Section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed	<p>Skin contact may provoke the following symptoms: Skin irritation</p> <p>Eye contact may provoke the following symptoms: Eye irritation</p> <p>Inhalation may provoke the following symptoms: Respiratory tract irritation Cough</p>
Indication of immediate medical attention and special treatment needed, if necessary	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for local circumstances and the surrounding environment.
Specific hazards arising from the substance or mixture	No information identified. May emit carbon monoxide, carbon dioxide, and oxides of sulfur and/or nitrogen, and/or other fluorine-, sulfur-, or nitrogen-containing compounds. Exposure to combustion products may be a hazard to health.
Flammability/Explosivity	No information identified. High concentrations of finely divided organic particles can explode if ignited.
Unsuitable extinguishing media	None known.
Special protective equipment for fire-fighters	Wear full protective clothing and a NIOSH-approved (or equivalent) self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures	If substance is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
Environmental precautions	Avoid emptying into drains and release to the environment, prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water (see Section 12).
Methods and material for containment and cleaning up	Surround spill with absorbents and place a damp cloth. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spilled materials into a leak-proof container suitable for disposal in. Local or national regulations may apply to the release and disposal of this material, as well as those materials and items employed in. Keep in suitable, closed containers for disposal. Wipe up with absorbent material (e.g. cloth, fleece). (see section 13). Decontaminate the area.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling.
Conditions for safe storage including any incompatibilities	Store in a closed container. Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid	None Known
Packaging material	Unsuitable material: None known
Specific end use(s)	No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Note	Wash hands, face, and other potentially exposed areas immediately in the event of physical contact.
Control Parameters/Occupational Exposure Limit Values	This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure/Engineering controls	Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential.
Respiratory protection	None Known.
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible.

Skin protection	Wear disposable coveralls appropriate to the task, booties, and safety glasses with side shields. Ensure gloves are protective against solvents in use. Protective garments (coveralls, disposable coveralls, lab coats) are not to be worn in common areas (e.g., cafeterias) or out-of-doors. Employees must be trained in proper gowning and de-gowning practices.
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full-face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Environmental Exposure Controls	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
Other protective measures	Wash hands in the event of contact with this substance, especially before eating, drinking, or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Homogeneous emulsion, practically free of extraneous particulate contamination and large oil droplets
Color	White or almost white. Slight creaming may be visible on prolonged standing
Odor	No information identified.
Odor threshold	No information identified.
pH	6.0 – 8.5
Melting point/freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified.
Vapor density	No information identified.
Relative density	No information identified.
Water solubility	No information identified.
Solvent solubility	No information identified.

Partition coefficient (<i>n</i>-octanol/water)	No information identified
Auto-ignition temperature	No information identified.
Decomposition temperature	No information identified.
Viscosity	No information identified.
Explosive properties	No information identified.
Oxidizing properties	No information identified.
Other information	
Molecular formula	No information identified.
Molecular weight	No information identified.
Density	No information identified.

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Not classified as a reactivity hazard.
Chemical stability	No decomposition if stored and applied as directed. Stable under normal conditions.
Possibility of hazardous reactions	Stable under recommended storage conditions. No hazards to be specially mentioned. None known.
Conditions to avoid	No information identified.
Incompatible materials	No information identified.
Hazardous decomposition products	No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Information on toxicological effects

Route of entry May be exposed *via* ingestion, inhalation, or skin contact.

Product/Mixture: No data available

Components/Ingredients:

Propofol

Acute toxicity LD₅₀ Oral - Rat - 500 mg/kg
 Remarks: (RTECS)
 Inhalation: No data available
 Dermal: No data available

Skin corrosion/irritation No data available.

Respiratory or skin sensitization No data available

Germ cell mutagenicity No data available

Carcinogenicity No data available

Reproductive toxicity No data available.

Specific target organ toxicity - single exposure No data available.

Specific target organ toxicity - repeated exposure Inhalation - May cause respiratory irritation.

Aspiration hazard No data available

Benzyl alcohol

Acute toxicity LD₅₀ 1.55 mL/kg (rat)
 LD₅₀ 1580 mg/kg (mouse)
 Adverse effect observed LD₅₀ 1 620 mg/kg
 Inhalation: LC₅₀ (4 h) 4.178 mg/L air (rat)
 Dermal: LD₅₀ 2000 mg/kg (rabbit)

Skin corrosion/irritation No adverse effect observed (not irritating)

Serious eye damage/eye irritation Adverse effect observed (irritating)

Respiratory or skin sensitization No adverse effect observed (not sensitizing)

Germ cell mutagenicity No adverse effect observed (negative).

