

## Inj 50 MG/ML



Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations Revision Date: 02/09/2022 Date of Issue: 03/09/2022

Version: 1.0

#### **SECTION 1: IDENTIFICATION**

# 1.1. Product Identifier Product Form: Mixture

Product Name: Carprodyl® (carprofen) Inj 50 MG/ML

#### 1.2. Intended Use of the Product

Use of the Substance/Mixture: Pharmaceuticals

#### 1.3. Name, Address, and Telephone of the Responsible Party

#### Company

# = 00# k k 0

#### 1.4. Emergency Telephone Number

**Emergency Number** : 1-800-424-9300

Call CHEMTREC Day or Night

## **SECTION 2: HAZARDS IDENTIFICATION**

#### 2.1. Classification of the Substance or Mixture

Acute Tox. 4 (Oral) H302 STOT RE 2 H373 Aquatic Acute 3 H402 Aquatic Chronic 3 H412

Full text of hazard classes and H-statements: see section 16

#### 2.2. Label Elements

**GHS-US Labeling** 

Hazard Pictograms (GHS-US)





Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : H302 - Harmful if swallowed.

H373 - May cause damage to organs (liver, digestive system) through prolonged or

repeated exposure (Oral). H402 - Harmful to aquatic life.

H412 - Harmful to aquatic life with long lasting effects.

**Precautionary Statements (GHS-US)**: P260 - Do not breathe vapors, mist, or spray.

P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.

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

P273 - Avoid release to the environment.

P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.

P314 - Get medical advice/attention if you feel unwell.

P330 - Rinse mouth.

P501 - Dispose of contents/container in accordance with local, regional, national,

and international regulations.

## 2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

#### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

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## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

Name	Synonyms	Product Identifier	GHS US classification
N-(3a,7a,12a Tri- hydroxycholan-24-oyl) glycine	Glycocholic acid / Glycine, N- [(3.alpha.,5.beta.,7.alpha.,12.alpha.)- 3,7,12-trihydroxy-24-oxocholan-24-yl]- / glycocholic acid	(CAS-No.) 475-31-0	Aquatic Acute 2, H401 Aquatic Chronic 2, H411
Carprofen	9H-Carbazole-2-acetic acid, 6-chloro- .alphamethyl-, (.+)- / 9H-Carbazole-2- acetic acid, 6-chloroalphamethyl- / 9H-Carbazole-2-acetic acid, 6-chloro- .alphamethyl-, (+-)- / carprofen	(CAS-No.) 53716-49-7	Acute Tox. 3 (Oral), H301 STOT RE 2, H373
Benzyl alcohol	BENZYL ALCOHOL / .alpha Hydroxytoluene / Phenylmethyl alcohol / Phenylmethanol / Methanol, phenyl- / Benzylalcohol / Benzenemethanol / Benzenecarbinol	(CAS-No.) 100-51-6	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:dust,mist), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401
Hydrochloric acid	Hydrogen chloride / Muriatic acid / HYDROCHLORIC ACID / Hydrochloric acid, anhydrous / hydrochloric acid	(CAS-No.) 7647-01-0	Press. Gas (Comp.), H280 Acute Tox. 3 (Inhalation:gas), H331 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Sodium hydroxide	Caustic soda / Sodium hydroxide (Na(OH)) / SODIUM HYDROXIDE / LYE	(CAS-No.) 1310-73-2	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 3, H402

Full text of H-phrases: see section 16

#### **SECTION 4: FIRST AID MEASURES**

#### 4.1. Description of First-aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

**First-aid Measures After Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Eye Contact:** Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

## 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms/Injuries:** May cause damage to organs (liver, digestive system) through prolonged or repeated exposure (Oral). Harmful if swallowed.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: May cause damage to organs (liver, digestive system) through prolonged or repeated exposure (Oral).

## 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

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## **SECTION 5: FIRE-FIGHTING MEASURES**

#### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Water spray, fog, carbon dioxide (CO<sub>2</sub>), alcohol-resistant foam, or dry chemical. **Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

#### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Not considered flammable but may burn at high temperatures.

**Explosion Hazard:** Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

#### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire. **Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Nitrogen oxides, Carbon oxides (CO, CO<sub>2</sub>), Smoke.

