



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: DICLOFENAC SODIUM GEL, 3%

SDS NO. : SDSGHS.049.00

EFFECTIVE DATE :14/06/2016

PAGE No. : 1 of 19

Section 1. Identification

1.1 Substance Name: Diclofenac Sodium Gel, 3%

1.2 Chemical Name: Not Known

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

Prescription medicine, indicated for the management of actinic keratosis.

1.4 Company Identification: Glenmark Pharmaceuticals Inc., USA
750 Corporate Drive

Mahwah, NJ 07430

1.6 Emergency Contact details: (201) 684-8000

Section 2. Hazard Identification

2.1 Classification of the substance or mixture

Classification according to Regulation GHS

Chemwatch Hazard Ratings

		MinMax
Flammability	0	
Toxicity	2	■
Body Contact	0	
Reactivity	0	
Chronic	2	■

0 = Minimum

1 = Low

2 = Moderate

3 = High

4 = Extreme

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Classification

Acute Toxicity (Oral) Category 4, Skin Sensitizer Category 1
*Limited Evidence



2.2 Label elements:

Signal Word

WARNING

2.3 Risk Phrase:

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.

2.4 Safety Advice:

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P261	Avoid breathing mist/vapours/spray.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P363	Wash contaminated clothing before reuse.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P501	Dispose of contents/container in accordance with local regulations.

2.5 Other hazards: Not Known



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Section 3- Composition/Information on Ingredients

3.1 Substances

Components	CAS	% w/w
Diclofenac sodium	15307-79-6	3 %
ingredients determined not to be hazardous [Mfr]	-	Proprietary

Section 4. First aid Measures

4.1 Inhalation:

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.
- Transport to hospital, or doctor.

4.2 Skin: If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

4.3 Eyes: If this product comes in contact with the eyes:

- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Seek medical attention without delay; if pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

4.4 Ingestion:

- For advice, contact a Poisons Information Centre or a doctor.
- If swallowed do NOT induce vomiting.



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- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

4.5 Most important symptoms and effects, both acute and delayed

Treat symptomatically.

- for non-steroidal anti-inflammatories (NSAIDs)
- Symptoms following acute NSAIDs overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression, and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.
- Patients should be managed by symptomatic and supportive care following a NSAIDs overdose.
- There are no specific antidotes.
- Emesis and/or activated charcoal (60 to 100 grams in adults, 1 to 2 g/kg in children), and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose).
- Forced diuresis, alkalinisation of urine, hemodialysis, or haemoperfusion may not be useful due to high protein binding.

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Section 5. Fire-fighting Measures

5.1 General Information:

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves in the event of a fire.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use fire fighting procedures suitable for surrounding area.

5.2 Extinguishing Media:

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

5.3 Fire/Explosion Hazard:

- Non combustible.
- Not considered a significant fire risk, however containers may burn.

Decomposes on heating and produces toxic fumes of: carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x), chlorides

5.4 Fire Incompatibility:



5.5 NFPA Rating:

Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)



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Section 6. Accidental Release Measures

6.1 General Information: Personal Protective Equipment advice is contained in Section 8 of the SDS.

6.2 Minor Spills: Slippery when spilt.

- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Wear impervious gloves and safety goggles.
- Trowel up/scrape up.

6.3 Major Spills: Slippery when spilt.

Minor hazard.

- Clear area of personnel.
- Alert Fire Brigade and tell them location and nature of hazard.
- Control personal contact with the substance, by using protective equipment as required.

Section 7. Handling and Storage

7.1 Handling:

- Limit all unnecessary personal contact.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- When handling DO NOT eat, drink or smoke.

7.2 Storage:

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- DO NOT allow to freeze.
- Keep cool. Store below 25 °C.

7.3 Suitable Container: Aluminium tube.



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7.4 Storage incompatibility: Not Known

Section 8. Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits (OEL):

Ingredient Data

Not Available

Emergency Limits

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
Benzyl Alcohol	Benzyl alcohol	30 ppm	49 ppm	49 ppm

Ingredient	Original IDLH	Revised IDLH
Diclofenac sodium	Not Available	Not Available
Benzyl alcohol	Not Available	Not Available
ingredients determined not to be hazardous	Not Available	Not Available

Material Data

None assigned. Refer to individual constituents.

8.2 Exposure controls:

Appropriate engineering controls	General exhaust is adequate under normal operating conditions.
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Personal protection



Eye and face protection

No special equipment for minor exposure i.e. when handling small quantities.

Otherwise:

- Safety glasses with side shields.
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task.

Skin protection

See Hand protection below

Hands/feet

No special equipment needed when handling small quantities.



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protection	Otherwise: Wear chemical protective gloves, e.g. PVC.
Body protection	See Other protection below
Other protection	No special equipment needed when handling small quantities. Otherwise: <ul style="list-style-type: none">• Overalls.• Barrier cream.• Eyewash unit.
Thermal hazards	Not Available

Recommended material(s)

Glove Selection Index

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the *computer-generated* selection:

SOLARAZE diclofenac sodium 3% gel

Material	CPI
BUTYL	C
VITON	C

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

Note: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.



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Respiratory protection

Type A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required.

Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	A-AUS	-	A-PAPR-AUS / Class 1
up to 50 x ES	-	A-AUS / Class 1	-
up to 100 x ES	-	A-2	A-PAPR-2 ^

^ - Full-face

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

Section 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	:	Gel
Appearance	:	Clear, colourless to light orange gel. Slight characteristic odour of benzyl alcohol.
Colour	:	colourless to light orange gel
pH Value	:	6-8



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Vapor Pressure	:	Not Known
Vapor Density	:	Not Known
Evaporation Rate	:	Not Known
Other information		
Flash point	:	Not Known
Molecular Weight	:	Not Known
Melting point/range	:	Not Known
Boiling point/boiling range	:	Not Known
Density	:	Not Known
Viscosity	:	Not Known
Water solubility	:	Not Known
Solubility in other solvents	:	Not Known
Minimum ignition energy (MIE)	:	Not Known
Minimum ignition temperature (MIT)	:	Not Known
Layer ignition temperature (LIT)	:	Not Known
Flammability/explosivity	:	Not Known
Reactivity/exotherms	:	Not Known
Electrostatic nature	:	Not Known
Highly dusty material	:	Not Known
Any other properties which cause handling or processing difficulties	:	Not Known



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Average PSD (particle size distribution
(micron)

: Not Known

9.2 Other Information: Not Known

Section 10. Stability and Reactivity

10.1 Reactivity: Product is considered stable

10.2 Chemical stability: Product is considered stable

10.3 Conditions to Avoid: Keep away from food stuff

10.4 Incompatibilities with Other Materials: Keep away from food stuff

10.5 Hazardous Decomposition Products: Decomposes on heating and produces toxic fumes of: carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x), chlorides

10.6 Hazardous Polymerization: Will not occur

Section 11. Toxicological Information

11.1 Information on toxicological effects

Inhaled

The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models). Nevertheless inhalation, of the material, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.

Ingestion

Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
Non-steroidal anti-inflammatory drugs (NSAID) can cause serious



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	Not Available	Not Available
Diclofenac Sodium	Toxicity	Irritation
	Oral (rat) LD50: 53 mg/kgd ^[2]	Nil reported
Benzyl Alcohol	Toxicity	Irritation
	dermal (rat) LD50: 1000000 ppm/90M ^[2]	Eye (rabbit): 0.75 mg open SEVERE
	Inhalation (rat) LC50: >4.178 mg/L/4h ^[2]	Skin (man): 16 mg/48h-mild
	Oral (rat) LD50: 1560 mg/kg ^[2]	Skin (rabbit): 10 mg/24h open-mild
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	
Diclofenac Sodium	Altered sleep time, human anorexia, ataxia, respiratory stimulation, proteinuria, dermatitis after systemic exposure, effects on fertility, foetotoxicity, specific developmental abnormalities (cardiovascular system), effects on newborn recorded.	
Benzyl Alcohol	<p>The following information refers to contact allergens as a group and may not be specific to this product.</p> <p>Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions.</p> <p>For benzyl alkyl alcohols:</p> <p>Unlike benzylic alcohols, the beta-hydroxyl group of the members of this cluster is unlikely to undergo phase II metabolic activation. Instead, the beta-hydroxyl group is expected to contribute to detoxification via oxidation to hydrophilic acid. Despite structural similarity to carcinogenic ethyl benzene, only a marginal concern has been assigned to phenethyl alcohol due to limited mechanistic analogy.</p> <p>For benzoates:</p> <p>Acute toxicity: Benzyl alcohol, benzoic acid and its sodium and potassium salt can be considered as a single category regarding human health, as they</p>	



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are all rapidly metabolized and excreted via a common pathway within 24 hrs. Systemic toxic effects of similar nature (e.g. liver, kidney) were observed. However with benzoic acid and its salts toxic effects are seen at higher doses than with benzyl alcohol.

