SAFETY DATA SHEET  
Isotretinoin  
according to Regulation (EC) No. 1907/2006 as amended by (EC) No. 1272/2008  

Section 1. Identification of the Substance/Mixture and of the Company/Undertaking  

1.1 Product Code: 21648  
Product Name: Isotretinoin  
Synonyms: 13-cis-retinoic acid; AGN 190013; 13(Z)-Retinoic Acid; 13-cis-Vitamin A Acid;  

1.2 Relevant identified uses of the substance or mixture and uses advised against:  
Relevant identified uses: For research use only, not for human or veterinary use.  

1.3 Details of the Supplier of the Safety Data Sheet:  
Company Name: Cayman Chemical Company  
1180 E. Ellsworth Rd.  
Ann Arbor, MI 48108  
Web site address: www.caymanchem.com  
Information: Cayman Chemical Company  
Emergency Contact: CHEMTREC Within USA and Canada: +1 (800)424-9300  
CHEMTREC Outside USA and Canada: +1 (703)527-3887  

1.4 Emergency telephone number:  
Emergency Contact: CHEMTREC Within USA and Canada: +1 (800)424-9300  
CHEMTREC Outside USA and Canada: +1 (703)527-3887  

Section 2. Hazards Identification  

2.1 Classification of the Substance or Mixture:  
Toxic To Reproduction, Category 1B  
Aquatic Toxicity (Acute), Category 1  
Aquatic Toxicity (Chronic), Category 1  

2.2 Label Elements:  

GHS Signal Word: Danger  
GHS Hazard Phrases:  
H360: May damage fertility or the unborn child.  
H400: Very toxic to aquatic life.  
H410: Very toxic to aquatic life with long lasting effects.  
GHS Precaution Phrases:  
P201: Obtain special instructions before use.  
P202: Do not handle until all safety precautions have been read and understood.  
P273: Avoid release to the environment.  
P280: Wear [protective gloves/protective clothing/eye protection/face protection].  
GHS Response Phrases:  
P308+313: IF exposed or concerned: Get medical attention/advice.  
P391: Collect spillage.  
GHS Storage and Disposal Phrases:  
Please refer to Section 7 for Storage and Section 13 for Disposal information.
2.3 Adverse Human Health Effects and Symptoms:
Material may be irritating to the mucous membranes and upper respiratory tract.
May be harmful by inhalation, ingestion, or skin absorption.
May cause eye, skin, or respiratory system irritation.
May damage fertility or the unborn child.
Very toxic to aquatic life with long lasting effects.
To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

Section 3. Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>CAS # / RTECS #</th>
<th>Hazardous Components (Chemical Name)/REACH Registration No.</th>
<th>Concentration</th>
<th>EC No./EC Index No.</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>4759-48-2</td>
<td>Isotretinoin</td>
<td>100.0 %</td>
<td>225-296-0 NA</td>
<td>Toxic Repro. 1B: H360 Aquatic (A) 1: H400 Aquatic (C) 1: H410</td>
</tr>
</tbody>
</table>

Section 4. First Aid Measures

4.1 Description of First Aid Measures:
In Case of Inhalation: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
In Case of Skin Contact: Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
In Case of Eye Contact: Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.
In Case of Ingestion: Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

Section 5. Fire Fighting Measures

5.1 Suitable Extinguishing Media:
Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.
Use water spray to cool fire-exposed containers.

Unsuitable Extinguishing Media:
A solid water stream may be inefficient.

5.2 Flammable Properties and Hazards:
No data available.

Flash Pt: No data.
Explosive Limits: LEL: No data. UEL: No data.
Autoignition Pt: No data.

5.3 Fire Fighting Instructions:
As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.
Section 6. Accidental Release Measures

6.1 Protective Precautions, Protective Equipment and Emergency Procedures:

- Avoid raising and breathing dust, and provide adequate ventilation.
- As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

6.2 Environmental Precautions:
- Take steps to avoid release into the environment, if safe to do so.

6.3 Methods and Material For Containment and Cleaning:
- Contain spill and collect, as appropriate.
- Transfer to a chemical waste container for disposal in accordance with local regulations.

Section 7. Handling and Storage

7.1 Precautions To Be Taken in Handling:
- Avoid breathing dust/fume/gas/mist/vapours/spray.
- Avoid prolonged or repeated exposure.

7.2 Precautions To Be Taken in Storing:
- Keep container tightly closed.
- Store in accordance with information listed on the product insert.

Section 8. Exposure Controls/Personal Protection

8.1 Exposure Parameters:

8.2 Exposure Controls:

8.2.1 Engineering Controls:
- Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

8.2.2 Personal protection equipment:
- Eye Protection: Safety glasses
- Protective Gloves: Compatible chemical-resistant gloves
- Other Protective Clothing: Lab coat
- Respiratory Equipment: NIOSH approved respirator, as conditions warrant.
- (Specify Type):
- Work/Hygiene/Maintenance Practices:
  - Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower.
  - Wash thoroughly after handling.
  - Do not take internally.
  - No data available.

