HALEON

SAFETY DATA SHEET

1. Identification

Product identifier **VOLTAREN 1% DICLOFENAC SODIUM GEL**

Other means of identification

Product code MFC51379

Synonyms MFC51379 * PROJECT MOONLIGHT * VOLTAREN US 1% DICLOFENAC SODIUM GEL

Recommended use Consumer Healthcare Product

Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 335879

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 1
Sensitization, skin	Category 1
Reproductive toxicity	Category 2
Specific target organ toxicity, single exposure	Category 3 narcotic effects
Specific target organ toxicity, repeated exposure	Category 1

Environmental hazards

Hazardous to the aquatic environment, acute hazard	Category 2

OSHA defined hazards Not classified.

Label elements

Signal word Danger

Hazard statement	Causes skin irritation. May cause an allergic skin reaction. Causes serious eye damage. May cause drowsiness or dizziness. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure. Toxic to aquatic life.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid breathing vapors. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Contaminated work clothing must not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If on skin: Wash with plenty of water/. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor/. Specific treatment (see on this label). If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	5% of the mixture consists of component(s) of unknown acute oral toxicity. 9.2% of the mixture consists of component(s) of unknown acute dermal toxicity. 5% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 8.2% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
ISOPROPYL ALCOHOL	ISOPROPANOL ETHYL CARBINOL DIMETHYLCARBINOL 2-PROPANOL ISOHOL SEC-PROPYL ALCOHOL PROPYL ALCOHOL DIMETHYL CARBINOL PROPANOL ISOPROPYL ALCOHOL A.R. 1-METHYLETHANOL 1-METHYLETHYL ALCOHOL 2-HYDROXYPROPANE 2-PROPYL ALCOHOL ISO-PROPANOL ISO-PROPYL ALCOHOL ISOPRANOL LUTOSOL N-PROPAN-2-OL SEC-PROPANOL PROPOL IPA GR 95896X 206W94	67-63-0	20 - < 30

Chemical name	Common name and synonyms	CAS number	%
PROPYLENE GLYCOL	1,2-PROPANEDIOL 1,2-DIHYDROXYPROPANE 2-HYDROXYPROPANOL ISOPROPYLENE GLYCOL METHYLETHYLENE GLYCOL METHYLETHYL GLYCOL MONOPROPYLENE GLYCOL 2,3-PROPANEDIOL ALPHA-PROPYLENE GLYCOL 1,2-PROPYLENE GLYCOL (RS)-1,2-PROPANEDIOL 1,2-(RS)-PROPANEDIOL 1,2-PROPANDIOL DL-1,2-PROPANEDIOL DL-PROPYLENE GLYCOL PROPANE-1,2-DIOL (PROPYLENE GLYCOL) PROPANE-1-2-DIOL PROPANEDIOL,1,2-	57-55-6	5 - < 10
AMMONIUM HYDROXIDE	AMMONIA AQUEOUS AMMONIA SOLUTION AMMONIA WATER	1336-21-6	1 - < 3
CETOMACROGOL 1000 BP	ETHOXY (20-24) CETOSTEARYL ALCOHOL ETHOXYLATED CETOSTEARYL ALCOHOL ALCOHOLS, C16-C18), ETHOXYLATED CETOSTEARYL ALCOHOL ETHOXYLATED TALLOW ALCOHOL	68439-49-6	1 - < 3
DICLOFENAC SODIUM	BENZENEACETIC ACID, 2-((2,6-DICHLOROPHENYL)AMINO)-, MONOSODIUM SALT SODIUM (2-((2,6-DICHLOROPHENYL)AMINO)PHENYL)ACETATE SODIUM (2-(2,6-DICHLOROANILINO)PHENYL)ACETATE DICLOFENAC SODIUM SALT DICLOPHENAC SODIUM GP 45840 SODIUM DICLOFENAC	15307-79-6	1 - < 3
MINERAL OIL U.S.P.	WHITE MINERAL OIL WHITE MINERAL OIL, (PETROLEUM) WHITE OIL(REFINED PETROLEUM OIL) LIQUID PARAFFIN BP MINERAL OIL, WHITE PARAFFIN OIL	8042-47-5	1 - < 3
LAVENDER ROSEMARY EMOW 646900 015		Mixture	< 0.2
Other components below reportable levels			60 - < 70

4. First-aid measures

Inhalation
Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a poison center or doctor/physician if you feel unwell.

Skin contact
Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.

Eye contact
Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.

Ingestion
Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed
May cause drowsiness or dizziness. Headache. Nausea, vomiting. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash.

Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	IF exposed or concerned: Get medical advice/attention. If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Alcohol resistant foam. 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	Use water spray to cool unopened containers.
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. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. 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	Prevent product from entering drains. Large Spills: Stop the flow of material, if this is without risk. Following product recovery, flush area with water. Small Spills: 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. Contact local authorities in case of spillage to drain/aquatic environment. 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	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get this material in contact with eyes. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store locked up. Store in tightly closed container. 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.

GSK

Components	Type	Value	Form
DICLOFENAC SODIUM (CAS 15307-79-6)	8 HR TWA	160 mcg/m3	REPRODUCTIVE HAZARD
	OHC	2	REPRODUCTIVE HAZARD
LAVENDER ROSEMARY EMOW 646900 015	OHC	3	>10 - </=100 mcg/m3 SKIN SENSITISER

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

Components	Type	Value	Form
AMMONIUM HYDROXIDE (CAS 1336-21-6)	PEL	35 mg/m3	
		50 ppm	
ISOPROPYL ALCOHOL (CAS 67-63-0)	PEL	980 mg/m3	
		400 ppm	
MINERAL OIL U.S.P. (CAS 8042-47-5)	PEL	5 mg/m3	Mist.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
AMMONIUM HYDROXIDE (CAS 1336-21-6)	STEL	35 ppm	
	TWA	25 ppm	
ISOPROPYL ALCOHOL (CAS 67-63-0)	STEL	400 ppm	
	TWA	200 ppm	
MINERAL OIL U.S.P. (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
AMMONIUM HYDROXIDE (CAS 1336-21-6)	STEL	27 mg/m3	
		35 ppm	
	TWA	18 mg/m3	
		25 ppm	
ISOPROPYL ALCOHOL (CAS 67-63-0)	STEL	1225 mg/m3	
		500 ppm	
	TWA	980 mg/m3	
		400 ppm	
MINERAL OIL U.S.P. (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
PROPYLENE GLYCOL (CAS 57-55-6)	TWA	10 mg/m3	Aerosol.

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time
ISOPROPYL ALCOHOL (CAS 67-63-0)	40 mg/l	Acetone	Urine	*

* - For sampling details, please see the source document.

Appropriate engineering controls Good general ventilation 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. Provide eyewash station and safety shower.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles) and a face shield.

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other	Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Observe any medical surveillance requirements. 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. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance	
Physical state	Solid - Determined to be a pasty solid via the ADR test for determining fluidity; the penetrometer test.
Form	Gel.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	84.2 °F (29 °C) (Estimation based on components).
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
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.
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	Avoid temperatures exceeding the flash point. Contact with incompatible materials.
Incompatible materials	Acids. Strong oxidizing agents. Chlorine. Isocyanates.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause drowsiness or dizziness. Headache. Nausea, vomiting. Prolonged inhalation may be harmful.
Skin contact	Causes skin irritation. May cause an allergic skin reaction.

Eye contact Causes serious eye damage.

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics May cause drowsiness or dizziness. Headache. Nausea, vomiting. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash.

Information on toxicological effects

Acute toxicity Not known.

Components	Species	Test Results
DICLOFENAC SODIUM (CAS 15307-79-6)		
Acute		
Oral		
LD50	Rat	53 mg/kg
Subacute		
Oral		
LOAEL	Dog	>= 0.3 mg/kg/day, 4 weeks
Subchronic		
Oral		
NOAEL	Dog	0.03 - 0.3 mg/kg/day, 13 weeks
	Rat	2.5 mg/kg/day, 13 weeks
TD	Rat	>= 5 mg/kg/day, 13 weeks
ISOPROPYL ALCOHOL (CAS 67-63-0)		
Acute		
Dermal		
LD50	Rabbit	12.8 g/kg
Inhalation		
LC50	Rat	39 mg/l 8-hr
Oral		
LD50	Rat	5045 mg/kg
Subchronic		
Inhalation		
LOEL	Mouse	1500 ppm
	Rat	1500 ppm
NOEL	Mouse	500 ppm, 13 weeks
	Rat	500 ppm, 13 weeks

Skin corrosion/irritation Causes skin irritation.

Irritation Corrosion - Skin

ISOPROPYL ALCOHOL	Acute dermal irritation; OECD 404 Result: Non-irritant Notes: UN SIDS evaluation: 2-Propanol

Serious eye damage/eye irritation Causes serious eye damage.

