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

Product name : Tolperisone hydrochloride

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

According to Regulation (EC) No1272/2008
Acute toxicity, Inhalation (Category 4)
Acute toxicity, Dermal (Category 4)
Acute toxicity, Oral (Category 4)
Eye irritation (Category 2)

According to European Directive 67/548/EEC as amended.
Harmful by inhalation, in contact with skin and if swallowed. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Label elements

Pictogram

Signal word Warning

Hazard statement(s)
H302 Harmful if swallowed.
H312 Harmful in contact with skin.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.

Precautionary statement(s)
P280 Wear protective gloves/protective clothing.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Hazard symbol(s)
Xn Harmful

R-phrase(s)
R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S-phrase(s)
S36/37 Wear suitable protective clothing and gloves.
S61 Avoid release to the environment. Refer to special instructions/ Safety data sheets.

Other hazards - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms : 2-Methyl-1-(4-methylphenyl)-3-(1-piperidyl)propan-1-onehydrochloride

Formula : C16H23NO · HCl
Molecular Weight : 281.82 g/mol

CAS-No.	EC-No.		Classification	Concentration
2,4'-Dimethyl-3-piperidinopropiophenone hydrochloride				
3644-61-9	222-876-5	-	Acute Tox. 4; Eye Irrit. 2; H302, H312, H319, H332 Xn; R20/21/22 - R52/53	-

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled
If breathed in, move person into fresh air. If not breathing give artificial respiration Consult a physician.

In case of skin contact
Wash off with soap and plenty of water. Consult a physician.

In case of eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special protective equipment for fire-fighters
Wear self contained breathing apparatus for fire fighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions
Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.

Environmental precautions
Do not let product enter drains. Discharge into the environment must be avoided.

Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

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. Normal measures for preventive fire protection.

Conditions for safe storage
Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal protective equipment

Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 (US) or type P1 (EN 143) respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection
The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Handle with gloves.

Eye protection
Safety glasses with side-shields conforming to EN166

Skin and body protection
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	solid

Safety data

pH	no data available
Melting point	no data available
Boiling point	no data available
Flash point	no data available
Ignition temperature	no data available
Lower explosion limit	no data available
Upper explosion limit	no data available
Water solubility	no data available

10. STABILITY AND REACTIVITY

Chemical stability
Stable under recommended storage conditions.

Conditions to avoid
no data available

Materials to avoid
Strong oxidizing agents

Hazardous decomposition products
Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Hydrogen chloride gas

11. TOXICOLOGICAL INFORMATION

Acute toxicity
LD50 Oral - rat - 1.450 mg/kg

Skin corrosion/irritation
no data available

Serious eye damage/eye irritation
no data available

Respiratory or skin sensitization
no data available

Germ cell mutagenicity
no data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity
no data available

Specific target organ toxicity - single exposure
no data available

Specific target organ toxicity - repeated exposure
no data available

Aspiration hazard
no data available

Potential health effects

Inhalation	Harmful if inhaled. May cause respiratory tract irritation.
Ingestion	Harmful if swallowed.
Skin	Harmful if absorbed through skin. May cause skin irritation.
Eyes	May cause eye irritation.

Signs and Symptoms of Exposure
Nausea, Vomiting, Constipation, , Diarrhoea, Drowsiness, Dizziness, Rash, Headache

Additional Information
RTECS: UH1575500

12. ECOLOGICAL INFORMATION

Toxicity

no data available

Persistence and degradability
no data available

Bioaccumulative potential
no data available

Mobility in soil
no data available

PBT and vPvB assessment
no data available

Other adverse effects
Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
no data available

13. DISPOSAL CONSIDERATIONS

Product
Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.
Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

ADR/RID
Not dangerous goods

IMDG
Not dangerous goods

IATA
Not dangerous goods

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Text of H-code(s) and R-phrase(s) mentioned in Section 3

Acute Tox.	Acute toxicity
Eye Irrit.	Eye irritation
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
Xn	Harmful
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed.
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Further information