Section 9. Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties:

- Physical States: [ ] Gas [ ] Liquid [ X ] Solid
- Appearance and Odor: A crystalline solid
- pH: No data.
- Melting Point: No data.
- Boiling Point: No data.
- Flash Pt: No data.
- Evaporation Rate: No data.
- Flammability (solid, gas): No data available.
- Explosive Limits: LEL: No data. UEL: No data.
- Vapor Pressure (vs. Air or mm Hg): No data.
- Vapor Density (vs. Air = 1): No data.
Isotretinoin

Specific Gravity (Water = 1): No data.
Solubility in Water: No data.
Solubility Notes: ~0.2 mg/ml in 1:4 solution of DMF:PBS (pH 7.2); ~1 mg/ml in DMSO; ~5 mg/ml in DMF;
Octanol/Water Partition Coefficient: No data.
Autoignition Pt: No data.
Decomposition Temperature: No data.
Viscosity: No data.

9.2 Other Information
Percent Volatile: No data.
Molecular Formula & Weight: C20H28O2 300.4

Section 10. Stability and Reactivity
10.1 Reactivity: No data available.
10.2 Stability: Unstable [ ] Stable [ X ]
10.3 Stability Note(s): Stable if stored in accordance with information listed on the product insert.
Polymerization: Will occur [ ] Will not occur [ X ]
10.4 Conditions To Avoid: No data available.
10.5 Incompatibility - Materials strong oxidizing agents
To Avoid:
10.6 Hazardous carbon dioxide
Decomposition or carbon monoxide
Byproducts:

Section 11. Toxicological Information
11.1 Information on Toxicological Effects: Isotretinoin - Toxicity Data: Oral TDLO (child): 30 mg/kg/21W; Oral TDLO (man): 24 mg/kg/4W (intermittent); Oral TDLO (woman): 56 mg/kg/8W (intermittent); Intraperitoneal LD50 (rat): 901 mg/kg; Oral LD50 (mouse): 3389 mg/kg; Intraperitoneal LD50 (mouse): 138 mg/kg; Oral LD50 (rat): >4000 mg/kg;
Chronic Toxicological Effects: Isotretinoin - Investigated as a drug, mutagen, and reproductive effector.

<table>
<thead>
<tr>
<th>CAS #</th>
<th>Hazardous Components (Chemical Name)</th>
<th>NTP</th>
<th>IARC</th>
<th>ACGIH</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>4759-48-2</td>
<td>Isotretinoin</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

Section 12. Ecological Information
12.1 Toxicity: Avoid release into the environment.
Runoff from fire control or dilution water may cause pollution.
12.2 Persistence and Degradability: No data available.
12.3 Bioaccumulative Potential: No data available.
12.4 Mobility in Soil: No data available.
12.5 Results of PBT and vPvB assessment: No data available.
12.6 Other adverse effects: No data available.
Section 13. Disposal Considerations

13.1 Waste Disposal Method: Dispose in accordance with local, state, and federal regulations.

Section 14. Transport Information

14.1 LAND TRANSPORT (US DOT):
   DOT Proper Shipping Name: Not dangerous goods.
   DOT Hazard Class:
   UN/NA Number:

14.1 LAND TRANSPORT (European ADR/RID):
   ADR/RID Shipping Name: Not dangerous goods.
   UN Number:
   Hazard Class:

14.3 AIR TRANSPORT (ICAO/IATA):
   ICAO/IATA Shipping Name: Not dangerous goods.
   Additional Transport Information: Transport in accordance with local, state, and federal regulations.

Section 15. Regulatory Information

EPA SARA (Superfund Amendments and Reauthorization Act of 1986) Lists

<table>
<thead>
<tr>
<th>CAS #</th>
<th>Hazardous Components (Chemical Name)</th>
<th>S. 302 (EHS)</th>
<th>S. 304 RQ</th>
<th>S. 313 (TRI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4759-48-2</td>
<td>Isotretinoin</td>
<td>No</td>
<td>No</td>
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<tr>
<th>CAS #</th>
<th>Hazardous Components (Chemical Name)</th>
<th>Other US EPA or State Lists</th>
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</thead>
<tbody>
<tr>
<td>4759-48-2</td>
<td>Isotretinoin</td>
<td>CAA HAP,ODC: No; CWA NPDES: No; TSCA: Yes - Inventory; CA PROP.65: Yes; RDTox.</td>
</tr>
</tbody>
</table>

Regulatory Information Statement: This SDS was prepared in accordance with 29 CFR 1910.1200 and Regulation (EC) No.1272/2008.

Section 16. Other Information

Revision Date: 06/25/2018

Additional Information About This Product: No data available.

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