Eye

ISOPROPYL ALCOHOL	OECD 405 Result: Mild irritant Species: Rabbit Notes: UN SIDS evaluation: 2-Propanol

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization May cause an allergic skin reaction.

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

Mutagenicity

DICLOFENAC SODIUM	Ames Result: Negative
ISOPROPYL ALCOHOL	Ames Result: Negative
DICLOFENAC SODIUM	Chromosomal Aberration Assay In Vitro Result: Negative chromosome aberration - male germinal epithelium Result: Negative Species: Mouse Dominant lethal assay Result: Negative Species: Mouse GreenScreen mammalian cell mutation assay Result: Negative HPRT gene mutation in human lymphocytes Result: Negative
ISOPROPYL ALCOHOL	In vivo Micronucleus Result: Negative Species: Mouse
DICLOFENAC SODIUM	L5178Y mouse lymphoma thymidine kinase locus assay Result: Negative
ISOPROPYL ALCOHOL	mammalian cell mutation assay (CHO/HGPRT forward mutation assay) Result: Negative SA7 - Sister Chromatid Exchange Result: Negative Sister Chromatid Exchange, V79 cells Result: Negative

Carcinogenicity Not classifiable as to carcinogenicity to humans.

ISOPROPYL ALCOHOL	0, Inhalation study Result: Negative Species: Mouse Notes: UN SIDS evaluation: 2-Propanol 2 year bioassay, Inhalation study Result: Negative Species: Rat Notes: UN SIDS evaluation: 2-Propanol
DICLOFENAC SODIUM	Result: Negative Species: Mouse Result: Negative Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

MINERAL OIL U.S.P. (CAS 8042-47-5)	3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Suspected of damaging fertility or the unborn child.

Reproductivity

ISOPROPYL ALCOHOL	< 1200 mg/kg/day Embryo-foetal development, Developmental neurotoxicity Result: Foetal NOAEL Species: Rabbit Notes: UN SIDS evaluation: 2-Propanol < 240 mg/kg/day Epidemiology Result: Maternal NOAEL Species: Human < 400 mg/kg/day Embryo-foetal development Result: Maternal NOAEL Species: Rabbit Notes: UN SIDS evaluation: 2-Propanol < 480 mg/kg/day Epidemiology Result: Foetal NOAEL Species: Human

Reproductivity

ISOPROPYL ALCOHOL

< 500 mg/kg/day Two generation study
Result: Maternal toxicity; adverse effects on offspring.
Species: Rat
Notes: UN SIDS evaluation: 2-Propanol

DICLOFENAC SODIUM

>= 2 mg/kg/day Embryofetal Development
Result: maternal toxicity; reduced foetal weight; foetal resorptions
Species: Rat
>= 2 mg/kg/day Embryofetal Development
Result: Reduced survival, reduced birth rate, reduced growth rate
Species: Rat
>= 2.5 mg/kg/day Embryofetal Development
Result: maternal toxicity; reduced foetal weight; foetal resorptions
Species: Rabbit
>= 4 mg/kg/day Fertility
Result: NOAEL
Species: Rat
>= 5 mg/kg/day Embryofetal Development
Species: Rabbit
10 mg/kg/day Teratogenicity
Result: NOAEL
Species: Rabbit
10 mg/kg/day Teratogenicity
Result: NOAEL
Species: Rat
Embryofetal Development
Species: Rabbit

Specific target organ toxicity - single exposure

May cause drowsiness or dizziness.

ISOPROPYL ALCOHOL

Result: Narcosis
Organ: Central Nervous System.

Specific target organ toxicity - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

DICLOFENAC SODIUM

Epidemiology
Species: Human
Organ: Gastro-intestinal tract; Cardiovascular system.

Aspiration hazard

Not an aspiration hazard.

Chronic effects

Prolonged inhalation may be harmful. Causes damage to organs through prolonged or repeated exposure.

Further information

DICLOFENAC SODIUM

Clinical experience, Anaphylactoid response
Species: Human

12. Ecological information

Ecotoxicity

Toxic to aquatic life.

