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MATERIAL SAFETY DATA SHEET					Page 1 of 11
ENVIRONMENT, HEALTH & SAFETY				Copy No.	
	MSDS No.	FP/MSDS/002	05	Effective Date	08-08-16
	Issue date	05-08-16		Review date	07-08-19
	TITLE	KETOPROFEN			

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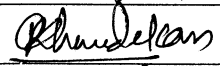


Maharashtra, India.

Tel : +91 22 28505152

Fax: +91 22 28503153

Email: post@becchemicals.com**1 Identification of the substance/mixture and of the company/undertaking**

- **1.1 Trade name: Ketoprofen**
- **CAS Number:** 22071-15-4
- **EC number:** 244-759-8
- **Registration number** Please provide pre-registration number.
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture**
 - * It is as used as a mild painkiller in smaller animals, generally following surgical procedures.
 - * It is most commonly used for musculoskeletal pain, joint problems, and soft tissue injury, as well as laminitis.
 - * It is also used to control fevers and prevent endotoxemia.
 - * Ketoprofen used as Anti-inflammatory; analgesic.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
BEC Chemicals Pvt. Ltd.
S-86, IBI House,
Chimatpada, Marolnaka,
Andheri-Kurla Road, Andheri-(E),
Mumbai-400059.
- **Further information obtainable from:**
Tel : +91 22 28505152
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WWW.becchemicals.com
Email: Post@becchemicals.com
- **1.4 Emergency telephone number:**
Emergency telephone number: 9890771676
Other Comments (e.g. language(s) of the phone service): English

SIGNATORIES				
	Name	Designation	Signatures	Date
Prepared by	G.D. Narvekar	Supervisor-EHS		04/08/16
Reviewed by	R.G. Khandekar	Asst. Manager-EHS		04/08/16
Approved by	P. B. Gitsa	GM-WREKS		04-08-16
Approved by	Rajon Kumar	Mgr-QA		04-08-16

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2. Hazard Information

Classification of the substance or mixture

- Classification according to Regulation (EC) No 1272/2008



Skull and crossbones

Acute Tox. 3 H301 Toxic if swallowed.

Acute Tox. 3 H311 Toxic in contact with skin.



Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

2.2 Label elements

- Labeling according to Regulation (EC) No 1272/2008

The substance is classified and labeled according to the CLP regulation.

- Hazard pictograms



GHS06

- Signal word Danger

- Hazard statements

H301+H311 Toxic if swallowed or in contact with skin.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

- Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- 2.3 Other hazards

- Results of PBT and vPvB assessment

- PBT: Not applicable.

- vPvB: Not applicable.

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3 Composition/information on ingredients

- **3.1 Chemical characterisation: Substances**
- **CAS No. Description**
22071-15-4 ketoprofen
- **Identification number(s)**
- **EC number:** 244-759-8
- **Additional information:**
Molecular Formula:- C16-H14-O3
Molecular Weight :- 254.28 g/mol
- **SVHC** The substance is not in the list of SVHC substances

4 First aid measures

- **4.1 Description of first aid measures**
- **General information:**
Consult a physician. Show this safety data sheet to the doctor in attendance
- **After inhalation:**
If breathed in, move person into fresh air. If not breathing give artificial respiration.
Seek immediate medical advice.
- **After skin contact:**
In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.
- **After eye contact:**
Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid.
- **After swallowing:**
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
- **4.2 Most important symptoms and effects, both acute and delayed**
Skin contact with chemical is toxic and causes skin irritation
Eye contact causes eye irritation
Toxic effects if swallowed
- **4.3 Indication of any immediate medical attention and special treatment needed**
Immediate medical attention is required.
Treat symptomatically

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5 Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
- **For safety reasons unsuitable extinguishing agents:**
Water jet:- this may increase fire intensity.
- **5.2 Special hazards arising from the substance or mixture**
Carbon dioxide (CO₂)
Carbon monoxide (CO)
- **5.3 Advice for firefighters**
- **Protective equipment:**
Wear self contained breathing apparatus for fire fighting if necessary.

6 Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment.
- **6.2 Environmental precautions:**
Prevent further leakage or spillage if safe to do so. Do not let product enter drains
- **6.3 Methods and material for containment and cleaning up:**
Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.
- **6.4 Reference to other sections**
Refer to section 8 and 13 for additional information on personal protection equipment and disposal methods.

