1. IDENTIFICATION OF SUBSTANCE/PREPARATION AND THE COMPANY UNDERTAKING

Chemical Name: 13-cis-Retinoic acid
Product Code: FR27714
Synonyms: Isotretinoin, 13-cis-Vitamin A acid, 3,7-Dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2Z,4E,6E,8E-nonatetranenoic acid.

Recommended uses: For R&D purposes
Supplier: Carbosynth Ltd, 8&9 Old Station Business Park, Compton, Berkshire, RG20 6NE, UK.
Emergency contact numbers:
   Telephone: +44 (0)1635 578 444
   Fax: +44 (0)1635 579 444
   Mobile: +44 (0)7887 998 634

2. HAZARDS IDENTIFICATION

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

Classification:

Skin irritation (Category 2)
Eye irritation (Category 2A)
Reproductive toxicity (Category 1A)
Specific target organ toxicity - single exposure (Category 3)

Labelling and precautionary statements:
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.
   P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
   P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
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13-CIS-RETINOIC ACID

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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.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard symbol(s):
T Toxic.
Xi Irritant.

R-phrase(s):
R36/37/38 Irritating to eyes, respiratory system and skin.
R61 May cause harm to the unborn child.

S-phrase(s):
S22 Do not breathe dust.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S53 Avoid exposure – obtain special instructions before use.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Molecular Formula: \( \text{C}_{20}\text{H}_{28}\text{O}_{2} \)
Molecular weight: 300.44
CAS Number: 4759-48-2
EINECS Number: 225-296-0

Synonyms:
Isotretinoin,
13-cis-Vitamin A acid,
3,7-Dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2Z,4E,6E,8E-nonatetraenoic acid.

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: In case of contact remove contaminated clothing and immediately wash affected areas with copious quantities of water and soap for at least 15 minutes. Get medical aid immediately. 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 powder, carbon dioxide, or alcohol-resistant foam.

**Special hazards arising from the substance or mixture:**
Thermal decomposition can lead to release of irritating gases and vapours.

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. Evacuate personnel to safe areas.

**Environmental precautions:**
Do not let product enter the drains. Prevent further leakage or spillage if safe to do so.

**Spills/Leaks:**
Vacuum or sweep up and place the material in appropriate container for disposal without creating dust 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:**
Wear appropriate protective clothing - see Section 8. Wash and dry hands thoroughly after handling. Use only under a chemical fume hood. Use with adequate ventilation. Avoid exposure – obtain special instructions before use. Avoid contact with skin and eyes. Avoid ingestion and inhalation. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

**Storage:**
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 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).

Hygiene measures: Use good working practices. Wash hands and face thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance:</td>
<td>Yellow-orange to orange solid.</td>
</tr>
<tr>
<td>Odour:</td>
<td>Data not available/does not apply.</td>
</tr>
<tr>
<td>Odour threshold:</td>
<td>Data not available/does not apply.</td>
</tr>
<tr>
<td>pH:</td>
<td>Data not available/does not apply.</td>
</tr>
<tr>
<td>Melting point:</td>
<td>Data not available/does not apply.</td>
</tr>
<tr>
<td>Boiling point:</td>
<td>Data not available/does not apply.</td>
</tr>
<tr>
<td>Flash point:</td>
<td>Data not available/does not apply.</td>
</tr>
<tr>
<td>Evaporation rate:</td>
<td>Negligible</td>
</tr>
<tr>
<td>Flammability:</td>
<td>Data not available/does not apply.</td>
</tr>
<tr>
<td>Flammability or explosive limits:</td>
<td>Data not available/does not apply.</td>
</tr>
<tr>
<td>Vapor pressure:</td>
<td>Data not available/does not apply.</td>
</tr>
<tr>
<td>Vapor density:</td>
<td>Data not available/does not apply.</td>
</tr>
<tr>
<td>Relative density:</td>
<td>Data not available/does not apply.</td>
</tr>
<tr>
<td>Solubility:</td>
<td>Insoluble (water).</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Data not available/does not apply.</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>Data not available/does not apply.</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>Data not available/does not apply.</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Chemical stability: Stable under recommended storage conditions.
Incompatibilities with other materials: Oxidizing agents.
Hazardous decomposition products: Carbon oxides.
Hazardous polymerization: Do not occur.

11. TOXICOLOGICAL INFORMATION

RTCS #: VH6440000.
Acute toxicity: LD50 Oral: rat: > 4000 mg/kg.
Skin corrosion/irritation: Causes skin irritation.
Serious eye damage/eye irritation: Causes serious eye irritation.
Respiratory or skin sensitization: Data not available.
Germ cell mutagenicity: Data not 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:
May cause congenital malformation in the fetus.
Presumed human reproductive toxicant.

Developmental Toxicity: Hamster: Oral
Effects on Embryo or Fetus: Fetotoxicity (except death, e.g., stunted fetus). Specific Developmental Abnormalities: Central nervous system. Specific Developmental Abnormalities: Craniofacial (including nose and tongue).

Specific target organ toxicity - single exposure: Inhalation - May cause respiratory irritation.
Specific target organ toxicity - repeated exposure: Data not available.
Aspiration hazard: Data not available.
Signs and symptoms of exposure: Dermatitis.
To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Target organs:**

Data not available.

**Potential health effects:**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eye:</strong></td>
<td>Causes serious eye irritation.</td>
</tr>
<tr>
<td><strong>Skin:</strong></td>
<td>May be harmful by skin absorption.</td>
</tr>
<tr>
<td></td>
<td>Causes skin irritation.</td>
</tr>
<tr>
<td><strong>Ingestion:</strong></td>
<td>May be harmful if swallowed.</td>
</tr>
<tr>
<td><strong>Inhalation:</strong></td>
<td>May be harmful if inhaled.</td>
</tr>
<tr>
<td></td>
<td>Causes respiratory tract irritation.</td>
</tr>
<tr>
<td><strong>Chronic:</strong></td>
<td>No information found.</td>
</tr>
</tbody>
</table>

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12. **ECOLOGICAL INFORMATION**

**General notes:**

Water hazard class 1 (Self-assessment): Slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system. Do not allow material to be released to the environment without proper governmental permits. Avoid transfer into the environment.

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13. **DISPOSAL CONSIDERATIONS**

Observe all federal, state and local environmental regulations. Mix or dissolve the material in a combustible solvent and burn in chemical incinerator equipped with an afterburner and scrubber. Contact a licensed professional waste disposal service to dispose of this material.

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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.

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15. **REGULATORY INFORMATION**

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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.