

SAFETY DATA SHEET



Revision date: 20-Mar-2015

Version: 2.5

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Ketofen

Trade Name: Ketofen
Synonyms: Ketoprofen
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as non-steroidal, anti-inflammatory drug (nsaid)
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Clear liquid

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 4
Skin Corrosion/Irritation: Category 2
Serious Eye Damage/Eye Irritation: Category 2A
Specific target organ systemic toxicity (repeated exposure): Category 1

EU Classification:

EU Indication of danger: Harmful
Toxic

EU Symbol: T
EU Risk Phrases:

R22 - Harmful if swallowed.
R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed.

Label Elements

Signal Word: Danger

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2. HAZARDS IDENTIFICATION

- Hazard Statements:** H372 - Causes damage to organs through prolonged or repeated exposure if swallowed (gastrointestinal system , kidneys)
H302 - Harmful if swallowed
H319 - Causes serious eye irritation
H315 - Causes skin irritation
- Precautionary Statements:** P280 - Wear protective gloves/protective clothing/eye protection/face protection
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P314 - Get medical attention/advice if you feel unwell
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

- Short Term:** Causes eye irritation . Signs and symptoms might include redness, swelling, blurred vision or pain. Causes skin irritation. Signs and symptoms might include skin rash, itching, redness or swelling.
- Long Term:** May cause effects on fertility and reproductive system ; may have the potential to produce effects on the developing fetus.
- Known Clinical Effects:** Adverse effects most commonly reported in clinical use include serious gastrointestinal toxicity such as bleeding, ulceration, and perforation and kidney toxicity. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Ketoprofen	22071-15-4	Not Listed	T;R25 Xi;R36/38 T;R48/25	Acute Tox. 3 (H301) Eye Irrit. 2A (H319) Skin Irrit. 2 (H315) STOT RE 1 (H372)	10
Arginine	74-79-3	200-811-1	Not Listed	Not Listed	7
Benzyl Alcohol	100-51-6	202-859-9	Xn; R20/22	Acute Tox.4 (H302) Acute Tox.4 (H332)	0.25

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	Not Listed	82.8

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not flammable.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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Additional Information: This product is a nonflammable aqueous solution.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

When handling, use appropriate personal protective equipment (see Section 8). Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Avoid accidental injection. Wash thoroughly after handling. Releases to the environment should be avoided.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store out of direct sunlight in a well ventilated area at room temperature. Protect from direct heat and sunlight. Do not freeze.

Incompatible Materials: Acids , Bases , Metals , Oxidising agents

Specific end use(s): Veterinary anti-inflammatory

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Ketoprofen

Zoetis OEL TWA 8-hr 75 µg/m³

Arginine

Latvia OEL - TWA 10 mg/m³

Benzyl Alcohol

Bulgaria OEL - TWA 5.0 mg/m³

Czech Republic OEL - TWA 40 mg/m³

Finland OEL - TWA 10 ppm

45 mg/m³

Latvia OEL - TWA 5 mg/m³

Lithuania OEL - TWA 5 mg/m³

Poland OEL - TWA 240 mg/m³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Safety glasses or goggles
Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Clear
Odor:	Slight	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	Soluble
pH:	No data available.
Melting/Freezing Point (°C):	0 (H ₂ O)
Boiling Point (°C):	100 (H ₂ O)
Partition Coefficient: (Method, pH, Endpoint, Value)	No data available
Decomposition Temperature (°C):	No data available.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	1 (H ₂ O)
Viscosity:	No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	Acids , Bases , Metals , Oxidising agents
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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11. TOXICOLOGICAL INFORMATION

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.
Routes of exposure: eye contact , skin contact

Acute Toxicity: (Species, Route, End Point, Dose)

Ketoprofen

Rat Oral LD50 62.4 mg/kg

Benzyl Alcohol

Rat Oral LD50 1230 mg/kg
Rat Para-periosteal LD50 53mg/kg
Rat Inhalation LC50 >4.178mg/L

Ingestion Acute Toxicity Harmful if swallowed.

Irritation / Sensitization: (Study Type, Species, Severity)

Ketoprofen

Eye Irritation Irritant
Skin Irritation Irritant

Benzyl Alcohol

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Minimal
Skin Irritation Guinea Pig Moderate

Irritation / Sensitization Comments: May cause eye irritation.

Skin Irritation / Sensitization May cause skin irritation.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Ketoprofen

3 Month(s) Rat Oral 6 mg/kg/day LOAEL Gastrointestinal System, Kidney, Blood
3 Month(s) Dog Oral 3 mg/kg/day LOAEL Gastrointestinal system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Ketoprofen

Not specified Rat 6 mg/kg/day Reproductive toxicity,

Reproductive & Development Toxicity Comments: may have the potential to produce effects on the developing fetus.

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Ketoprofen

Bacterial Mutagenicity (Ames) *Salmonella* Negative with activation , without activation
Sister Chromatid Exchange Human Lymphocytes Negative

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11. TOXICOLOGICAL INFORMATION

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Ketoprofen

Not specified Mouse Oral up to 32 mg/kg/day Not carcinogenic
Not specified Rat Oral up to 12.5 mg/kg/day Deaths, No tumors

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Product Level Toxicity Data

Acute Toxicity Estimate (ATE), 625 mg/kg
oral

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Benzyl Alcohol

Pimephales promelas (Fathead Minnow) EPA LC50 96 Hours 460 mg/L
Daphnia magna (Water Flea) OECD EC50 48 Hours 230 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 500 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Benzyl Alcohol

Daphnia magna (Water Flea) OECD 21 Day(s) EC50 66 mg/L Reproduction

Persistence and Degradability:

Benzyl Alcohol

OECD Activated sludge Ready 92% After 14 Day(s) Ready

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



Ketoprofen

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Arginine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-811-1

Benzyl Alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
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15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation
Specific target organ toxicity, repeated exposure-Cat.1; H372 - Causes damage to organs through prolonged or repeated exposure if swallowed

Xn - Harmful
Xi - Irritant
T - Toxic

R25 - Toxic if swallowed.
R20/22 - Harmful by inhalation and if swallowed.
R36/38 - Irritating to eyes and skin.
R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed.

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet