

DSI ApexSil RC

Root Canal Obturation Cement

Material safety data sheet (MSDS)
Version 1.0 / EN

26/12/2022

SECTION 1: PRODUCT AND COMPANY INFORMATION

1.1. Product identifier

Product Name	DSI ApexSil RC
Intended use	Root Canal Filling Material
Structure	Powder/Liquid

1.2. Details of the supplier of the safety data sheet:

Company Name	DSI Ltd.
Company Address	59 haAvoda str., Ashdod 7706300 Israel
Contact Name	Shlomi Krasner
Phone / Fax	+972.893.172.35
E-mail	info@dsisrael.com

Emergency telephone number:

Phone / Fax +972.893.172.35

SECTION 2: COMPOSITION /INFORMATION ON INGREDIENTS

Chemical characterization:

COMPONENTS Powder	C.A.S.	% by Wt
Zinc oxide	1314-13-2	60-65 %
Radiopacifier*	—	15-20 % (trade secret*)
Excipients*	—	(trade secret*)

* SDS indicates the ingredient name and/or exact percentage is being withheld as a trade secret.

SECTION 3: HAZARDS IDENTIFICATION

3.1 Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2008:

Acute Tox. 4	H302 Harmful if swallowed.
Aquatic Acute 1	H400 Very toxic to aquatic life.
Aquatic Chronic 1	H410 Very toxic to aquatic life with long lasting effects.

3.2 Label elements

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

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

· 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.

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.

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

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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: MEASURES AND MEANS OF MAINTENANCE OF FIRE SAFETY

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.

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: The product should be stored in cool and dry environment between 10°C to 24°C.

Replace cap tightly after use.

· 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:

The product does not contain any significant quantities of materials with critical values that have to be monitored at the workplace.

· 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 pet food. 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 cannot be calculated in advance and has therefore to be checked before use.

· Eye protection: Not required.

SECTION 9: PHYSICAL/CHEMICAL CHARACTERISTICS

Information on basic physical and chemical properties

Appearance:	
Form:	powder
Colour:	Light yellow
Odour:	Characteristic
Odour threshold:	Not determined
pH-value:	Not applicable
Melting point/Melting range	Not determined
Boiling point/Boiling range	Not determined
Flash Point	Not Applicable
Ignition temperature:	Not Applicable
Decomposition temperature	Not determined
Self-igniting	Product is not self igniting
Danger of explosion	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
Segregation coefficient (n-octanol/water):	Not determined
Viscosity:	
Dynamic	Not applicable
Kinematic	Not applicable
Other information	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.

SECTION 11: TOXICOLOGICAL INFORMATION

Primary irritant effect

On the skin : caustic affect on skin and mucous membrane

On the eyes : strong caustic affect

- Sensitization: No sensitizing effects known.

- Additional toxicological information:

Swallowing will lead to a strong caustic effect on mouth and throat.

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.

- General notes: Must not reach sewage water or drainage ditch undiluted or unneutralized. 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 CONSIDERATION

Waste treatment methods

- Recommendation: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packaging:

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

SECTION 14: TRANSPORT INFORMATION

<ul style="list-style-type: none">· UN-Number· ADR, ADN, IMDG, IATA	Not classified as hazardous for transport
<ul style="list-style-type: none">· UN proper shipping name· ADR, ADN, IMDG, IATA	Not classified as hazardous for transport
<ul style="list-style-type: none">· Transport hazard class(es)· ADR, ADN, IMDG, IATA· Class	Not classified as hazardous for transport

· Packing group · ADR, IMDG, IATA	Not classified as hazardous for transport
Environmental hazards: · Marine pollutant:	No
Special precautions for user	Not applicable
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable
· UN “Model Regulation”:	–

SECTION 15: REGULATORY INFORMATION

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

SECTION 16: OTHER INFORMATION

*Changes in content as per regulations – GHS classification

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 Harmonized System of Classification and Labeling 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)

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

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Skin Sens. 1: Sensitization - Skin, Hazard Category 1

Repeated exposure, Hazard Category 2

Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2 Aquatic Chronic 4:

Hazardous to the aquatic environment - Chronic Hazard, Category 4

Disclaimer:

Since the working conditions of the final user are unknown, the information presented in this safety data sheet is based on the current level of our knowledge, based on national and general standards.

The product should not be used for any other purpose than those indicated under heading without first receiving written instructions for use. The user must take all necessary measures to comply with the requirements and rules of the law. The information in this safety data sheet should be considered as a description of the safety requirements that apply to our product and does not guarantee its properties.

