

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

SECTION 1. IDENTIFICATION

Product name : Diclofenac Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral) : Category 4
Reproductive toxicity : Category 2
Specific target organ toxicity : Category 1 (Gastrointestinal tract, Blood, lymphatic system,
- repeated exposure Liver, Prostate)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.
H361d Suspected of damaging the unborn child.
H372 Causes damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version 1.8 Revision Date: 09/30/2023 SDS Number: 4780246-00009 Date of last issue: 04/04/2023
Date of first issue: 08/23/2019

Response:

P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.

P308 + P313 IF exposed or concerned: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Polyethylene glycol	25322-68-3	≥ 50 - < 70
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	≥ 5 - < 10
Benzyl alcohol	100-51-6	≥ 1 - < 5

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
Suspected of damaging the unborn child.
Causes damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection,

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

Notes to physician : and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Chlorine compounds
Nitrogen oxides (NO_x)
Sodium oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version 1.8 Revision Date: 09/30/2023 SDS Number: 4780246-00009 Date of last issue: 04/04/2023
Date of first issue: 08/23/2019

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapors.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Polyethylene glycol	25322-68-3	TWA (aerosol)	10 mg/m ³	US WEEL
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	TWA	100 µg/m ³ (OEB 2)	Internal
Further information: Skin				
Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL

- Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

Personal protective equipment

- | | | |
|--|---|---|
| Respiratory protection | : | General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection. |
| Hand protection
Material | : | Chemical-resistant gloves |
| Eye protection | : | Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Skin and body protection
Hygiene measures | : | Work uniform or laboratory coat.
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|---|---|--------------------|
| Appearance | : | liquid |
| Color | : | yellow |
| Odor | : | characteristic |
| Odor Threshold | : | No data available |
| pH | : | No data available |
| Melting point/freezing point | : | -65 °F / -54 °C |
| Initial boiling point and boiling range | : | 209.3 °F / 98.5 °C |
| Flash point | : | No data available |
| Evaporation rate | : | No data available |

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	1.09 - 1.15
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	soluble
Solubility in other solvents	:	soluble Solvent: Ethanol
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition	:	No hazardous decomposition products are known.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,952 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 200 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Polyethylene glycol:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Acute oral toxicity : LD50 (Rat): 55 - 240 mg/kg
LD50 (Mouse): 170 - 389 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 97 - 161 mg/kg
Application Route: Intravenous
LD50 (Mouse): 92 - 147 mg/kg
Application Route: Intravenous

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

Skin corrosion/irritation

Not classified based on available information.

Components:

Polyethylene glycol:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Result	:	irritating
--------	---	------------

Benzyl alcohol:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Polyethylene glycol:

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405
Remarks	:	Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Result	:	Mild eye irritation
--------	---	---------------------

Benzyl alcohol:

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days
Method	:	OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Polyethylene glycol:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials

Benzyl alcohol:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Polyethylene glycol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration
Species: CHO
Result: negative

Benzyl alcohol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Method : OECD Test Guideline 451
Result : negative

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Effects on fertility : Test Type: Fertility
Species: Rat, male and female
Application Route: Oral
Fertility: NOAEL: 4 mg/kg body weight
Result: No effects on fertility.

Effects on fetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Embryo-fetal toxicity., No teratogenic effects.

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 5 mg/kg body weight
Result: Embryo-fetal toxicity., No teratogenic effects.

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development
Species: Mouse
Application Route: Ingestion
Result: negative

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

Components:

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Target Organs : Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Species : Rat
LOAEL : 0.25 mg/kg
Application Route : Oral
Exposure time : 98 w
Target Organs : Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

Species : Dog
LOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 12 w
Target Organs : Blood

Species : Baboon
NOAEL : 0.5 mg/kg
LOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 52 w
Target Organs : Gastrointestinal tract, Blood
Symptoms : constipation, Diarrhea

Benzyl alcohol:

Species : Rat
NOAEL : 1.072 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 28 Days

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

Method : OECD Test Guideline 412

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Ingestion : Symptoms: Abdominal pain, Diarrhea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Polyethylene glycol:

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 80.1 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 71.9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 49.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.32 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Persistence and degradability

Components:

Polyethylene glycol:

Biodegradability : Result: rapidly degradable
Remarks: Based on data from similar materials

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Bioaccumulative potential

Components:

Polyethylene glycol:

Partition coefficient: n-octanol/water : log Pow: < 3

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Partition coefficient: n-octanol/water : log Pow: 4.51

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

Mobility in soil

No data available

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards	:	Acute toxicity (any route of exposure) Reproductive toxicity Specific target organ toxicity (single or repeated exposure)
-----------------------------	---	---

SARA 313	:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
-----------------	---	---

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

US State Regulations

Pennsylvania Right To Know

Polyethylene glycol	25322-68-3
Water	7732-18-5
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6
Benzyl alcohol	100-51-6

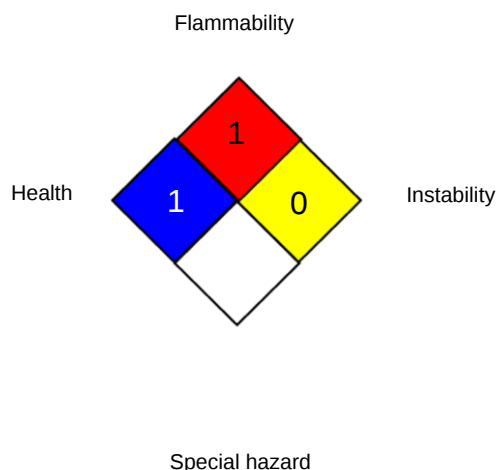
The ingredients of this product are reported in the following inventories:

AICS	: not determined
DSL	: not determined
IECSC	: not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

US WEEL	: USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA	: 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	4780246-00009	Date of first issue: 08/23/2019

tem; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 09/30/2023

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

US / Z8