SAFETY DATA SHEET

1. Identification

Product identifier **DOLOFLEX TOPICAL GEL**

Other means of identification

Synonyms MFC 51131 * DICLOFENAC GEL (CONTAINING ISOPROPYL ALCOHOL) * DICLOFENAC SODIUM, FORMULATED PRODUCT

Recommended use 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

Manufacturer

GlaxoSmithKline Canada
Canadian Head Office
7333 Mississauga Road
Mississauga, Ontario L5N 6L4
Canada
General Information Phone Number (normal business hours): 905-819-3000
Consumer Healthcare Product Inquiries (toll free): 1-800-250-8866
Pharmaceutical, Stiefel, and Vaccine Inquiries (toll free): 1-800-387-7374

CHEMTREC TRANSPORTATION EMERGENCY NUMBERS
Customer Number: CCN9484
(available 24hrs/7days: multi-language response)
International Toll Call +(1) 703 527 3887
Email Address: msds@gsk.com
Website: www.gsk.com

Supplier Not available.

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

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 UN 1219 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 C3H8O OHS12090 RTECS NT8050000 IPA GR 95896X 206W94 85 (GW ACN)	67-63-0	25
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	20 - 25

Chemical name	Common name and synonyms	CAS number	%
DICLOFENAC SODIUM	BENZENEACETIC ACID, 2-((2,6-DICHLOROPHENYL)AMINO)-, MONOSODIUM SALT 2-((2,6-DICHLOROPHENYL)AMINO) BENZENEACETIC ACID MONOSODIUM SALT 2-((2,6-DICHLOROPHENYL)AMINO) BENZENE ACETIC ACID MONOSODIUM SALT (O-(2,6-DICHLOROANILINO)PHENYL) ACETIC ACID SODIUM SALT (ORTHO-(2,6-DICHLOROANILINO) PHENYL)ACETIC ACID SODIUM SALT (O-((2,6-DICHLOROANILINO)PHENYL)) ACETIC ACID SODIUM SALT (ORTHO-((2,6-DICHLOROANILINO) PHENYL))ACETIC ACID SODIUM SALT (O-(2,6-DICHLOROANILINO)PHENYL) ACETIC ACID MONOSODIUM SALT (ORTHO-(2,6-DICHLOROANILINO) PHENYL)ACETIC ACID MONOSODIUM SALT 2-(2,6-DICHLOROANILINO) PHENYLACETIC ACID SODIUM SALT SODIUM (2-((2,6-DICHLOROPHENYL) AMINO)PHENYL)ACETATE SODIUM 2-(2,6-DICHLOROANILINO)-PHENYL-ACETATE (O(-2,6-DICHLOROANILINO)PHENYL) ACETIC ACID SODIUM SALT SODIUM (O-((2,6-DICHLOROPHENYL) AMINO)PHENYL)ACETATE SODIUM (ORTHO-((2,6-DICHLOROPHENYL)AMINO)PHENYL) ACETATE SODIUM (2-(2,6-DICHLOROANILINO) PHENYL)ACETATE ACETIC ACID, (O-(2,6-DICHLOROANILINO) PHENYL)-, MONOSODIUM SALT ACETIC ACID, (ORTHO-(2,6-DICHLOROANILINO)PHENYL)-, MONOSODIUM SALT N-(2,6-DICHLOROPHENYL)-O-AMINOPHENYLACETIC ACID SODIUM SAL T N-(2,6-DICHLOROPHENYL)-ORTHO-AMINOPHENYLACETIC ACID SODIUM SAL T SODIUM (O-(2,6-DICHLOROANILINO) PHENYL)ACETATE SODIUM (ORTHO-(2,6-DICHLOROANILINO)PHENYL)ACETATE DICLOFENAC SODIUM SALT DICLOPHENAC SODIUM DICHRONIC FELORAN GP 45840 GP-45840 HYANALGESE D INFLABAN ORTHOFEN ORTHOPHEN SODIUM DICLOFENAC VOLTAROL C14H10Cl2NNaO2	15307-79-6	1

Chemical name	Common name and synonyms	CAS number	%
Diethylamine	DIETHAMINE N-ETHYL-ETHANAMINE N,N-DIETHYLAMINE DEN D-46 UN 1154 STCC 4907815 OHS07250 RTECS HZ8750000 DEA 830 (GW ACN)	109-89-7	< 1
MENTHOL	HEXAHYDROTHYMOL MENTHACAMPHOR MENTHOMENTHOL PEPPERMINT CAMPHOR NATURAL MENTHOL	89-78-1	< 0.1
Other components below reportable levels			< 50

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. #: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

4. First-aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed Behavioural changes. Decrease in motor functions. Oedema. Narcosis. May cause drowsiness and dizziness. Headache. Nausea, vomiting. Jaundice. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Irritation of nose and throat. May cause respiratory irritation. Skin irritation. May cause redness and pain.

