



Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: Calcimol

Manufacturer: VOCO

SDS Expiry: 3 May 2028

Supplier Details: Henry Schein New Zealand

243-249 Bush Road, Rosedale, Auckland, 0632 PO Box 101 140, North Shore, Auckland 0745

Ph. 0800 808 855

www.henryschein.co.nz

Emergency Contacts: Poisons/Hazardous Chemical Info Centre –

0800POISON/0800764766 (24 Hours) Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 6 / 9

HSNO Group Standard: Dental Products Subsidiary Hazard Group Standard 2020

HSR002558

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared – May 2023

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.



Printing date 03.05.2023

Version number 9

Revision: 03.05.2023

Hazardous according to criteria of Australian Safety and Compensation Council.

SECTION 1: Identification

- · 1.1 Product identifier
- · Trade name: Calcimol base
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the mixture self-curing radiopaque calcium hydroxide paste
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Australien contact and address:

VOCO Australia Pty Ltd.

Suite 406-408, 251 Oxford Street,

Bondi Junction, NSW 2022

- · Further information obtainable from: Australia 02 9369 1770
- · 1.4 Emergency telephone number: Australia: 131126

SECTION 2: Hazard(s) Identification

- · 2.2 Label elements
- · Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2

H315 Causes skin irritation.

Serious eye damage/irritation - Category 2A H319 Causes serious eye irritation.

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

As a medical device the product is not subject to labelling regulations under 1272/2008/EC.

- · Hazard pictograms GHS07
- · Hazard statements

Causes skin irritation.

Causes serious eye irritation.

· Precautionary statements

Wash thoroughly after handling.

Wear eye protection / face protection.

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

If skin irritation occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

If eye irritation persists: Get medical advice/attention.

- · 2.3 Other hazards Use only for intended scope of application
- Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition and Information on Ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous comp	ponents:	
	salicylate	25-50%
	Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	
CAS: 1314-13-2	zinc oxide	5-10%
	Aquatic Chronic 1, H410	

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Trade name: Calcimol base

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SECTION 4: First Aid Measures

- · 4.1 Description of first aid measures
- · After inhalation: Seek medical treatment in case of complaints.
- · 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: If symptoms persist consult doctor.
- 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: Fire Fighting Measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- 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 to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 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

For dental use only.

No special precautions are necessary if used correctly.

Follow the instructions for use.

- · 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: See storage instructions on package
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls and personal protection

- · 8.1 Control parameters
- · Additional information about design of technical facilities: No further data; see item 7.
- Ingredients with limit values that require monitoring at the workplace:

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

· Additional information: The lists valid during the making were used as basis.

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- · 8.2 Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals. Avoid contact with the eyes and skin.

· Protection of hands:



Protective gloves

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies 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 prior to the application.

· Eye protection: Safety glasses

SECTION 9: Physical and Chemical Properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance:

· Form:

· Colour:

· Odour:

· pH-value:

Pasty Beige

Aromatic Not determined.

· Change in condition

· Melting point/freezing point:

Undetermined. · Initial boiling point and boiling range: Undetermined.

Flash point:

Not applicable.

Auto-ignition temperature:

Product is not selfigniting.

Explosive properties:

Product does not present an explosion hazard.

Density:

Not determined.

· Solubility in / Miscibility with

· water:

Not miscible or difficult to mix.

· Viscosity:

· Dynamic: · Kinematic: Not determined. Not determined.

· 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 Based on available data, the classification criteria are not met.

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· Skin corrosion/irritation

Causes skin irritation.

· Serious eye damage/irritation Causes serious eye irritation.

- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · 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.
- · Ecotoxical effects:
- · Remark: Toxic for fish
- · Additional ecological information:
- · General notes:

Also poisonous for fish and plankton in water bodies.

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.

- · 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 together with household garbage. Do not allow product to reach sewage system.

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

· 14.1 UN-Number	Attention: special provisions A197 IATA, 375 ADR and/or IMDG-Code paragraph 2.10.2.7 may be applied during transport.
· ADG, IMDG, IATA	UN3082
· 14.2 UN proper shipping name	
ADG	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (zinc oxide)
· IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (zinc oxide), MARINE POLLUTANT
· IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (zinc oxide)

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14.3 Transport hazard class(es)	
ADG, IMDG, IATA	
₩ <u>2</u>	
Class	9 Miscellaneous dangerous substances and articles.
Label	9
14.4 Packing group	
ADG, IMDG, IATA	III
14.5 Environmental hazards:	Product contains environmentally hazardous substance. zinc oxide
Marine pollutant:	Yes Symbol (fish and tree)
Special marking (ADG):	Symbol (fish and tree)
Special marking (IATA):	Symbol (fish and tree)
14.6 Special precautions for user	Warning: Miscellaneous dangerous substances an articles.
Hazard identification number (Kemler code):	90
EMS Number:	F-A,S-F
14.7 Transport in bulk according to Annex II of	pf
Marpol and the IBC Code	Not applicable.
Transport/Additional information:	
ADG	
Limited quantities (LQ)	5L
Transport category	3
Tunnel restriction code	E
UN "Model Regulation":	UN 3082 ENVIRONMENTALLY HAZARDOU SUBSTANCE, LIQUID, 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
- · Australian Inventory of Industrial Chemicals

All ingredients are listed.

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category E2 Hazardous to the Aquatic Environment
- Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t

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.

