MATERIAL SAFETY DATA SHEET

DICLOFENAC DIETHYLAMINE

1. IDENTIFICATION OF SUBSTANCE/PREPARATION AND THE COMPANY UNDERTAKING

Chemical Name:	Diclofenac diethylamine
Product Code:	FD16054
Synonyms:	-
Recommended uses:	For Pharmaceutical purposes
Supplier:	Metapharamceutical Industrial, SL c/ Josep Plà 193, 2º 5ª, 08020 Barcelona (SPAIN)
Emergency contact numbers:	Telephone: +34 933 089 976 email: info@metapharmaceutical.com

2. HAZARDS IDENTIFICATION

- **Classification of the substance or mixture**

Classification according to Regulation (EC) No 1272/2008

GHS06 skull and crossbones

Signal word: Warning

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
STOT SE 3 H335 May cause respiratory irritation

· **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
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.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT: Not applicable.**
· **vPvB: Not applicable.**

3. COMPOSITION/INFORMATION ON INGREDIENTS

Molecular Formula:	Molecular weight:	CAS Number:	EINECS Number:
$C_{14}H_{11}Cl_2NO_2 \cdot C_4H_{11}N$	369.28	78213-16-8	-

4. FIRST AID MEASURES

Eye contact:	Immediately flush eye with copious amounts of water for at least 15 minutes. Get medical aid immediately.
Skin contact:	Get medical aid. Immediately wash skin with soap and copious amounts of water for at least 15 minutes. Wash contaminated clothing before reuse.
Inhalation:	Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult give oxygen. Get medical aid.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water provided person is conscious. Call a physician.
Notes to Physician:	Treat symptomatically and supportively.

5. FIRE-FIGHTING MEASURES

Personal precautions:	As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.
Extinguishing media:	In case of fire use water spray, dry chemical, carbon dioxide, or alcohol-resistant foam.

Special hazards arising from the substance or mixture: Carbon oxides, nitrogen oxides (NOx), hydrogen chloride.

6. ACCIDENTAL RELEASE MEASURES

General Information:	Use proper personal protective equipment as indicated in Section 8.
Personal precautions:	Wear self-contained breathing apparatus, eye protection and gloves. Keep personal hygiene. Avoid contact with skin and eyes. Avoid dust formation. Avoid breathing dust, vapours, mist or gas. Ensure adequate ventilation. Keep unprotected personnel away.
Environmental precautions:	Do not let product enter the drains, other waterways or soil.
Spills/Leaks:	Sweep up and place the material in appropriate container for disposal and dispose of as hazardous waste. Ventilate area, clean up spills and wash spill site after material pickup is complete, observing precautions in the Protective Equipment section.

7. HANDLING AND STORAGE

Handling:	Wash hands thoroughly after handling. Remove contaminated clothing and wash before reuse. Use with adequate ventilation. Avoid contact with eyes, skin, and clothing. Keep container tightly closed. Avoid ingestion and inhalation. Provide appropriate exhaust ventilation at places where dust is formed. Do not eat, drink or smoke while handling.
Storage:	Store in a cool, dry, well-ventilated area. Keep container tightly closed. Store away from incompatible materials. Keep away from sources of ignition.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protection equipment:

Eye protection:	Wear appropriate protective safety glasses with side-shields conforming to EN166, chemical safety goggles or face-shield (min. 8-inch) as described by OSHA's eye and face protection regulations. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).
Skin protection:	Wear appropriate protective gloves to prevent skin exposure, as defined in EU Directive 89/686/EEC and the standard EN 374 derived from it.
Body protection:	Appropriate protective clothing, overalls.
Respiratory protection:	Where risk assessment indicates air-purifying respirators are required use a dust mask type N95 (US) or type P1 (EN 143) respirator. Respirators and components must tested and approved under appropriate government standards - NIOSH (US) or CEN (EU).
Hygiene measures:	Use good working practices. Wash hands and face thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White to yellowish solid.
Odour:	Data not available/does not apply.
Odour threshold:	Data not available/does not apply.
pH:	Data not available/does not apply.
Melting point:	150 – 156 °C.
Boiling point:	Data not available/does not apply.
Flash point:	Data not available/does not apply.
Evaporation rate:	Data not available/does not apply.
Flammability:	Data not available/does not apply.
Flammability or explosive limits:	Data not available/does not apply.
Vapor pressure:	Data not available/does not apply.
Vapor density:	Data not available/does not apply.
Density:	Data not available/does not apply.
Solubility:	Data not available/does not apply.
Partition coefficient: n-octanol/water	Data not available/does not apply.
Auto-ignition temperature:	Data not available/does not apply.
Decomposition temperature:	Data not available/does not apply.
Viscosity:	Data not available/does not apply.

10. STABILITY AND REACTIVITY

Chemical stability:	Stable under recommended storage conditions.
Conditions to avoid:	Heat, flames and sparks. Avoid dust formation.
Incompatibilities with other materials:	Oxidizing agents.

Hazardous decomposition products:	Carbon oxides, nitrogen oxides (NOx), hydrogen chloride.
Hazardous polymerization:	Data not available.

11. TOXICOLOGICAL INFORMATION

RTCS #:	Data not available.
Acute toxicity:	Data not available.
Skin corrosion/irritation:	Data not available.
Serious eye damage/eye irritation:	Data not available.
Respiratory or skin sensitization:	Data not available.
Germ cell mutagenicity:	Data not available.
Carcinogenicity:	No classification data on carcinogenic properties of this material is available from EPA, IARC, NTP, OSHA or ACGIH.
Reproductive toxicity:	Data not available.

Specific target organ toxicity - single exposure: Data not available.

Specific target organ toxicity - repeated exposure: Data not available.

Aspiration hazard:	Data not available.
Signs and symptoms of exposure:	To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Potential health effects:

Eye:	May cause eye irritation.
Skin:	May be harmful by skin absorption. May cause skin irritation.
Ingestion:	May be harmful if swallowed.
Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Chronic:	No information found.

12. ECOLOGICAL INFORMATION

Data not available.

13. DISPOSAL CONSIDERATIONS

Dispose of in a manner consistent with federal, state, and local regulations.

14. TRANSPORT INFORMATION

ADR/RID
Not classified as hazardous for transport.

IMDG
Not classified as hazardous for transport.

IATA
Not classified as hazardous for transport.

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

16. ADDITIONAL INFORMATION

Further information on PPE:
European Standard & performance category markings:

EN143 -	Particulates filter.
EN166 -	Standard applicable to all types of personal eye protectors.
EN374 -	Protects hands against chemicals and/or microorganisms.

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process unless specified in the text.