Indication of immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

General information In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media Water.

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 Flammable liquid and vapour.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Use appropriate containment to avoid environmental contamination. Transfer by mechanical means such as vacuum truck to a salvage tank or other suitable container for recovery or safe disposal. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

Methods and materials for containment and cleaning up

Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Keep combustibles (wood, paper, oil etc) away from spilled material. Take precautionary measures against static discharge. Use only non-sparking tools. Prevent entry into waterways, sewer, basements or confined areas.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water.

Small Spills: Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. 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. Use appropriate containment to avoid environmental contamination.

7. Handling and storage

Precautions for safe handling

Keep away from sources of ignition - No smoking. Avoid contact with eyes. Wash hands thoroughly after handling. Wear personal protective equipment. Avoid prolonged exposure. Observe good industrial hygiene practices. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Keep away from heat, sparks and open flame. Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Form
DICLOFENAC SODIUM (CAS 15307-79-6)	OHC	2	PROVISIONAL
MENTHOL (CAS 89-78-1)	8 HR TWA	1000 mcg/m3	

US. ACGIH Threshold Limit Values

Components	Type	Value
Diethylamine (CAS 109-89-7)	STEL	15 ppm
	TWA	5 ppm
Isopropyl alcohol (CAS 67-63-0)	STEL	400 ppm
	TWA	200 ppm

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value
Diethylamine (CAS 109-89-7)	STEL	45 mg/m3
		15 ppm
	TWA	15 mg/m3
		5 ppm
Isopropyl alcohol (CAS 67-63-0)	STEL	984 mg/m3
		400 ppm
	TWA	492 mg/m3
		200 ppm

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value
Diethylamine (CAS 109-89-7)	STEL	15 ppm
	TWA	5 ppm
Isopropyl alcohol (CAS 67-63-0)	STEL	400 ppm
	TWA	200 ppm

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value
Diethylamine (CAS 109-89-7)	STEL	15 ppm
	TWA	5 ppm
Isopropyl alcohol (CAS 67-63-0)	STEL	400 ppm
	TWA	200 ppm

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value	Form
Diethylamine (CAS 109-89-7)	STEL	15 ppm	
	TWA	5 ppm	
Isopropyl alcohol (CAS 67-63-0)	STEL	400 ppm	
	TWA	200 ppm	
Propylene glycol (CAS 57-55-6)	TWA	155 mg/m3	Vapor and aerosol, inhalable fraction.
		10 mg/m3	Aerosol
		50 ppm	Vapor and aerosol, inhalable fraction.

Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Diethylamine (CAS 109-89-7)	STEL	45 mg/m3
		15 ppm
	TWA	15 mg/m3
		5 ppm
Isopropyl alcohol (CAS 67-63-0)	STEL	1230 mg/m3
		500 ppm
	TWA	983 mg/m3
		400 ppm

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.

Exposure guidelines

Canada - Alberta OELs: Skin designation

Diethylamine (CAS 109-89-7) Can be absorbed through the skin.

Canada - British Columbia OELs: Skin designation

Diethylamine (CAS 109-89-7) Can be absorbed through the skin.

Canada - Manitoba OELs: Skin designation

Diethylamine (CAS 109-89-7) Can be absorbed through the skin.

Canada - Ontario OELs: Skin designation

Diethylamine (CAS 109-89-7) Can be absorbed through the skin.

Canada - Quebec OELs: Skin designation

Diethylamine (CAS 109-89-7)	Can be absorbed through the skin.

Canada - Saskatchewan OELs: Skin designation

Diethylamine (CAS 109-89-7)	Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Diethylamine (CAS 109-89-7)	Can be absorbed through the skin.

Appropriate engineering controls General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Gel.

Colour Not available.

Odour Not available.

Odour threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range > 82 °C (> 179.6 °F) (Estimation based on components).

Flash point 25 °C (77 °F) Closed cup (Estimation based on components).

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.

Vapour pressure Not available.

Vapour 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.

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 heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
Incompatible materials	Strong oxidising agents. Isocyanates Chlorine.
Hazardous decomposition products	None known. 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	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Causes serious eye irritation.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms related to the physical, chemical and toxicological characteristics	Behavioural changes. Decrease in motor functions. Oedema. Narcosis. May cause drowsiness and dizziness. Headache. Nausea, vomiting. Jaundice. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Irritation of nose and throat. May cause respiratory irritation. Skin irritation. May cause redness and pain.

Information on toxicological effects

Acute toxicity Narcotic effects.