Carcinogenicity No data available

Reproductive toxicity No data available

Specific target organ toxicity - single exposure	No data available
Specific target organ toxicity - repeated exposure	NOAEL (rat): 400 - 500 mg/kg/day NOAEL (mouse): 200 - 250 mg/kg/day
Aspiration hazard	No data available
Oleic acid	
Acute toxicity	LD ₅₀ Oral - Rat - 25.000 mg/kg Remarks: (RTECS) Inhalation: No data available Dermal: No data available
Skin corrosion/irritation	Skin - Rabbit Result: No skin irritation Remarks: (External MSDS)
Serious eye damage/eye irritation	Eyes - Rabbit Result: No eye irritation Remarks: (External MSDS)
Respiratory or skin sensitization	No data available
Germ cell mutagenicity	No data available
Carcinogenicity	No data available
Reproductive toxicity	No data available
Specific target organ toxicity - single exposure	No data available.
Specific target organ toxicity - repeated exposure	No data available
Aspiration hazard	No data available
Egg lecithin	
Acute oral toxicity	No data available
Skin corrosion/irritation	No data available
Serious eye damage/eye irritation	No data available
Respiratory or skin sensitization	No data available
Germ cell mutagenicity	No data available
Carcinogenicity	No data available

Reproductive toxicity	No data available
Specific target organ toxicity - single exposure	No data available.
Specific target organ toxicity - repeated exposure	No data available
Aspiration hazard	No data available
Soybean oil	
Acute oral toxicity	No data available
Skin corrosion/irritation	No data available
Serious eye damage/eye irritation	No data available
Respiratory or skin sensitization	No data available
Germ cell mutagenicity	No data available
Carcinogenicity	No data available
Reproductive toxicity	No data available.
Specific target organ toxicity - single exposure	No data available.
Specific target organ toxicity - repeated exposure	NOAEL (rat): 1 000 mg/kg/day
Aspiration hazard	No data available
Glycerin	
Acute oral toxicity	LD ₅₀ 27200 mg/kg (rat) LD ₅₀ 2300 mg/kg (mouse) LD ₅₀ 10000 mg/kg (guinea pig) No adverse effect observed LD50 11500 mg/kg Inhalation: LC50 (4 h) 5.85 mg/L air (rat) LC ₀ (4 h) 5.85 mg/L air (rat) Dermal: LD ₅₀ 45 mL/kg (guinea pig)
Skin corrosion/irritation	No adverse effect observed (not irritating)
Serious eye damage/eye irritation	No adverse effect observed (not irritating)
Respiratory or skin sensitization	No adverse effect observed (not sensitizing)

Germ cell mutagenicity	No adverse effect observed (negative)
Carcinogenicity	No data available
Reproductive toxicity	No adverse effect observed NOAEL 2 000 mg/kg/day (chronic, rat)
Specific target organ toxicity - single exposure	No data available.
Specific target organ toxicity - repeated exposure	NOAEL (rat): 1600 - 10000 mg/kg/day No adverse effect observed NOAEL 10000 mg/kg/day (chronic, rat) NOEL (rat): 50000 ppm No adverse effect observed NOAEL 5040 mg/kg/day (sub chronic, rabbit) LOEL (rat): 200000 ppm
Aspiration hazard	No adverse effect observed NOAEC 662 mg/m ³ (sub chronic, rat) No data available

SECTION 12 - ECOLOGICAL INFORMATION

Ecotoxicity

Product/Mixture: No data available

Components/Ingredients:

Propofol

Toxicity to fish No data available

Toxicity to daphnia and other aquatic invertebrates No data available

Toxicity to algae/aquatic plants No data available

Toxicity to fish (Chronic toxicity) No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) No data available

Persistence and degradability No data available

Bioaccumulative potential No data available

Benzyl alcohol

Toxicity to fish LC₅₀ (4 days) 460 mg/L
LC₅₀ (72 h) 460 mg/L
LC₅₀ (48 h) 770 mg/L
LC₅₀ (24 h) 770 mg/L
LC₅₀ (60 min) 770 mg/L
NOEC (30 days) 48.897 mg/L

Toxicity to daphnia and other aquatic invertebrates EC₅₀ (48 h) 230 mg/L
LC₅₀ (48 h) 260.415 mg/L
NOEC (21 days) 51 - 66 mg/L
EC₅₀ (21 days) 66 mg/L