The compounds exhibit low acute toxicity as for the oral and dermal route. Adverse reactions to fragrances in perfumes and in fragranced cosmetic products include allergic contact dermatitis, irritant contact dermatitis, photosensitivity, immediate contact reactions (contact urticaria), and pigmented contact dermatitis. Airborne and connubial contact dermatitis occur.

Intolerance to perfumes, by inhalation, may occur if the perfume contains a sensitizing principal. Symptoms may vary from general illness, coughing, phlegm, wheezing, chest-tightness, headache, exertional dyspnoea, acute respiratory illness, hayfever, and other respiratory diseases (including asthma).

Fragrance allergens act as haptens, i.e. low molecular weight chemicals that are immunogenic only when attached to a carrier protein. However, not all sensitizing fragrance chemicals are directly reactive, but require previous activation. A prehapten is a chemical that itself is non- or low-sensitizing, but that is transformed into a hapten outside the skin by simple chemical transformation (air oxidation, photoactivation) and without the requirement of specific enzymatic systems. A prohapten is a chemical that itself is non- or low-sensitizing but that is transformed into a hapten in the skin (bioactivation) usually via enzyme catalysis.

The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterized by skin redness (erythema) and swelling the epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.



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Section 12. Ecological Information

12.1 Toxicity:

Ingredient	Endpoint	Test Duration (hr)	Species	Value	Source
Diclofenac sodium	LC50	96	Fish	214mg/L	2
Diclofenac sodium	EC50	48	Crustacea	68mg/L	2
Diclofenac sodium	EC50	72	Algae or other aquatic plants	72mg/L	2
Diclofenac sodium	EC50	168	Algae or other aquatic plants	7.5mg/L	2
Benzyl alcohol	EC03	168	Algae or other aquatic plants	=16mg/L	4
Benzyl alcohol	LC50	96	Fish	10mg/L	4
Benzyl alcohol	NOEC	336	Fish	5.1mg/L	2
Benzyl alcohol	EC50	48	Crustacea	230mg/L	2
Benzyl alcohol	EC50	72	Algae or other aquatic plants	500mg/L	2

Legend:

Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability:

Ingredient	Persistence: Water/Soil	Persistence: Air
Benzyl Alcohol	LOW	LOW

12.3 Bioaccumulative Potential:

Ingredient	Bioaccumulation



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Benzyl Alcohol | LOW (LogKOW = 1.1)

12.4 Mobility in soil:

Ingredient	Mobility
Benzyl Alcohol	LOW (KOC = 15.66)

12.5 Other: Not Known

Section 13. Disposal Considerations

13.1 Waste treatment methods

Product / Packaging disposal:

Recycle wherever possible or consult manufacturer for recycling options.

Consult State Land Waste Management Authority for disposal.

Bury residue in an authorized landfill.

Recycle containers if possible, or dispose of in an authorized landfill.

Section 14. Transport Information

14. 1 Special precautions for user:

Labels Required

Marine Pollutant | NO

Land transport (DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable



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Section 15. Regulatory Information

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

Diclofenac Sodium(15307-79-6) is found on the following regulatory lists

- Not Applicable

Benzyl Alcohol(100-51-6) is found on the following regulatory lists

- US AIHA Workplace Environmental Exposure Levels (WEELs)
- US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SECTION 311/312 HAZARD CATEGORIES

Immediate (acute) health hazard	Yes
Delayed (chronic) health hazard	No
Fire hazard	No
Pressure hazard	No
Reactivity hazard	No

US. EPA CERCLA HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES (40 CFR 302.4)

None Reported

State Regulations

US. CALIFORNIA PROPOSITION 65

None Reported

National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (Benzyl Alcohol; Diclofenac Sodium)
China - IECSC	N (Diclofenac Sodium)
Europe - EINEC / ELINCS / NLP	Y



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Japan - ENCS	Y
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	N (Diclofenac Sodium)
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

Section 16. Additional Information

Disclaimer:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Compiled By (R & D)	Approved by (EHS Head)
Signature /Date	Signature /Date



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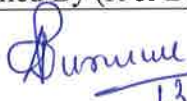
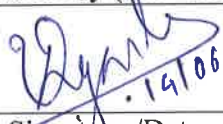
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Japan - ENCS	Y
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	N (Diclofenac Sodium)
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Compiled By (R & D)	Approved by (EHS Head)
 13/06/16	 14/06/2016
Signature /Date	Signature /Date