

SAFETY DATA SHEETS

This SDS packet was issued with item:

078660155

N/A

1. Identification

Product identifier	SURPASS® (1% diclofenac sodium) Topical Anti-Inflammatory Cream
Other means of identification	Not available.
Recommended use	Indicated for the control of pain and inflammation associated with osteoarthritis (OA) in animals
Recommended restrictions	Not for human use.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	Boehringer Ingelheim Vetmedica, Inc.
Address	2621 North Belt Hwy St. Joseph, MO 64506-2002
Transportation emergency	For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 Outside USA and Canada: +1 703-527-3887 (collect calls accepted)
Medical Emergency (24HR):	(866)638-2226
Non-Emergency calls:	(800) 821-7467

2. Hazard(s) identification

Physical hazards	Flammable solids	Category 1
Health hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Danger
Hazard statement	Flammable solid.
Precautionary statement	
Prevention	Keep away from heat/sparks/open flames/hot surfaces. No smoking. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting// equipment. Wear protective gloves/protective clothing/eye protection/face protection.
Response	In case of fire: Use appropriate media to extinguish.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Not applicable.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Ethanol	64-17-5	proprietary
Propylene glycol	57-55-6	proprietary
Diclofenac sodium	15307-79-6	<1

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	Persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Alcohol resistant foam. Water spray. Water fog. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	No restrictions known.
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	Use water spray to cool unopened containers.
Specific methods	Prevent build-up of vapors or gasses to explosive concentrations.
General fire hazards	Solid wet with flammable liquid and vapor. Vapors may cause a flash fire or ignite explosively.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	HANDLING SIGNIFICANT QUANTITIES OF PRODUCT: Avoid breathing vapors or mists of this product. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

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

Components	Type	Value
Ethanol (CAS 64-17-5)	PEL	1900 mg/m ³ 1000 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
Ethanol (CAS 64-17-5)	STEL	1000 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1900 mg/m ³ 1000 ppm

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
Propylene glycol (CAS 57-55-6)	TWA	10 mg/m ³	Aerosol.
Biological limit values	No biological exposure limits noted for the ingredient(s).		
Exposure guidelines	Where lower governmentally imposed exposure limits exist, such limits should take precedence.		
Appropriate engineering controls	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	Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear safety glasses with side shields (or goggles).		
Skin protection			
Hand protection	Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear suitable gloves.		
Other	Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear lab coat, apron or appropriate clothing to prevent skin contact.		
Respiratory protection	Not generally required when handling vials or containers. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved organic vapor respirator.		
Thermal hazards	Not anticipated.		
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

Physical state	Solid.
Form	Cream.
Color	White to pinkish-white

Odor Nearly odorless.

Odor threshold Not available.

pH 6 - 8 (1:4 dispersion in water)

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point 125.0 °F (51.7 °C)

Evaporation rate Not available.

Flammability (solid, gas) Not available.

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 0.98

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

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	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Avoid temperatures exceeding the flash point. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Carbon dioxide (CO ₂). Carbon monoxide. Nitrogen oxides. Hydrogen chloride.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Expected to be a low ingestion hazard.
Inhalation	No adverse effects due to inhalation are expected. Skin
contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.

Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation.
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Information on toxicological effects

Acute toxicity	Not expected to be acutely toxic.
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Components	Species	Test Results
Ethanol (CAS 64-17-5)		
Acute		
<i>Inhalation</i>		
LC50	Mouse	39 mg/l, 4 Hours
	Rat	20000 mg/l, 10 Hours
<i>Oral</i>		
LD50	Dog	5.5 g/kg
	Guinea pig	5.6 g/kg
	Mouse	3450 mg/kg
	Rat	6.2 g/kg
<i>Other</i>		
LD50	Mouse	933 mg/kg
	Rat	1440 mg/kg
Propylene glycol (CAS 57-55-6)		
Acute		
<i>Oral</i>		
LD50	Rat	30 g/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.
Respiratory or skin sensitization	
Respiratory sensitization	Not available.
Skin sensitization	This product is not expected to cause skin sensitization.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity IARC has classified ethanol in alcoholic beverages as Group 1 (carcinogenic to humans). Ethanol alone has not been evaluated for carcinogenicity by IARC.

IARC Monographs. Overall Evaluation of Carcinogenicity

Ethanol (CAS 64-17-5) 1 Carcinogenic to humans.

NTP Report on Carcinogens

Ethanol (CAS 64-17-5) Known To Be Human Carcinogen.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not available.

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.

Components	Species	Test Results
Ethanol (CAS 64-17-5)		
Aquatic		
Crustacea	EC50	Water flea (Daphnia magna) 7.7 - 11.2 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas) > 100 mg/l, 96 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

Ethanol (CAS 64-17-5)	-0.31
Propylene glycol (CAS 57-55-6)	-0.92

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 Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

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 Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number	UN3175
UN proper shipping name	Solids containing flammable liquid, n.o.s. (Ethanol RQ = 200 lbs)
Transport hazard class(es)	
Class	4.1
Subsidiary risk	-
Packing group	II
Special precautions for user	This material qualifies as a limited quantity and has been reclassified to consumer commodity for US DOT for ground shipments. Read safety instructions, SDS and emergency procedures before handling.
Special provisions	47, IB6, IP2, T3, TP33

Packaging exceptions 151
Packaging non bulk 212
Packaging bulk 240

IATA

UN number UN3175
UN proper shipping name Solids containing flammable liquid, n.o.s. (Ethanol)
Transport hazard class(es)
Class 4.1
Subsidiary risk -
Label(s) Packing 4.1
group Environmental II
hazards ERG Code no
3L
Special precautions for user This material is shipped as limited quantity in non UN specification packaging when shipping less than 5kg (11lbs). Read safety instructions, SDS and emergency procedures before handling.

IMDG

UN number UN3175
UN proper shipping name SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.
Transport hazard class(es)
Class 4.1
Subsidiary risk -
Packing group II
Environmental hazards
Marine pollutant No.
EmS F-A, S-I
Special precautions for user This material is shipped as limited quantity in non UN specification packaging when shipping less than 5kg (11lbs). Read safety instructions, SDS and emergency procedures before handling.

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

15. Regulatory information

US federal regulations One or more components are not listed on TSCA. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use. FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.

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

Not regulated.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Ethanol (CAS 64-17-5) LISTED

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

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.**US state regulations****US. Massachusetts RTK - Substance List**

Ethanol (CAS 64-17-5)

US. New Jersey Worker and Community Right-to-Know Act

Ethanol (CAS 64-17-5)

Propylene glycol (CAS 57-55-6)

US. Pennsylvania Worker and Community Right-to-Know Law

Ethanol (CAS 64-17-5)

Propylene glycol (CAS 57-55-6)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Ethanol (CAS 64-17-5)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies 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	16-June-2014
Revision date	13-September-2016
Version #	02

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