Toxicity to algae/aquatic plants	EC ₅₀ (4 days) 76.828 mg/L EC ₅₀ (72 h) 500 - 770 mg/L NOEC (30 days) 23.486 mg/L NOEC (72 h) 310 mg/L
Toxicity to microorganisms	IC ₅₀ (49 h) 2.1 g/L IC ₅₀ (24 h) 390 mg/L
Persistence and degradability	No data available
Bioaccumulative potential	No data available
Oleic acid	
Toxicity to fish	LC ₅₀ - Pimephales promelas (fathead minnow) - 205 mg/l - 96 h Remarks: (ECOTOX Database)
Toxicity to daphnia and other aquatic invertebrates	EC ₅₀ - Daphnia - > 2,8 mg/l - 48 h (OECD Test Guideline 202) Remarks: (above the solubility limit in the test medium)
Toxicity to algae/aquatic plants	No data available
Toxicity to microorganisms	No data available
Persistence and degradability	No data available
Bioaccumulative potential	No data available
Egg lecithin	
Toxicity to fish	No data available
Toxicity to daphnia and other aquatic invertebrates	No data available
Toxicity to algae/aquatic plants	No data available
Toxicity to microorganisms	No data available
Persistence and degradability	No data available
Bioaccumulative potential	No data available
Glycerin	
Toxicity to fish	LC ₅₀ (4 days) 54 g/L
Toxicity to daphnia and other aquatic invertebrates	EC ₅₀ (24 h) 10 g/L
Toxicity to algae/aquatic plants	No data available
Toxicity to microorganisms	No data available
Persistence and degradability	No data available
Bioaccumulative potential	No data available
Toxicity to fish	No data available
Toxicity to daphnia and other aquatic invertebrates	No data available
Toxicity to algae/aquatic plants	No data available

Toxicity to microorganisms No data available
Persistence and degradability No data available
Bioaccumulative potential No data available

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not let down the drain or flush down the toilet. All waste containing the material should be properly labelled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility. Follow all applicable regional, national, and local laws.

SECTION 14 - TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : Not applicable
 Proper shipping name : Not applicable
 Class : Not applicable
 Subsidiary risk : Not applicable
 Packing group : Not applicable
 Labels : Not applicable

IATA-DGR

UN/ID No. : Not applicable
 Proper shipping name : Not applicable
 Class : Not applicable
 Subsidiary risk : Not applicable
 Packing group : Not applicable
 Labels : Not applicable
 Packing instruction (cargo aircraft) : Not applicable
 Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
 Proper shipping name : Not applicable
 Class : Not applicable
 Subsidiary risk : Not applicable
 Packing group : Not applicable
 Labels : Not applicable
 EmS Code : Not applicable
 Marine pollutant : Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation**NZS 5433**

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Hazchem Code : Not applicable

49 CFR Road

Not regulated as a dangerous good

ADG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Hazchem Code : Not applicable

TDG

Not regulated as a dangerous good

SECTION 15 - REGULATORY INFORMATION

Safety, health, and environmental regulations/legislation specific for the substance or mixture This SDS generally complies with the requirements listed under current guidelines in the USA, Australia, New Zealand, and Canada.

Chemical safety assessment Not conducted.

The ingredients of this product are reported in the following inventories:

TSCA : Product contains substance(s) not listed on TSCA inventory.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SARA 311/312 Hazards:

No Hazards category to report.

Massachusetts Right to Know Components:

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right to Know Components:

No components are subject to the Pennsylvania Right to Know Act.

New Jersey Right to Know Components:

No components are subject to the New Jersey Right to Know Act.

California Prop. 65 Components:

Not listed.

Safety, health, and environmental regulations/legislation specific for the substance or mixture

Standard for the Uniform Scheduling of Medicines and Poisons No poison schedule number allocated (Please use the original publication of the SUSMP to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation, and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

DSL : This product contains components that are not listed on the Canadian DSL nor NDSL.

HSNO Approval Number

Not applicable

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

SECTION 16 - OTHER INFORMATION

Full text of H phrases and GHS classifications No information identified.

Sources of data Information from published literature and internal company data.

Abbreviations

ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PBT - Persistent, Bioaccumulative, and Toxic; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Revision Date

01/11/2024

Disclaimer

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

	Category: Safety Data Sheets (SDS) Title: PropofolVet Multi Dose SDS		
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REVISION HISTORY

Version 01 Effective on 29-Aug-2024

New document

Version 02 Effective on 01-Nov-2024

Minor correction

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

Con Benikos
Vice President Quality
con.benikos@parnell.com

I am the author of this document.
Signed 3:27:29 AM UTC 01-Nov-2024