Components		Species	Test Results
DICLOFENAC SODIUM (CAS 15307-79-6)			
Aquatic			
Acute			
Algae	EC50	Green algae (Pseudokirchnereilla subcapitata)	16.3 mg/l, 96 hours
	NOEC	Green algae (Pseudokirchnereilla subcapitata)	10 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	22.4 mg/l, 48 hours
Microtox	EC50	Microtox	11.5 mg/l, 30 minutes
Chronic			
Crustacea	NOEC	Water flea (Ceriodaphnia dubia)	1 mg/l, 7 days
Fish	Growth test NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	0.344 mg/l, 95 days

Components		Species	Test Results
		Zebra fish (Adult Brachydanio rerio)	0.344 mg/l, 34 days
Terrestrial			
Acute			
Earthworm	LC50	Earthworm (Eisenia foetida)	0.097 mg/kg, 14 days
ISOPROPYL ALCOHOL (CAS 67-63-0)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Industrial sludge	> 1000 mg/l, 3 hours
Algae	EC50	Green algae (Scenedesmus subspicatus)	> 1000 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	13299 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Juvenile Lepomis macrochirus)	> 1400 mg/l, 96 hours Static test
		Fathead minnow (Juvenile Pimephales promelas)	> 6550 to < 10400 mg/l, 96 hours Flow-through test
		Mosquito fish (Juvenile Gambusia affinis)	> 1400 mg/l, 96 hours Static test
PROPYLENE GLYCOL (CAS 57-55-6)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days
	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days
Crustacea	EC50	Daphnia	43500 mg/l, 48 hours
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes

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

Photolysis

Half-life (Photolysis-aqueous)

PROPYLENE GLYCOL	1.3 - 2.3 Years Estimated

Half-life (Photolysis-atmospheric)

ISOPROPYL ALCOHOL	3.1 - 14.5 Days Measured
PROPYLENE GLYCOL	32 Hours Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

DICLOFENAC SODIUM	10 - 80 % Other degradation test system, Activated sludge 30 % Other degradation test system, Activated sludge
ISOPROPYL ALCOHOL	99.9 %, 28 days Coupled Unit test (OECD 303A), Activated sludge
PROPYLENE GLYCOL	62 %, 5 days BOD5, Activated sludge 79 %, 20 Days BOD20, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

ISOPROPYL ALCOHOL	95 %, 20 Days Batch activated sludge (BAS), Activated sludge

Biodegradability

Percent degradation (Anaerobic biodegradation)

PROPYLENE GLYCOL	100 %, 9 days

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

AMMONIUM HYDROXIDE	-2.66
DICLOFENAC SODIUM	4.5 (Measured).
ISOPROPYL ALCOHOL	0.26
PROPYLENE GLYCOL	-1.35

Bioconcentration factor (BCF)

DICLOFENAC SODIUM	3 - 5 , OECD 305, Measured Species: Rainbow trout (Juvenile Oncorhyncus mykiss)
PROPYLENE GLYCOL	< 1 Estimated

Mobility in soil No data available.

Mobility in general

Volatility

Henry's law

ISOPROPYL ALCOHOL	0.000008 atm m^3/mol Measured, 25 °C
PROPYLENE GLYCOL	0 atm m^3/mol Estimated

Distribution

Octanol/water distribution coefficient log DOW

DICLOFENAC SODIUM	1.1, pH 7.4

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 Dispose of this material and its container to hazardous or special waste collection point. Incinerate the material under controlled conditions in an approved incinerator. Do not incinerate sealed containers. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. If discarded, this product is considered a RCRA ignitable waste, D001. 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. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as a dangerous good.

Read safety instructions, SDS and emergency procedures before handling.

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 applicable.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

AMMONIUM HYDROXIDE (CAS 1336-21-6) Listed.
ISOPROPYL ALCOHOL (CAS 67-63-0) Listed.

SARA 304 Emergency release notification

Ammonia; Ammonia (anhydrous) (CAS 1336-21-6) 100 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
AMMONIUM HYDROXIDE	1336-21-6	100	500		

SARA 311/312 Hazardous chemical Yes

Classified hazard categories
Skin corrosion or irritation
Serious eye damage or eye irritation
Respiratory or skin sensitization
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
ISOPROPYL ALCOHOL	67-63-0	20 - < 30

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)

AMMONIUM HYDROXIDE (CAS 1336-21-6)

Safe Drinking Water Act (SDWA) Not regulated.

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

ISOPROPYL ALCOHOL (CAS 67-63-0) Low priority

US state regulations

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

AMMONIUM HYDROXIDE (CAS 1336-21-6)
ISOPROPYL ALCOHOL (CAS 67-63-0)
MINERAL OIL U.S.P. (CAS 8042-47-5)

California Proposition 65

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. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
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)	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

Country(s) or region	Inventory name	On inventory (yes/no)*
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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 03-28-2023

Version # 01

HMIS® ratings Health: 3*
Flammability: 0
Physical hazard: 0

NFPA ratings Health: 3
Flammability: 0
Instability: 0

Disclaimer Haleon cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.