7 Handling and storage

- **7.1 Precautions for safe handling**
Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.
- **Information about fire - and explosion protection:**
Normal measures for preventive fire protection.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store in a tightly closed container.
- **Information about storage in one common storage facility:**
Keep away from incompatibles such as oxidizing agents
- **Further information about storage conditions:**
Store in a tightly closed container.
- **7.3 Specific end use(s)**
 - *It is used as a mild painkiller in smaller animals, generally following surgical procedures.
 - *It is most commonly used for muscoskeletal pain, joint problems, and soft tissue injury, as well as laminitis.
 - *It is also used to control fevers and prevent endotoxemia.
 - *Ketoprofen used as Anti-inflammatory; analgesic.

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8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** Local exhaust ventilation required plus good work practice. Safety shower. Eye fountain.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Handle in accordance with good industrial hygiene and safety practice.
Contaminated clothing should be thoroughly cleaned.
Provide good ventilation and /or an exhaust system in the work area.
Immediately remove all soiled and contaminated cloth.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**



Tightly sealed goggles

Body protection: Protective work clothing

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9 Physical and chemical properties

<ul style="list-style-type: none"> General Information Appearance: <ul style="list-style-type: none"> Form: Solid (Crystalline powder) Colour: White to Off-white Odour: Odorless 	
<ul style="list-style-type: none"> Change in condition <ul style="list-style-type: none"> Melting point/Melting range: 94°C Boiling point/Boiling range: 431.3°C (at 760 mm Hg) 	
<ul style="list-style-type: none"> Flash point: 147°C 	
<ul style="list-style-type: none"> Danger of explosion: Product does not present an explosion hazard. 	
<ul style="list-style-type: none"> Vapour pressure at 25°C: 3.72E-07 mmHg 	
<ul style="list-style-type: none"> Density at 22°C: 1.198 g/cm³ 	
<ul style="list-style-type: none"> Solubility in / Miscibility with water at 25°C: 51 mg/l 	
<ul style="list-style-type: none"> Partition coefficient (n-octanol/water): 3.12 log POW 	
<ul style="list-style-type: none"> Viscosity: <ul style="list-style-type: none"> Dynamic: Not Applicable 9.2 Other information No further relevant information available. 	

10 Stability and reactivity

- 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided:
 - Keep away from excess heat
 - Protect from moisture.
 - Stable under recommended storage condition
- 10.3 Possibility of hazardous reactions React with oxidising agent.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: Incompatible with oxidizing materials.
- 10.6 Hazardous decomposition products:
 - Carbon monoxide
 - Carbon dioxide
- Additional information: Corrosivity: Non-corrosive in presence of glass.

11 Toxicological information

- 11.1 Information on toxicological effects
- Acute toxicity
 - Toxic if swallowed or in contact with skin.

LD/LC50 values relevant for classification:

Oral	LD50	62.4 mg/kg (rat)
Derm	0	550 mg/kg (mouse)

- Primary irritant effect:
- Skin corrosion/irritation
 - Causes skin irritation.
 - The test chemical causes erythema or other skin discoloration when tested in human

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- **Serious eye damage/irritation**
Causes serious eye irritation.
The test chemical causes swollen, pain and irritated eye when tested in human
- **Respiratory or skin sensitisation**
Skin sensitization: when tested in Hartley albino guinea pigs produced no sensitization reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
The substance is not carcinogenic, non-mutagenic and non-toxic for reproduction.
- **Germ cell mutagenicity**
Test System: AMES SALMONELLA TYPHIMURIUM
Strain/Indicator: TA97A
Metabolic Activation: RAT, LIVER, S-9, PHENOBARBITAL
Method: STANDARD PLATE
Dose Range: 1-5000 UG/PLATE (TEST MATERIAL SOLVENT: DMSO) Results: NEGATIVE
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**
In fertility studies, in rats, effects of ketoprofen on male and female reproduction functions were observed with a NOEL of 3 mg/kg/day
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological information

- **12.2 Persistence and degradability**
Biodegradation in water:
Half life=15 days(predicted)
Result: Readily biodegradable
- **12.3 Bioaccumulative potential**
Bioaccumulation factor:
BEF=3.2(predicted) Result: Non-bioaccumulative
- **12.4 Mobility in soil**
Soil Adsorption Coefficient=390 (Estimated)
result: The test chemical is moderately mobile in soil.
- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment** To be provided after the REACH registration.
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available

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13 Disposal Consideration

- **13.1 Waste treatment methods**
- **Recommendation**
Observe all federal, state, and local environmental regulations.
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **European waste catalogue**
07 05: Wastes from the manufacture, Supply, Formulation and Use (MFSU) of pharmaceuticals.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations

14 Transport Information

Land transport ADR/RID (cross-border)



- **ADR/RID class:** 6.1 Toxic substances.
- **Danger code (Kemler):** 60
- **UN-Number:** 2811
- **Packaging group:** III
- **Hazard label:** 6.1
- **Description of goods:** 2811 TOXIC SOLID, ORGANIC, N.O.S. (Ketoprofen)
- **Tunnel restriction code** D/E



...me transport IMDG:

- **IMDG Class:** 6.1
- **UN Number:** 2811
- **Label** 6.1
- **Packaging group:** III
- **EMS Number:** F-A, S-A
- **Marine pollutant:** No
- **Proper shipping name:** TOXIC SOLID, ORGANIC, N.O.S. (Ketoprofen)

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Transport ICAO-TI and IATA-DGR:

- ICAO/IATA Class: 6.1
- UN/ID Number: 2811

- Label 6.1
- Packaging group: III
- Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (Ketoprofen)

- UN "Model Regulation": UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, III

15 Regulatory Information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Labeling according to Regulation (EC) No 1272/2008
The substance is classified and labeled according to the CLP regulation.
- Hazard pictograms



GHS06

- Signal word Danger
- Hazard statements
 - H301+H311 Toxic if swallowed or in contact with skin.
 - H315 Causes skin irritation.
 - H319 Causes serious eye irritation.
- Precautionary statements
 - P280 Wear protective gloves/protective clothing/eye protection/face protection.
 - P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
 - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - P321 Specific treatment (see on this label).
 - P405 Store locked up.
 - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- National regulations:
- Other regulations, limitations and prohibitive regulations
 - Japan MITI - Listed
 - New Zealand (NZioC) - Listed
 - Australian Inventory of Chemical Substances (AICS) - Listed
 - Philippine Inventory of Chemicals and Chemical Substances (PICCS) - Listed
 - Canada-DSL-Listed
 - US-TSCA-Listed

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· **Substances of very high concern (SVHC) according to REACH, Article 57**

The substance is not listed as SVHC.

· **15.2 Chemical safety assessment:**

A Chemical Safety Assessment has not been carried out

16 Other Information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing MSDS:** Product safety department.

· **Contact:**

Tel : +91 22 28505152

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· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer

(Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association"

(IATA) ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and

Labeling of Chemicals EINECS: European Inventory of

Existing Commercial Chemical Substances CAS: Chemical

Abstracts Service (division of the American Chemical

Society) LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity, Hazard Category 3

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

· **Sources**

-REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

-Chemidplus <http://chem.sis.nlm.nih.gov/chemidplus/rn/22071-15-4>

-Committee for veterinary medical products-Summary report

http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_Report/2009/11/WC500014541.pdf

KETOPROFEN Veterinary-Systemic

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<http://c.ymcdn.com/sites/www.aavpt.org/resource/resmgr/imported/ketoprofen.pdf>

-RTECS document <http://www.drugfuture.com/toxic/q107-q948.html>

-PBT profiler

<http://www.pbtprofiler.net/Result.asp>

-Genetox database

<http://www.expub.com/Members/>

Documents/5JX4JMWXD0I3MWQN4W79BBGOF82M32.pdf

* Data compared to the previous version altered.

Section 1: Identification of substance/mixture and of the company/undertaking.

Section 2: Hazards identification

Section 3: Composition/Information on Ingredients

Section 4: First-aid measures.

Section 5: Fire-fighting measures

Section 6: Accidental Release measures

Section 7: Handling and storage.

Section 8: Exposure Controls/Personal protection.

Section 9: Physical and Chemical properties.

Section 10: Stability and Reactivity.

Section 11: Toxicological Information.

Section 12: Ecological Information.

Section 13: Disposal consideration

Section 14: Transport information

Section 15: Regulatory information

Section 16: Other information.

REVISION HISTORY: N.A.

Revision No.	Date Revised	CC No.	CC Approval Date	Reason for Revision
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01	04-10-14	CC/072/EHS/14-15	03-10-14	MSDS Reviewed
02	16-03-16	CC/104/QAD/15-16	23-12-15	Storage condition revised as per monograph for better clarity.
03	25-04-16	CC/012/QAD/16-17	23-04-16	MSDS revised as per EU directives.
04	09-07-16	CC/051/EHS/16-17	09-07-16	Transport information to be added.
05	04-08-16	CC/069/QAD/16-17	01-08-16	Storage Condition revised.

END OF DOCUMENT