Other Information: Do not allow run-off from fire fighting to enter drains or water courses.

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

## 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Avoid breathing (vapor, mist, spray).

#### 6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

## 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

#### 6.2. Environmental Precautions

Avoid unnecessary release into environment.

## 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. **Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material, then place in suitable container. Contact competent authorities after a large spill.

## 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## **SECTION 7: HANDLING AND STORAGE**

## 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents.

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing vapors, mist, spray. Handle empty containers with care because they may still present a hazard. Do not get in eyes, on skin, or on clothing.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

#### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

**Incompatible Materials:** Strong acids, strong bases, strong oxidizers.

**Storage Temperature:** 2°-8°C (36°-46°F)

#### 7.3. Specific End Use(s)

**Pharmaceuticals** 

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

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Benzyl alcohol (100-51-6)			
USA AIHA	WEEL TWA [ppm]	10 ppm	
Sodium hydr	Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH OEL Ceiling	2 mg/m³	
USA NIOSH	NIOSH REL (Ceiling)	2 mg/m³	
USA IDLH	IDLH	10 mg/m³	
USA OSHA	OSHA PEL (TWA) [1]	2 mg/m³	
Hydrochloric	acid (7647-01-0)		
USA ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm	
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen	
USA NIOSH	NIOSH REL (Ceiling)	7 mg/m³	
USA NIOSH	NIOSH REL C [ppm]	5 ppm	
USA IDLH	IDLH [ppm]	50 ppm	
USA OSHA	OSHA PEL (Ceiling)	7 mg/m³	
USA OSHA	OSHA PEL C [ppm]	5 ppm	
Nitrogen (77)	Nitrogen (7727-37-9)		
USA ACGIH	ACGIH chemical category	Simple asphyxiant See Appendix F: Minimal Oxygen Content	
-			

#### 8.2. **Exposure Controls**

**Appropriate Engineering Controls** 

: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas.

Ensure all national/local regulations are observed. **Personal Protective Equipment** : Gloves. Protective clothing. Protective goggles.







**Materials for Protective Clothing** 

**Hand Protection** 

**Eye and Face Protection** 

**Respiratory Protection** 

Relative Vapor Density at 20°C

**Skin and Body Protection** 

: Chemically resistant materials and fabrics.

: Wear protective gloves.

: Chemical goggles or safety glasses. : Wear suitable protective clothing.

: If exposure limits are exceeded or irritation is experienced, approved respiratory

protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory

protection.

**Environmental Exposure Controls** : Avoid unnecessary release into the environment. **Consumer Exposure Controls** : Not required for normal conditions of use. **Other Information** : When using, do not eat, drink or smoke.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### **Information on Basic Physical and Chemical Properties**

**Physical State** : Liquid : Clear liquid **Appearance** Odor Not determined **Odor Threshold** : No data available

pН : 5.8 - 6.2**Evaporation Rate** : No data available **Melting Point** : No data available **Freezing Point** : No data available **Boiling Point** : No data available **Flash Point** : No data available **Auto-ignition Temperature** : No data available **Decomposition Temperature** : No data available Flammability (solid, gas) : Not applicable **Vapor Pressure** : No data available

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: No data available



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Relative Density : No data available

Specific Gravity : 1.04 @ 25 °C / 77 °F

Solubility : Fully miscible in water.

Partition Coefficient: N-Octanol/Water : No data available

Viscosity : No data available

**9.2.** Other Information No additional information available

## **SECTION 10: STABILITY AND REACTIVITY**

- **10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).
- **10.3.** Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
- **10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- **10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- **10.6.** Hazardous Decomposition Products: Thermal decomposition may produce: Nitrogen oxides, Carbon oxides (CO, CO<sub>2</sub>), Smoke.

## **SECTION 11: TOXICOLOGICAL INFORMATION**

#### 11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Harmful if swallowed.

**Acute Toxicity (Dermal):** Not classified (Based on available data, the classification criteria are not met) **Acute Toxicity (Inhalation):** Not classified (Based on available data, the classification criteria are not met)

CARPROFEN INJ 50 MG/ML	
ATE (Oral)	1,389.69 mg/kg body weight
Carprofen (53716-49-7)	
LD50 Oral Rat	74 mg/kg
Benzyl alcohol (100-51-6)	
LD50 Oral Rat	1230 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 4.178 mg/l/4h
ATE (Dust/Mist)	1.50 mg/l/4h

Skin Corrosion/Irritation: Not classified (Based on available data, the classification criteria are not met)

**pH:** 5.8 - 6.2

Serious Eye Damage/Irritation: Not classified. (Based on available data, the classification criteria are not met)

**pH:** 5.8 – 6.2

Respiratory or Skin Sensitization: Not classified (Based on fragrance supplier data, the classification criteria are not met.)

Germ Cell Mutagenicity: Not classified (Based on available data, the classification criteria are not met)

Carcinogenicity: Not classified (Based on available data, the classification criteria are not met)

Reproductive Toxicity: Not classified (Based on available data, the classification criteria are not met)

Specific Target Organ Toxicity (Single Exposure): Not classified (Based on available data, the classification criteria are not met)

Specific Target Organ Toxicity (Repeated Exposure): May cause damage to organs through prolonged or repeated exposure.

CARPROFEN INJ 50 MG/ML		
Additional information	May cause damage to organs (liver, digestive system) through prolonged or repeated exposure	
	(Oral).	

Aspiration Hazard: Not classified (Based on available data, the classification criteria are not met)

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: May cause damage to organs (liver, digestive system) through prolonged or repeated exposure (Oral).

## **SECTION 12: ECOLOGICAL INFORMATION**

#### 12.1. Toxicity

**Ecology - General** : Harmful to aquatic life with long lasting effects.

Benzyl alcohol (100-51-6)	
LC50 Fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])

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EC50 - Crustacea [1] 23 mg/l (Exposure time: 48 h - Species: water flea)	
LC50 Fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
ErC50 (Algae)	770 mg/l

## 12.2. Persistence and Degradability

CARPROFEN INJ 50 MG/ML	
Persistence and Degradability	May cause long-term adverse effects in the environment.

#### 12.3. Bioaccumulative Potential

CARPROFEN INJ 50 MG/ML	
Bioaccumulative Potential	Not established.
Benzyl alcohol (100-51-6)	
Partition coefficient n-octanol/water (Log	1.1
Pow)	

#### 12.4. Mobility in Soil

CARPROFEN INJ 50 MG/ML	
Ecology - Soil	Leaches if exposed to water.

#### 12.5. Other Adverse Effects

Other Adverse Effects : None known.

Other Information : Avoid release to the environment.

#### **SECTION 13: DISPOSAL CONSIDERATIONS**

#### 13.1. Waste Treatment Methods

Waste Treatment Methods: Incineration is the preferred method for disposal of waste product.

Sewage Disposal Recommendations: Do not dispose of waste into sewer.

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

**Ecology - Waste Materials:** Avoid release to the environment. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

## **SECTION 14: TRANSPORT INFORMATION**

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

**14.1.** In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

## **SECTION 15: REGULATORY INFORMATION**

#### 15.1. US Federal Regulations

CARPROFEN INJ 50 MG/ML	
SARA Section 311/312 Hazard Classes	Health hazard - Specific target organ toxicity (single or repeated exposure)  Health hazard - Acute toxicity (any route of exposure)
Benzyl alcohol (100-51-6)	
Listed on the United States TSCA (Toxic Substance	ces Control Act) inventory

#### 15.2. US State Regulations

Benzyl alcohol (100-51-6)
U.S Pennsylvania - RTK (Right to Know) List
U.S Massachusetts - Right To Know List

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 04/27/2021

Other Information: This document has been prepared in accordance with the SDSrequirements of the OSHA Hazard Communication Standard 29 CFR

1910.1200

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## **GHS Full Text Phrases:**

Full Text Phrases:	
Acute Tox. 3 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 4	Flammable liquids Category 4
Met. Corr. 1	Corrosive to metals Category 1
Press. Gas (Comp.)	Gases under pressure Compressed gas
Simple Asphy	Simple Asphyxiant
Skin Corr. 1A	Skin corrosion/irritation Category 1A
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H227	Combustible liquid
H280	Contains gas under pressure; may explode if heated
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
H332	Harmful if inhaled
H335	May cause respiratory irritation
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H411	Toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)

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