- · Department issuing SDS: Scientific department
- · Contact: Tel.: +49 (0)4721-719-0

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· 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)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO: International Civil Aviation Organisation
ICAO: International Civil Aviation Organisation" (ICAO)
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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Hazardous according to criteria of Australian Safety and Compensation Council.

SECTION 1: Identification

- · 1.1 Product identifier
- · Trade name: Calcimol catalyst
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the mixture self-curing radiopaque calcium hydroxide paste
- · 1.3 Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

Australien contact and address:

VOCO Australia Pty Ltd.

Suite 406-408, 251 Oxford Street,

Bondi Junction, NSW 2022

- · Further information obtainable from: Australia 02 9369 1770
- · 1.4 Emergency telephone number: Australia: 131126

SECTION 2: Hazard(s) Identification

- · 2.2 Label elements
- · Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.

Eve Dam. 1 H318 Causes serious eye damage.

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

As a medical device the product is not subject to labelling regulations under 1272/2008/EC.

- · Hazard pictograms GHS05
- · Hazard statements

Causes skin irritation.

Causes serious eye damage.

· Precautionary statements

Wear eye protection / face protection.

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

Immediately call a POISON CENTER/doctor.

Specific treatment (see on this label).

Take off contaminated clothing and wash it before reuse.

If skin irritation occurs: Get medical advice/attention.

- · 2.3 Other hazards Use only for intended scope of application
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition and Information on Ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:				
CAS: 1305-62-0	calcium dihydroxide	Eye Dam. 1, H318 Skin Irrit. 2, H315; STOT SE 3, H335	25-50%	
CAS: 1314-13-2	zinc oxide	Aquatic Chronic 1, H410	5-10%	

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SECTION 4: First Aid Measures

- · 4.1 Description of first aid measures
- · After inhalation: Seek medical treatment in case of complaints.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing: If symptoms persist consult doctor.
- · 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: Fire Fighting Measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- · 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 to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 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

For dental use only.

No special precautions are necessary if used correctly.

Follow the instructions for use.

- · 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: See storage instructions on package
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls and personal protection

- · 8.1 Control parameters
- · Additional information about design of technical facilities: No further data; see item 7.
- · Ingredients with limit values that require monitoring at the workplace:

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

· Additional information: The lists valid during the making were used as basis.

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- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals. Avoid contact with the eyes and skin.

· Protection of hands:



Protective gloves

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies 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 prior to the application.

· Eye protection: Safety glasses

SECTION 9: Physical and Chemical Properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance:

· Form:

· Colour:

· Odour:

· pH-value:

Pasty White

Light

Not determined.

· Change in condition

Melting point/freezing point:

Undetermined. · Initial boiling point and boiling range: Undetermined.

Flash point:

Not applicable.

Auto-ignition temperature:

Product is not selfigniting.

· Explosive properties:

Product does not present an explosion hazard.

· Density:

Not determined.

· Solubility in / Miscibility with

· water:

Not miscible or difficult to mix.

· Viscosity:

· Dynamic: · Kinematic: Not determined. Not determined.

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 Based on available data, the classification criteria are not met.

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· LD/LC50 values relevant for classification:

CAS: 1305-62-0 calcium dihydroxide

Oral LD50 7,340 mg/kg (rat)

Skin corrosion/irritation

Causes skin irritation.

· Serious eye damage/irritation

Causes serious eye damage.

- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · 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.
- · Ecotoxical effects:
- · Remark: Toxic for fish
- · Additional ecological information:
- · General notes:

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

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Also poisonous for fish and plankton in water bodies.

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 together with household garbage. Do not allow product to reach sewage system.

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

· 14.1 UN-Number	Attention: special provisions A197 IATA, 375 ADR and/or IMDG-Code paragraph 2.10.2.7 may be applied during transport.
· ADG, IMDG, IATA	UN3082
· 14.2 UN proper shipping name	
· ADG	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE
	LIQUID, N.O.S. (zinc oxide)

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· IMDG · IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (zinc oxide), MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (zinc oxide)
· 14.3 Transport hazard class(es)	
· ADG, IMDG, IATA	
41 × 1	
· Class · Label	9 Miscellaneous dangerous substances and articles.9
· 14.4 Packing group · ADG, IMDG, IATA	III
· 14.5 Environmental hazards:	Product contains environmentally hazardous substances zinc oxide
· Marine pollutant:	Yes Symbol (fish and tree)
· Special marking (ADG): · Special marking (IATA):	Symbol (fish and tree) Symbol (fish and tree)
· 14.6 Special precautions for user	Warning: Miscellaneous dangerous substances an articles.
· Hazard identification number (Kemler code): · EMS Number:	90 F-A,S-F
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	o f Not applicable.
· Transport/Additional information:	
· ADG · Limited quantities (LQ) · Transport category · Tunnel restriction code	5L 3 E
· UN "Model Regulation":	UN 3082 ENVIRONMENTALLY HAZARDOU SUBSTANCE, LIQUID, 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
- · Australian Inventory of Industrial Chemicals

All ingredients are listed.

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category E2 Hazardous to the Aquatic Environment
- Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t

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Trade name: Calcimol catalyst

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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.

- · Department issuing SDS: Scientific department
- · Contact: Tel.: +49 (0)4721-719-0
- Abbreviations and acronyms:

Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1