SAFETY DATA SHEET

Diclofenac Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Diclofenac Formulation

Manufacturer or supplier's details

Company : MSD
Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Acute toxicity (Oral) : Category 4
Skin corrosion/irritation : Category 3
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)
Long-term (chronic) aquatic hazard : Category 3

GHS label elements
Hazard pictograms :  
Signal word : Warning
Hazard statements : H302 Harmful if swallowed.
H316 Causes mild skin irritation.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Gastrointestinal tract,
Precautionary statements:

**Prevention:**
- P203 Obtain, read and follow all safety instructions before use.
- P260 Do not breathe mist or vapours.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- P318 IF exposed or concerned, get medical advice.
- P332 + P317 If skin irritation occurs: Get medical help.

**Storage:**
- P405 Store locked up.

**Disposal:**
- P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification:
None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

### 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. Causes mild skin irritation. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

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

Hazardous combustion products: Carbon oxides
Chlorine compounds
Nitrogen oxides (NOx)
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 firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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 spills cannot be contained.

Methods and materials for: Soak up with inert absorbent material.
containment and cleaning up

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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 certain local or national requirements.

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 vapours.
- 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 labelled 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2-[(2,6-dichloro-phenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>TWA</td>
<td>100 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

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.
Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Combined particulates and organic vapour type

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: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

   Appearance: liquid
   Colour: yellow
   Odour: characteristic
   Odour Threshold: No data available
   pH: No data available
   Melting point/freezing point: -54 °C
   Initial boiling point and boiling range: 98.5 °C
   Flash point: No data available
   Evaporation rate: No data available
   Flammability (solid, gas): Not applicable
   Flammability (liquids): No data available
   Upper explosion limit / Upper flammability limit: No data available
   Lower explosion limit / Lower: No data available
SAFETY DATA SHEET

Diclofenac Formulation

Version 1.3
Revision Date: 09.04.2021
SDS Number: 4780240-00004
Date of last issue: 10.10.2020
Date of first issue: 23.08.2019

flammability limit
Vapour pressure : No data available
Relative vapour 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
Auto-ignition 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

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 products : No hazardous decomposition products are known.

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: > 10 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist
   Method: Calculation method

Components:
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

Skin corrosion/irritation
Causes mild skin irritation.

Components:
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:
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Result: Mild eye irritation

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

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Benzyl alcohol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
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
- **Species:** Mouse
- **Exposure time:** 2 Years
- **Result:** negative

### Benzyl alcohol
- **Species:** Mouse
- **Application Route:** Ingestion
- **Exposure time:** 103 weeks
- **Method:** OECD Test Guideline 451
- **Result:** negative

### 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 foetal development**
  - **Test Type:** Development
  - **Species:** Rat
  - **Application Route:** Oral
  - **Developmental Toxicity:** LOAEL: 1 mg/kg body weight
  - **Result:** Embryo-foetal toxicity, No teratogenic effects

  - **Test Type:** Development
  - **Species:** Rabbit
  - **Application Route:** Oral
  - **Developmental Toxicity:** LOAEL: 5 mg/kg body weight
  - **Result:** Embryo-foetal 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
  - **Application Route:** Ingestion
  - **Result:** negative
  - **Remarks:** Based on data from similar materials

- **Effects on foetal development**
  - **Test Type:** Embryo-foetal development
  - **Species:** Mouse
  - **Application Route:** Ingestion
  - **Result:** negative
STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause 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, Diarrhoea

Benzy1 alcohol:
Species: Rat
NOAEL: 1.072 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
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, Diarrhoea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**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: 0.32 mg/l
  - Exposure time: 32 d
  - Species: Pimephales promelas (fathead minnow)
  - Method: OECD Test Guideline 210

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

**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: 51 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

13. DISPOSAL CONSIDERATIONS

Disposal methods  
Waste from residues: Dispose of in accordance with local regulations.  
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.

14. TRANSPORT INFORMATION

International Regulations
SAFETY DATA SHEET

Diclofenac Formulation

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 IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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 System; GLP - Good Laboratory Practice; 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; ICSO - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECS - 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; KECl - 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect
Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

IN / EN