Components	Species	Test results
DICLOFENAC SODIUM (CAS 15307-79-6)		
Acute		
Oral		
LD50	Dog	500 mg/kg
	Monkey	3200 mg/kg
	Rat	55 - 240 mg/kg
		62.5 mg/kg
		55 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

Components	Species	Test results
Subchronic		
Inhalation		
LOEL	Mouse	1500 ppm
	Rat	1500 ppm
NOEL	Mouse	500 ppm, 13 weeks
	Rat	500 ppm, 13 weeks
MENTHOL (CAS 89-78-1)		
Acute		
Oral		
LD50	Rat	3200 mg/kg

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

Skin corrosion/irritation Due to partial or complete lack of data the classification is not possible.

Irritation Corrosion - Skin

MENTHOL	0, Literature data Result: Irritating to skin Species: Rabbit Notes: IUCLID data
Isopropyl alcohol	Acute dermal irritation; OECD 404 Result: Non-irritant Notes: UN SIDS evaluation: 2-Propanol

Serious eye damage/eye irritation Causes serious eye irritation.

Eye

MENTHOL	0, Literature data Result: MIld-moderate Species: Rabbit
Isopropyl alcohol	OECD 405 Result: Mild irritant Species: Rabbit Notes: UN SIDS evaluation: 2-Propanol

Respiratory or skin sensitisation

Canada - Alberta OELs: Irritant

Diethylamine (CAS 109-89-7)	Irritant

Respiratory sensitisation No studies have been conducted.

Skin sensitisation None known. This product is not expected to cause skin sensitisation.

Sensitisation

MENTHOL	Buehler assay, Literature data Result: negative Species: Guinea pig Notes: IUCLID data Epidemiology, Literature data Result: Low incidence of contact hypersensitivity. Notes: IUCLID data Modified Draize, Literature data Result: Positive Species: Guinea pig Notes: IUCLID data Open repetitive dermal test, Literature data Result: negative Species: Guinea pig Notes: IUCLID data

Germ cell mutagenicity Due to partial or complete lack of data the classification is not possible.

Mutagenicity

MENTHOL	725 mg/kg In vivo-In vitro Replicative DNA synthesis Result: Positive Species: Rat

Mutagenicity

MENTHOL	Alkaline Elution Assay In Vitro, Literature data Result: negative Notes: IUCLID data
DICLOFENAC SODIUM	Ames Result: negative
Isopropyl alcohol	Ames Result: negative
MENTHOL	Ames, Literature dataLiterature data Result: negative Notes: IUCLID data BlueScreen mammalian cell mutation assay, Literature data Result: negative Notes: IUCLID data
DICLOFENAC SODIUM	Chromosomal Aberration Assay In Vitro Result: negative
MENTHOL	Chromosomal Aberration Assay In Vitro, CHO cells, Literature data Result: negative Notes: IUCLID data Chromosomal Aberration Assay In Vitro, human lymphocytes, Literature data Result: negative Notes: IUCLID data
DICLOFENAC SODIUM	Dominant lethal assay Result: negative Species: Mouse GreenScreen mammalian cell mutation assay Result: negative
MENTHOL	GreenScreen mammalian cell mutation assay, Literature dat a Result: negative Notes: IUCLID data
DICLOFENAC SODIUM	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
MENTHOL	L5178Y mouse lymphoma thymidine kinase locus assay, Literature data Result: negative Notes: IUCLID data Micronucleus Test, Literature data Result: negative Species: Mouse Notes: IUCLID data Mutation in Drosophila melanogaster, Literature data Result: negative Notes: IUCLID data
Isopropyl alcohol	SA7 - Sister Chromatid Exchange Result: negative Sister Chromatid Exchange, V79 cells Result: negative
DICLOFENAC SODIUM	chromosome aberration - male germinal epithelium Result: negative Species: Mouse
Isopropyl alcohol	mammalian cell mutation assay (CHO/HGPRT forward mutation assay) Result: negative
MENTHOL	sister chromatid exchange, Literature data Result: negative Notes: IUCLID data

Carcinogenicity Carcinogenic effects are not expected as a result of occupational exposure. Not classifiable as to carcinogenicity to humans.

Carcinogenicity

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
MENTHOL	<= 1000 mg/kg/day, Literature data, dietary study. Result: negative Species: Rat Test Duration: 103 weeks Notes: IUCLID data <= 2143 mg/kg/day, Literature data, dietary study. Result: negative Species: Mouse Notes: IUCLID data
DICLOFENAC SODIUM	Result: negative Species: Mouse Result: negative Species: Rat

ACGIH Carcinogens

Diethylamine (CAS 109-89-7)	A4 Not classifiable as a human carcinogen.
Isopropyl alcohol (CAS 67-63-0)	A4 Not classifiable as a human carcinogen.

