



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 1.9
 30.09.2023
 4780247-00010
 Date of first issue: 23.08.2019

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Diclofenac Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

20 Spartan Road

1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person

responsible for the SDS

EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4 H302: Harmful if swallowed.

Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child. Specific target organ toxicity - repeated H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.

Long-term (chronic) aquatic hazard, Cat- H412: Harmful to aquatic life with long lasting ef-

fects.

2.2 Label elements

egory 3

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

!

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

H361d Suspected of damaging the unborn child.



Diclofenac Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 1.9
 30.09.2023
 4780247-00010
 Date of first issue: 23.08.2019

H373 May cause damage to organs through prolonged or

repeated exposure.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.

P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON

CENTER/ doctor if you feel unwell. Rinse mouth.

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Hazardous components which must be listed on the label:

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

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6 239-346-4	Acute Tox. 3; H301 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 (Gastrointestinal tract, Blood, lym- phatic system, Liv- er, Prostate) Aquatic Chronic 2; H411	>= 3 - < 10
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319	>= 1 - < 10

For explanation of abbreviations see section 16.





 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 1.9
 30.09.2023
 4780247-00010
 Date of first issue: 23.08.2019

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

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).

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, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Harmful if swallowed.

Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

: None known.





 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 1.9
 30.09.2023
 4780247-00010
 Date of first issue: 23.08.2019

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

Carbon oxides

Chlorine compounds Nitrogen oxides (NOx)

Sodium oxides

5.3 Advice for firefighters

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.

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 absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.





 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 1.9
 30.09.2023
 4780247-00010
 Date of first issue: 23.08.2019

6.4 Reference to other sections See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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 as-

sessment

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

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 contami-

nated 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Store locked up. Store in

accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sodium [2-[(2,6-	15307-79-6	TWA	100 μg/m3 (OEB 2)	Internal



Diclofenac Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.9 30.09.2023 4780247-00010 Date of first issue: 23.08.2019

dichloro- phe- nyl)amino]phenyl]a			
cetate			
	Further inform	ation: Skin	

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic effects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5,4 mg/m3
	Consumers	Inhalation	Acute systemic effects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	20 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0,1 mg/l
	Intermittent use/release	2,3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5,27 mg/kg
	Marine sediment	0,527 mg/kg
	Soil	0,456 mg/kg

8.2 Exposure controls

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

Eye/face 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



Diclofenac Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.9 30.09.2023 4780247-00010 Date of first issue: 23.08.2019

potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Filter type

Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

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

No data available



Diclofenac Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 1.9
 30.09.2023
 4780247-00010
 Date of first issue: 23.08.2019

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.

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of : Inhalation exposure Skin contact

Ingestion Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1.952 mg/kg



Diclofenac Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.9 30.09.2023 4780247-00010 Date of first issue: 23.08.2019

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 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

Not classified based on available information.

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



Diclofenac Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 1.9
 30.09.2023
 4780247-00010
 Date of first issue: 23.08.2019

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

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



Diclofenac Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.9 30.09.2023 4780247-00010 Date of first issue: 23.08.2019

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

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 develop-

ment

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 - As-

sessment

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 develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative



Diclofenac Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.9 30.09.2023 4780247-00010 Date of first issue: 23.08.2019

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs 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

Benzyl 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, heart-



Diclofenac Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 4780247-00010 Date of first issue: 23.08.2019 1.9

burn, Ulceration, Dizziness, Headache, Breathing difficulties,

Rash

SECTION 12: Ecological information

12.1 Toxicity

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

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 tox-

icity)

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 (Chron-

NOEC: 10 mg/l Exposure time: 21 d

ic toxicity)

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

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h



Diclofenac Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 1.9
 30.09.2023
 4780247-00010
 Date of first issue: 23.08.2019

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 51 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

12.2 Persistence and degradability

Components:

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 - 96 % Exposure time: 14 d

12.3 Bioaccumulative potential

Components:

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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting poten-

tial

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes



Diclofenac Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.9 30.09.2023 4780247-00010 Date of first issue: 23.08.2019

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable



Diclofenac Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 1.9
 30.09.2023
 4780247-00010
 Date of first issue: 23.08.2019

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

Full text of H-Statements

H301 : Toxic if swallowed. H302 : Harmful if swallowed. H315 : Causes skin irritation.

H319 : Causes serious eye irritation.

H332 : Harmful if inhaled.

H361d : Suspected of damaging the unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure.

H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity

Skin Irrit. : Skin irritation

STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonized System; GLP - Good La-



Diclofenac Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.9 30.09.2023 4780247-00010 Date of first issue: 23.08.2019

boratory 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; 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; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

Further information

Sources of key data used to compile the Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Classification of the mixture:

Classification procedure:

Acute Tox. 4	H302	Calculation method
Repr. 2	H361d	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Chronic 3	H412	Calculation method

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.

ZA / EN