

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

Printing date 09.06.2017

Version number 1

Revision: 09.06.2017

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

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· 1.4 Emergency telephone number:

France (INRS 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

Belgique - Tel : 32 070/245 245

UK : +44 (0)-870-190-6777 (CARECHEM24)

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.

Eye Dam. 1 H318 Causes serious 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.

· 2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

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· 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

P264 Wash hands thoroughly after handling.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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:

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

· **SVHC** No

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

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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:** Provide fresh air; consult a doctor in case of medical 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:**

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:

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow the product to enter sewers/ surface water 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.

See Section 13 for disposal information.

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.

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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:**

CAS: 1314-13-2 zinc oxide (25-50%)

MAK (Switzerland)	Short-term value: 3 a mg/m ³ Long-term value: 3 a mg/m ³ (Rauch)
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CAS: 7727-43-7 barium sulphate, natural (10-25%)

WEL (Great Britain)	Long-term value: 10* 4** mg/m ³ *inhalable dust **respirable dust
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· **Additional information:**

The most current valid lists have been used as a basis for the production of this document.

· **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 depend only 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.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not determined.

· **Ignition temperature:** Not applicable.

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· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not self igniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density:	Not determined.
· Relative density :	Not determined.
· Vapour density :	Not applicable.
· Evaporation rate :	Not applicable.
· Solubility in / Miscibility with water:	Insoluble.
· Segregation coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
VOC (EC)	0.00 %
· 9.2 Other information :	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **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**
Harmful if swallowed.

· **LD/LC50 values relevant for classification:**

CAS: 1314-13-2 zinc oxide

Oral	LD50	7950 mg/kg (mouse)
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CAS: 552-22-7 iodothymol

Oral	LD50	500 mg/kg (ATE)
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CAS: 50-03-3 acétate d'hydrocortisone USP

Dermal	LD50	45 mg/kg (mouse)
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- **Primary irritant effect:**
- **On the skin:**
Causes severe skin burns and eye damage.
- **On the eyes:**
Causes serious eye damage.
- **Respiratory or skin sensitization** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
- 
Do not allow product to reach ground water, water course or sewage system.
- Must not reach sewage water or drainage ditch undiluted or unneutralised.
Danger to drinking water if even small quantities leak into the ground.
Also poisonous for fish and plankton in water bodies.
Very toxic for aquatic organisms
- **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	UN3077
· ADR, IMDG, IATA	
· 14.2 UN proper shipping name	UN3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)
· ADR	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), MARINE POLLUTANT
· IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)
· IATA	
· 14.3 Transport hazard class(es)	
· ADR	
	
· Class	9 (M7) Miscellaneous dangerous substances and articles.
· Label	9
· IMDG	
	
· Class	9 Miscellaneous dangerous substances and articles.
· Label	9
· IATA	
	
· Class	9 Miscellaneous dangerous substances and articles.
· Label	9
· 14.4 Packing group	III
· ADR, IMDG, IATA	
· 14.5 Environmental hazards:	
· Marine pollutant:	Yes
· Special marking (ADR):	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

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· Stowage Category	A
· Stowage Code	SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· 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":	UN 3077 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**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category E1** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **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.
- **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

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*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**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**SVHC: Substances of Very High Concern**vPvB: very Persistent and very Bioaccumulative**Acute Tox. 4: Acute toxicity – Category 4**Acute Tox. 1: Acute toxicity – Category 1**Skin Corr. 1B: Skin corrosion/irritation – Category 1B**Eye Dam. 1: Serious eye damage/eye irritation – Category 1**Repr. 2: Reproductive toxicity – Category 2**Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1**Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1*

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