Canada - Manitoba OELs: carcinogenicity

2-Propanol (CAS 67-63-0)	Not classifiable as a human carcinogen.
Diethylamine (CAS 109-89-7)	Not classifiable as a human carcinogen.

Reproductive toxicity Due to partial or complete lack of data the classification is not possible.

Reproductivity

DICLOFENAC SODIUM	10 mg/kg/day Teratogenicity Result: NOAEL Species: Rabbit 10 mg/kg/day Teratogenicity Result: NOAEL Species: Rat
MENTHOL	185 mg/kg/day Embryo-foetal development, Literature data Result: NOAEL-Highest dose. Species: Mouse Notes: IUCLID data 218 mg/kg/day Embryo-foetal development - Oral, Literature data Result: NOAEL-Highest dose. Species: Rat Notes: IUCLID data 405 mg/kg/day Embryo-foetal development - Oral, Literature data Result: NOAEL-Highest dose. Species: Hamster Notes: IUCLID data 475 mg/kg/day Embryo-foetal development - Oral, Literature data Result: NOAEL-Highest dose. Species: Rabbit Notes: IUCLID data
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

Reproductivity

Isopropyl alcohol	< 480 mg/kg/day Epidemiology Result: Foetal NOAEL Species: Human < 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: Reduced survival, reduced birth rate, reduced growth rate Species: Rat >= 2 mg/kg/day Embryofetal Development Result: maternal toxicity; reduced foetal weight; foetal resorptions 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 Embryofetal Development Species: Rabbit

Specific target organ toxicity - single exposure

May cause drowsiness and dizziness.

Isopropyl alcohol	Result: Narcosis Organ: Central nervous system.

Specific target organ toxicity - repeated exposure

May cause damage to organs (Cardiovascular system, Gastrointestinal tract) through prolonged or repeated exposure.

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

Aspiration hazard

Not likely, due to the form of the product.

Chronic effects

Prolonged exposure may cause chronic effects.

Further information

Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

DICLOFENAC SODIUM	Clinical experience, Anaphylactoid response Species: Human

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
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)	0.32 mg/l, 95 days

Components		Species	Test results
		Zebra fish (Adult Brachydanio rerio)	0.32 mg/l, 34 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 - 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

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

Persistence and degradability

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

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

DICLOFENAC SODIUM	4.5 (Measured).
Diethylamine	0.58
Isopropyl alcohol	0.26
MENTHOL	3.4
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
MENTHOL	0.000015 atm m^3/mol, 25 C Estimated
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 Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable 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). Avoid discharge into water courses or onto the ground.

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

IATA

UN number UN1993

UN proper shipping name Flammable liquid, n.o.s. (ISOPROPYL ALCOHOL)

Transport hazard class(es)

Class 3

Subsidiary risk -

Label(s) 3

Packing group III

Environmental hazards No.

ERG Code 3L

Special precautions for user Not available.

Other information

Passenger and cargo aircraft Allowed with restrictions.

Cargo aircraft only Allowed with restrictions.

IMDG

UN number UN1993

UN proper shipping name FLAMMABLE LIQUID, N.O.S. (ISOPROPYL ALCOHOL)

Transport hazard class(es)

Class 3

Subsidiary risk -

Label(s) 3

Packing group	III
Environmental hazards	
Marine pollutant	No.
EmS	F-E, S-E
Special precautions for user	Not available.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

IATA; IMDG

General information

Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

15. Regulatory information

Canadian regulations

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

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)	No

Country(s) or region	Inventory name	On inventory (yes/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)	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 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

Issue date 01-September-2016

Revision date 01-September-2016

Version No. 03

References

ACGIH
EPA: AQUIRE database
NLM: Hazardous Substances Data Base
US. IARC Monographs on Occupational Exposures to Chemical Agents
HSDB® - Hazardous Substances Data Bank
IARC Monographs. Overall Evaluation of Carcinogenicity
National Toxicology Program (NTP) Report on Carcinogens
ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices
Japan Society for Occupational Health, Recommendation of Occupational Exposure Limits
GOST 30333-2007 - Chemical production safety passport. General requirements
JIS Z 7252:2009 Classification of chemicals based on ”Globally Harmonized System of Classification and Labelling of Chemicals (GHS)”
JIS Z 7253:2012 Hazard communication of chemicals based on GHS – Labelling and Safety Data Sheet (SDS)
Japan Chemical Industry Association (JCIA) GHS Guideline, June 2012
GSK Hazard Determination

Disclaimer

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Revision information

Product and Company Identification: Business Units
Composition / Information on Ingredients: Undisclosed Ingredient Statement
Physical & Chemical Properties: Multiple Properties
Transport Information: Material Transportation Information
Regulatory Information: United States
GHS: Classification