

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 16.10.2014

Version number 2

Revision: 16.10.2014

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** ENDOMETHASONE N**Article number / formula:** 149S**1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.**Application of the substance / the preparation :** dental product**1.3 Details of the supplier of the safety data sheet****Manufacturer/Supplier:**

SEPTODONT.

58 rue du Pont de Creteil

94100 Saint Maur des Fosses

France

Téléphone: +33(0)149767000

Fax: +33(0)148855401

msds@septodont.com

http://www.septodont.com

**1.4 Emergency telephone number:**

France (ORFILA 24h/24) - Tel : +33 (0)1 45 42 59 59

Ireland - Tel : 00 353 1 8092568 - 00 353 1 8379964 (24h/24)

EU Tel : 112

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008 :**

GHS05

Skin Corr. 1B      H314 Causes severe skin burns and eye damage.



GHS09

Aquatic Acute 1      H400 Very toxic to aquatic life.

Aquatic Chronic 1      H410 Very toxic to aquatic life with long lasting effects.



GHS07

Acute Tox. 4      H302 Harmful if swallowed.

**Classification according to Directive 67/548/EEC or Directive 1999/45/EC :**

C; Corrosive

R34: Causes burns.



Xn; Harmful

R22: Harmful if swallowed.



N; Dangerous for the environment

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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:**

*iodothymol*

· **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+P330+P331 **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:**

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



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CAS: 1314-13-2 EINECS: 215-222-5 Index number: 030-013-00-7 RTECS: ZH 4810000 Reg.nr.: 01-2119463881-32	zinc oxide  N R50/53  Aquatic Acute 1, H400; Aquatic Chronic 1, H410	25-50%
CAS: 552-22-7	iodothymol  C R34;  Xn R22  Skin Corr. 1B, H314;  Acute Tox. 4, H302	10-25%
CAS: 50-03-3	acétate d'hydrocortisone USP  Xn R63  Acute Tox. 1, H310;  Repr. 2, H361	≤ 1%

· **Additional information:** For the wording of the listed risk phrases, refer to section 16.

### SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **General information:**

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

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

· **After skin contact:** Generally the product does not irritate the skin.

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

· **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:**

CO<sub>2</sub>, 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.

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See Section 13 for disposal information.

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### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** : No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection**: No special measures required.
- **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

- **Additional information about design of technical facilities**: No further data; see section 7.

#### · 8.1 Control parameters

- **Ingredients with limit values that require monitoring at the workplace:**

**7727-43-7 barium sulphate, natural (10-25%)**WEL (Great Britain) Long-term value: 10\* 4\*\* mg/m<sup>3</sup>  
\*inhalable dust \*\*respirable dust

- **Additional information:**

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

#### · 8.2 Exposure controls

- **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.

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· <b>pH-value:</b>	Not applicable.
· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gaseous):</b>	Not determined.
· <b>Ignition temperature:</b>	Not applicable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Self-igniting:</b>	Product is not self igniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density:</b>	Not determined.
· <b>Relative density :</b>	Not determined.
· <b>Vapour density :</b>	Not applicable.
· <b>Evaporation rate :</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Segregation coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Solvent content:</b>	
<b>VOC (EC)</b>	0.00 %
· <b>9.2 Other information :</b>	No further relevant information available.

**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.

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**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)
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· **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.

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

**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**
- **Label**

9 (M7) Miscellaneous dangerous substances and articles.  
9

- **IMDG, IATA**



- **Class**
- **Label**

9 Miscellaneous dangerous substances and articles.  
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)

Symbol (fish and tree)

- **14.6 Special precautions for user**

Warning: Miscellaneous dangerous substances and articles.

- **Danger code (Kemler):**

90

- **EMS Number:**

F-A,S-F

- **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

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**· Transport/Additional information:**

**· ADR**

- **Limited quantities (LQ)** 5 kg
- **Excepted quantities (EQ)** Code: E1  
Maximum net quantity per inner packaging: 30 g  
Maximum net quantity per outer packaging: 1000 g
- **Transport category** 3
- **Tunnel restriction code** E

**· IMDG**

- **Limited quantities (LQ)** 5 kg
- **Excepted quantities (EQ)** Code: E1  
Maximum net quantity per inner packaging: 30 g  
Maximum net quantity per outer packaging: 1000 g

- **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

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*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 - AcuteHazard, Category 1*

*Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1*

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