SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
1.2 Relevant identified uses of the substance or mixture and uses advised against
1.3 Details of the supplier of the safety data sheet

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

(Contd. on page 2)
Trade name: ENDOMETHASONE N

(Contd. of page 1)

R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Information concerning particular hazards for human and environment:
The product has to be labelled in the latest valid version according to the calculation procedure of the "General Classification guideline for preparations of the EU".

Classification system:
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008
The product is classified and labelled according to the CLP regulation.
- Hazard pictograms
  
  GHS05  GHS07  GHS09

- Signal word Danger
- Hazard-determining components of labelling:
  - iodothyrol
- Hazard statements
  H302 Harmful if swallowed.
  H314 Causes severe skin burns and eye damage.
  H410 Very toxic to aquatic life with long lasting effects.
- Precautionary statements
  P273 Avoid release to the environment.
  P280 Wear protective gloves/protective clothing/eye protection/face protection.
  P264 Wash hands thoroughly after handling.
  P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  P301+P333+P321 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
  P302+P352 IF ON SKIN: Wash with plenty of water.
  P405 Store locked up.
  P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures
- Description: Mixture: consisting of the following components.
- Dangerous components:
SECTION 4: First aid measures

4.1 Description of first aid measures

4.1.1 General information:
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

4.1.2 After excessive inhalation: Supply fresh air; consult a doctor in case of complaints.

4.1.3 After skin contact: Generally the product does not irritate the skin.

4.1.4 After eye contact: Rinse opened eye for several minutes under running water.

4.1.5 After swallowing: Call for a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed:
No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed:
No further relevant information available.

SECTION 5: Firefighting measures

5.1 Suitable extinguishing agents:
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture: No further relevant information available.

5.3 Advice for firefighters
Protective equipment: No special measures required.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures: Not required.

6.2 Environmental precautions:
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up:
Dispose contaminated material as waste according to item 13.

6.4 Reference to other sections:
See Section 7 for information on safe handling.
See Section 8 for information on personal protective equipment.
SECTION 7: Handling and storage

- 7.1 Precautions for safe handling: No special precautions are necessary if used correctly.
- 7.2 Conditions for safe storage, including any incompatibilities
  - Storage:
    - Requirements to be met by storerooms and receptacles: No special requirements.
    - Information about storage in one common storage facility: Not required.
- Further information about storage conditions: None.
- 7.3 Specific end use(s): No further relevant information available.

SECTION 8: Exposure controls/personal protection

- 8.1 Control parameters
- Ingredients with limit values that require monitoring at the workplace:
<table>
<thead>
<tr>
<th>WEL (Great Britain)</th>
<th>Long-term value: 10+ 4** mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>7727-43-7 barium sulphate, natural (10-25%)</td>
<td>*inhalable dust **respirable dust</td>
</tr>
</tbody>
</table>

- Additional information:
  As a basis for the production of this document, the most current valid lists were used.

- 8.2 Exposure controls
- 8.3 Personal protective equipment:
- General protective and hygienic measures:
  Keep away from food, beverages and petfood.
  Wash hands before breaks and at the end of work.
- Respiratory protection: Not required.
- Protection of hands:
  The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
- Gloves material:
  The selection of suitable gloves does not only depend on the material, but also on further marks of quality which may vary from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked before use.
- Eye protection: Not required.

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
  - General Information
  - Appearance:
    - Form: Powder
    - Colour: Light beige
    - Odour: Characteristic
    - Odour threshold: Not determined.
SECTION 10: Stability and reactivity

- **10.1 Reactivity**
- **10.2 Chemical stability**
  - **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
  - **10.3 Possibility of hazardous reactions:** No dangerous reactions known.
  - **10.4 Conditions to avoid:** No further relevant information available.
  - **10.5 Incompatible materials:** No further relevant information available.
  - **10.6 Hazardous decomposition products:** No dangerous decomposition products known.
SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
  - **LD/LC50 values relevant for classification:**
    - 1314-13-2 zinc oxide
      - Oral LD50: 7950 mg/kg (mouse)
- **Primary irritant effect:**
  - **On the skin:** No irritant effect.
  - **On the eyes:** No irritant effect.
  - **Sensitisation:** No sensitising effects known.
- **Additional toxicological information:**
The product shows the following hazards according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Harmful