SECTION 1: PRODUCT AND COMPANY INFORMATION

1.1. Product identifier

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Contact Name	Shlomi Krasner
Phone / Fax	+972.893.172.35
E-mail	info@dsisrael.com

Emergency telephone number:	
Phone / Fax	+972.893.172.35

SECTION 2: COMPOSITION /INFORMATION ON INGREDIENTS

Chemical characterization:

COMPONENTS Liquid	C.A.S.	% by Wt
Eugenol	97-53-0	>90 %
Excipients*	—	(trade secret*)

* SDS indicates the ingredient name and/or exact percentage is being withheld as a trade secret.

SECTION 3: HAZARDS IDENTIFICATION

Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2008 :

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction

Skin Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects

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

R36: Irritating to eyes.

R43: May cause sensitization by skin contact.

R52/53: Harmful 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 labeled 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.

Label elements

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

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

· Hazard statements

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H412 Harmful 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.

P302+P352 IF ON SKIN: Wash with plenty of water.

Other hazards

· Results of PBT and vPvB assessment

· PBT: Not applicable.

· vPvB: Not applicable.

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 and to be sure call for a doctor.

In case of unconsciousness, place patient in a stable laying down side position for transportation.

· After skin contact: Immediately wash with water and soap and rinse thoroughly.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· 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: MEASURES AND MEANS OF MAINTENANCE OF FIRE SAFETY

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

Personal precautions, protective equipment and emergency procedures

Remove persons from danger area. Avoid contact with the eyes and skin. Wear protective clothing.

· Environmental precautions:

Do not allow product to reach sewage system or any water course. Do not allow to penetrate the ground/soil.

· Methods and material for containment and cleaning up:

Use neutralizing agent.

Absorb liquid components with liquid-binding material. Dispose of the material collected according to regulations.

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling :

Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols.

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: Keep container tightly sealed.

· 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:

The product does not contain any significant quantities of materials with critical values that have to be Monitored at the workplace.

· 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 pet food. Immediately remove all soiled and contaminated clothing Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· Respiratory protection: In case of brief exposure or low pollution use respiratory filter device.

In case of intensive or longer exposure use self-contained respiratory protective device.

Protection of hands: Protective gloves

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 cannot be calculated in advance and has therefore to be checked before use.

· Eye protection: Tightly sealed goggles

SECTION 9: PHYSICAL/CHEMICAL CHARACTERISTICS

Information on basic physical and chemical properties

· General Information

Appearance:	
Form:	Liquid
Colour:	pale yellow clear liquid
Odour:	Characteristic
Odour threshold:	Not determined
pH-value:	Not applicable
Change in condition	
Melting point/Melting range	Undetermined
Boiling point/Boiling range	Undetermined
Flash Point	Not Applicable
Flammability (solid, gaseous)	Not Applicable
Ignition temperature	Not Applicable
Decomposition temperature	Not determined
Self-igniting	Product is not self igniting
Danger of explosion	Product does not present an explosion hazard
Explosion limits	
Lower:	Not determined
Upper:	Not determined
Vapour pressure	Not determined
Relative density	Not determined
Vapour density	Not determined
Evaporation rate	Not determined

Segregation coefficient (n-octanol/water):	Not determined
Viscosity:	
Dynamic	Not determined
Kinematic	Not determined
Other information	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.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects

- Primary irritant effect:
- On the skin: No irritant effect.
- On the eyes: Irritating effect.
- Sensitization: Sensitization possible through skin contact.
- Additional toxicological information: none.

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:

· General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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 CONSIDERATION

Waste treatment methods

- Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packaging:

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

- Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: TRANSPORT INFORMATION

· UN-Number · ADR, ADN, IMDG, IATA	Not classified as hazardous for transport
UN proper shipping name · ADR, ADN, IMDG, IATA	Not classified as hazardous for transport
· Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	Not classified as hazardous for transport
· Packing group · ADR, IMDG, IATA	Not classified as hazardous for transport
Environmental hazards: · Marine pollutant:	No
Special precautions for user	Not applicable
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable
· UN "Model Regulation":	—

SECTION 15: REGULATORY INFORMATION

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

SECTION 16: OTHER INFORMATION

* Changes in content as per regulations – GHS classification

Abbreviations and acronyms:

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 Harmonized System of Classification and Labeling 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)

Flam. Liq. 3: Flammable liquids, Hazard Category 3 Acute Tox. 4: Acute toxicity, Hazard Category 4

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2 Skin Sens. 1: Sensitization - Skin, Hazard Category 1

Asp. Tox. 1: Aspiration hazard, Hazard Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1 Aquatic Chronic 2:

Hazardous to the aquatic environment - Chronic Hazard, Category 2 Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

Disclaimer:

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The product should not be used for any other purpose than those indicated under heading without first receiving written instructions for use. The user must take all necessary measures to comply with the requirements and rules of the law. The information in this safety data sheet should be considered as a description of the safety requirements that apply to our product and does not guarantee its properties.