

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

Product name : 13-*cis*-Retinoic acid

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

According to Regulation (EC) No1272/2008

Skin irritation (Category 2)

Eye irritation (Category 2)

Reproductive toxicity (Category 1B)

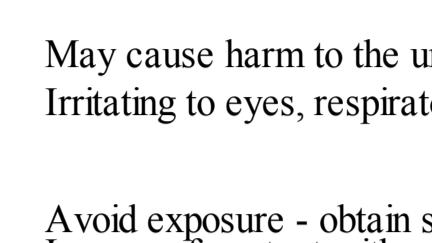
Specific target organ toxicity - single exposure (Category 3)

According to European Directive 67/548/EEC as amended.

May cause harm to the unborn child. Irritating to eyes, respiratory system and skin.

Label elements

Pictogram



Signal word Danger

Hazard statement(s)

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)

T Toxic

R-phrase(s)

R61 May cause harm to the unborn child.

R36/37/38 Irritating to eyes, respiratory system and skin.

S-phrase(s)

S53 A void exposure - obtain special instructions before use.

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.

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Restricted to professional users.

Other hazards - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms : Isotretinoin

Formula : C20H28O2

Molecular Weight : 300,44 g/mol

CAS-No.	EC-No.	Classification	Concentration
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Isotretinoin

4759-48-2 225-296-0 - Skin Irrit. 2; Eye Irrit. 2; Repr. 1B; STOT SE 3; H315, H319, H335, H360 T, R61 - R36/37/38

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. Evacuate personnel to safe areas.

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. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

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

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

Recommended storage temperature: -20 °C

Light sensitive.

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

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

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form solid

Safety data

pH no data available

Melting point 172 - 175 °C - lit.

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

11. TOXICOLOGICAL INFORMATION

Acute toxicity

LD50 Oral - rat > 4.000 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 a probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

May cause congenital malformation in the fetus.

Presumed human reproductive toxicant

Effects on Embryo / Fetus - Hamster - Oral

Abnormalities: Central nervous system, Specific developmental, Abnormalities: Craniofacial (including nose and tongue).

Specific target organ toxicity - single exposure

- 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 May be harmful if swallowed. Causes digestive tract irritation.

Skin May be harmful if absorbed through skin. Causes skin irritation.

Eyes Causes eye irritation.

Signs and Symptoms of Exposure

Dermatitis and allergic skin reactions may occur with repeated or prolonged use.

Eye irritation, redness, pain, lacrimation, blurred vision, eye irritation, conjunctival irritation.

Respiratory tract irritation, coughing, shortness of breath, respiratory distress, respiratory tract irritation.

Abnormalities: Central nervous system, Specific developmental, Abnormalities: Craniofacial (including nose and tongue).

Specific target organ toxicity - single exposure

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