SECTION 12: Ecological information

- **12.1 Toxicity**
  - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability:** No further relevant information available.
- **12.3 Bioaccumulative potential:** No further relevant information available.
- **12.4 Mobility in soil:** No further relevant information available.
- **Ecotoxicological effects:**
  - **Remark:** Very toxic for fish
- **Additional ecological information:**
  - **General notes:**
    - Also poisonous for fish and plankton in water bodies.
    - Very toxic for aquatic organisms
    - Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

**Do not allow product to reach ground water, water course or sewage system.**

Danger to drinking water if even small quantities leak into the ground.

- **12.5 Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
- **12.6 Other adverse effects:** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:**

  Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
### SECTION 14: Transport information

- **14.1 UN-Number**
  
  | ADR, IMDG, IATA | UN3077 |

- **14.2 UN proper shipping name**
  
  | ADR | 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide) |
  | IMDG | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), MARINE POLLUTANT |
  | IATA | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide) |

- **14.3 Transport hazard class(es)**
  
  | ADR |
  | Class | 9 (M7) Miscellaneous dangerous substances and articles. |
  | Label | 9 |

- **IMDG, IATA**
  
  | Class | 9 Miscellaneous dangerous substances and articles. |
  | Label | 9 |

- **14.4 Packing group**
  
  | ADR, IMDG, IATA | III |

- **14.5 Environmental hazards:**
  
  | Marine pollutant: | Yes |
  | Special marking (ADR): | Symbol (fish and tree) |
  | Special marking (IATA): | Symbol (fish and tree) |

- **14.6 Special precautions for user**
  
  | Danger code (Kemler): | Warning: Miscellaneous dangerous substances and articles. |
  | EMS Number: | F-A,S-F |

- **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**
  
  | Not applicable. |

(Contd. of page 8)
**Trade name: ENDOMETRASONE C**

**Transport/Additional information:**

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<th>Description</th>
<th>Value</th>
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<tbody>
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<td>5 kg</td>
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<tr>
<td><strong>Limited quantities (LQ)</strong></td>
<td>5 kg</td>
</tr>
<tr>
<td><strong>Excepted quantities (EQ)</strong></td>
<td>Code: E1</td>
</tr>
<tr>
<td><strong>Maximum net quantity per inner packaging:</strong></td>
<td>30 g</td>
</tr>
<tr>
<td><strong>Maximum net quantity per outer packaging:</strong></td>
<td>1000 g</td>
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<tr>
<td><strong>Transport category</strong></td>
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</tr>
<tr>
<td><strong>Tunnel restriction code</strong></td>
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</tr>
</tbody>
</table>

**IMDG**

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Limited quantities (LQ)</strong></td>
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</tbody>
</table>

**UN "Model Regulation":**

UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  
  No further relevant information available.

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

**Relevant phrases**

- H302  Harmful if swallowed.
- H310  Fatal in contact with skin.
- H314  Causes severe skin burns and eye damage.
- H361  Suspected of damaging fertility or the unborn child.
- H400  Very toxic to aquatic life.
- H410  Very toxic to aquatic life with long lasting effects.
- R22   Harmful if swallowed.
- R34   Causes burns.
- R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- R63   Possible risk of harm to the unborn child.

**Abbreviations and acronyms:**

- RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
- ICAO: International Civil Aviation Organisation
- ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- VOC: Volatile Organic Compounds (USA, EU)
- LC50: Lethal concentration, 50 percent

(Contd. on page 9)
**Trade name: ENDOMETHASONE N**

LD50: Lethal dose, 50 percent  
Acute Tox. 4: Acute toxicity, Hazard Category 4  
Acute Tox. 1: Acute toxicity, Hazard Category 1  
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B  
Repr. 2: Reproductive toxicity, Hazard Category 2  
Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1  
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1