

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

Product name : Flecainide acetate salt

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

According to Regulation (EC) No1272/2008
Acute toxicity, Oral (Category 4)
Skin irritation (Category 2)
Eye irritation (Category 2)
Reproductive toxicity (Category 1B)
Specific target organ toxicity - single exposure (Category 3)

According to European Directive 67/548/EEC as amended.
Possible risk of harm to the unborn child. Harmful if swallowed. Irritating to eyes, respiratory system and skin.

Label elements

Pictogram 

Signal word Danger

Hazard statement(s)
H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H360 May damage fertility or the unborn child.

Precautionary statement(s)
P201 Obtain special instructions before use.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Hazard symbol(s)
Xn Harmful

R-phrases(s)
R63 Possible risk of harm to the unborn child.
R22 Harmful if swallowed.
R36/37/38 Irritating to eyes, respiratory system and skin.

S-phrases(s)
S46 If swallowed, seek medical advice immediately and show this container or label.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S22 Do not breathe dust.

Other hazards - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms : N-(2-Piperidylmethyl)-2,5-bis-(2,2,2-trifluoroethoxy)benzamideacetate salt

Formula : C17H20F6N2O3 · C2H4O2

CAS-No.	EC-No.		Classification	Concentration
Flecainide acetate salt 54143-56-5	258-997-5	-	Acute Tox. 4; Skin Irrit. 2; Eye 99,9 % Irrit. 2; Repr. 1B; STOT SE 3; H302, H315, H319, H335, H360 Xn, R63 - R22 - R36/37/38	
Acetic acid 64-19-7	200-580-7	-	Flam. Liq. 3; Skin Corr. 1A; H314, H226 C, R10 - R35	0,1 %

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 vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. 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.Avoid exposure - obtain special instructions before use.
Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

Conditions for safe storage

Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: 2 - 8 °C

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal protective equipment

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

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

Eye protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

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
Partition coefficient: log Pow: 2,805
n-octanol/water

10. STABILITY AND REACTIVITY

Chemical stability

Stable under recommended storage conditions.

Conditions to avoid

no data available

Materials to avoid

no data available

Hazardous decomposition products

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

11. TOXICOLOGICAL INFORMATION

Acute toxicity

LD50 Oral - mouse - 170 mg/kg

LD50 Oral - dog - 50 mg/kg

TDLo Intravenous - Human - male - 1,714 mg/kg

Remarks: Cardiac:Arrythmias (including changes it conduction).

LDLO Other - dog - 15 mg/kg

LD50 Intravenous - rat - 16,2 mg/kg

LD50 Subcutaneous - rat - 215 mg/kg

LD50 Intravenous - mouse - 23,8 mg/kg

LD50 Subcutaneous - mouse - 188 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

no data available

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

Presumed human reproductive toxicant

Specific target organ toxicity - single exposure

Inhalation - May cause respiratory irritation.

Specific target organ toxicity - repeated exposure

no data available

Aspiration hazard

no data available

Potential health effects

Inhalation May be harmful if inhaled. Causes respiratory tract irritation.
Ingestion Harmful if swallowed.
Skin May be harmful if absorbed through skin. Causes skin irritation.
Eyes Causes serious eye irritation.

Additional Information

RTECS: no data available

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

no data available

13. DISPOSAL CONSIDERATIONS

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. 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-phrases(s) mentioned in Section 3

Acute Tox.	Acute toxicity
Eye Irrit.	Eye irritation
Flam. Liq.	Flammable liquids
H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360	May damage fertility or the unborn child.
Repr.	Reproductive toxicity
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritation
STOT SE	Specific target organ toxicity - single exposure
C	Corrosive
R10	Flammable.
R22	Harmful if swallowed.
R35	Causes severe burns.
R36/37/38	Irritating to eyes, respiratory system and skin.
R63	Possible risk of harm to the unborn child.
Xn	Harmful

Further information

For R&D use only. Not for drug, household or other uses.



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WARRANTY:

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