

MATERIAL SAFETY DATA SHEET

Issue date: August 2009
Replaces: New document

Manufacturer: Sigma Pharmaceuticals Pty Ltd.
Address: 96 Merrindale Drive, Croydon, Victoria 3139
Telephone: (03) 9839 2800

**Considered a dangerous substance according to directive 67/548/EEC and
OSHA 29 CFR 1910.1200(USA)**

Product: LEDERMIX Hardener 'N'

Other names: -
Manufacturer's Product Codes: 007696
UN Number: None allocated
Dangerous Goods Class: None allocated Subsidiary Risk: None
Packaging Class: Not applicable
HAZCHEM Code: Not applicable
Poisons Schedule: S6

PRODUCT TYPE AND USE

A dental restorative agent for the rapid relief of pain associated with acute pulpal and periodontal inflammations.

PHYSICAL PROPERTIES

Description: Clear, colourless to yellow liquid with clove oil odour
Melting Point: No data
Boiling Point: No data
Vapour Pressure: No data
Density: No data
Solubility in Water: Immiscible
Acidity or Alkalinity: No data
Flash Point: No data
Flammability Limits: No data

MATERIAL SAFETY DATA SHEET – Ledermix hardener ‘N’

COMPOSITION

Ingredient	CAS No.	Proportion
Eugenol	64-73-3	High

Other: turpentine oil, macrogol

Concentration guide: *Low (below 10%)* *Medium (10 to 60%)* *High (above 60%)*

HEALTH HAZARD DATA

Maximum allowable concentration in air: Estimated Daily: Up to 2.5 mg/ kg body weight

HEALTH EFFECTS

Swallowed: Mildly discomforting to gastro-intestinal tract.
 Eye: Mildly discomforting and capable of causing a mild, temporary redness of the conjunctiva, temporary impairment of vision.
 Inhaled: Not applicable
 Skin: Extremely discomforting and capable of causing skin reactions that may lead to dermatitis.

FIRST AID

Swallowed: Do not induce vomiting. Rinse out mouth with water, then provide liquid slowly for drinking.
 Eye: Immediately flush with water for several minutes. Get medical attention if pain persists.
 Inhaled: Remove to fresh air. Lay patient down, keep warm and rested. Seek medical attention if ill effects persist.
 Skin: Wash skin thoroughly with soap and water

REACTIVITY DATA

Stability: Store in a cool, dry place below 30°C.
 Hazardous incompatibilities: Avoid contact with strong oxidisers
 Hazardous polymerisation: Will not occur
 Spontaneous ignition: Combustible
 Fire fighting medium and protection: Not applicable

MATERIAL SAFETY DATA SHEET – Ledermix Hardener ‘N’

PRECAUTIONS IN USE

Personal Protection:

Respirator: Not required
Safety glasses/Face mask: Recommended
Gloves: Recommended
Ventilation: Recommended

Flammability: Not flammable

Situations to be avoided:

SAFE - HANDLING INFORMATION

Storage and Transport: Store below 30°C
Spills and Disposal: Clean up with warm water and detergent
Fire/Explosion Hazard: Slight fire hazard when exposed to heat or flame

DISCLAIMER

The information contained herein forms no part of any contract between Sigma and any other party. The information is supplied by Sigma in good faith and is believed by Sigma to be correct, but Sigma makes no representations or warranties as to its correctness or completeness, or to the degree of care or skill used in its creation and compilation. Persons using the information will have to make their own decisions, prior to using the information, as to its suitability for their purposes. Sigma accepts no legal liability for the reliance on the information.

SIGMA PHARMACEUTICALS PTY LTD
ACN 004 118 594

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Issue date: August 2009
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Manufacturer: Sigma Pharmaceuticals Pty Ltd.
Address: 96 Merrindale Drive, Croydon, Victoria 3139
Telephone: (03) 9839 2800

Not classified as hazardous according to worksafe Australia criteria

Product: LEDERMIX Paste

Other names: Ledermix refill No. 2
Manufacturer's Product Codes: 007698
UN Number: None allocated
Dangerous Goods Class: None allocated Subsidiary Risk: None
Packaging Class: Not applicable
HAZCHEM Code: Not applicable
Poisons Schedule: S4

PRODUCT TYPE AND USE

A dental restorative agent for the rapid relief of pain associated with acute pulpal and periodontal inflammations.

PHYSICAL PROPERTIES

Description: .Greyish yellow smooth paste)
Melting Point: No data
Boiling Point: No data
Vapour Pressure: No data
Density: No data
Solubility in Water: Miscible
Acidity or Alkalinity: No data
Flash Point: No data
Flammability Limits: No data

MATERIAL SAFETY DATA SHEET – Ledermix paste

COMPOSITION

Ingredient	CAS No.	Proportion
Demeclocycline HCl	64-73-3	Low
Triamcinolone Acetonitrile	76-25-5	Low

Excipients: Polyethylene glycol, zinc oxide, triethanolamine, calcium chloride

Concentration guide: *Low (below 10%)* *Medium (10 to 60%)* *High (above 60%)*

HEALTH HAZARD DATA

LD₅₀ (rats): 2372 mg/kg for demeclocycline

Maximum allowable concentration in air: Not applicable

HEALTH EFFECTS

Swallowed: Repeated ingestion or swallowing large amounts may cause laboured breathing, nose bleeds and diarrhoea.

Eye: Direct contact may cause moderate irritation. Not hazardous if washed away promptly.

Inhaled: Not applicable

Skin: No significant irritation expected from a single short-term exposure. Repeated or prolonged contact may cause minimal irritation with possible phototoxicity.

FIRST AID

Swallowed: Do not induce vomiting. Drink a glass of water.

Eye: Immediately flush with water for several minutes. Get medical attention.

Inhaled: Remove to fresh air. Seek medical attention if ill effects persist.

Skin: Wash skin thoroughly with soap and water

REACTIVITY DATA

Stability: Store in a cool, dry place below 30°C.

Hazardous incompatibilities: No specific hazardous incompatibilities

Hazardous polymerisation: Will not occur

Spontaneous ignition: Will not occur

Fire fighting medium and protection: Not applicable

MATERIAL SAFETY DATA SHEET – Ledermix Paste

PRECAUTIONS IN USE

Personal Protection:

Respirator: Not required
Safety glasses/Face mask: Not required
Gloves: Recommended
Ventilation: Recommended

Flammability: Not flammable

Situations to be avoided: Avoid contact with oxidising materials

SAFE - HANDLING INFORMATION

Storage and Transport: Store below 30°C

Spills and Disposal: Wash area with copious amounts of water.

Fire/Explosion Hazard: No hazard

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Manufacturer: Sigma Pharmaceuticals (Australia) Pty Ltd.
Address: 96 Merrindale Drive, Croydon, Victoria 3136
Telephone: (03) 9839 2800

Not classified as hazardous according to worksafe Australia criteria

Product: LEDERMIX Powder (cement)

Other names: Ledermix Refill No. 3
Manufacturer's Product Codes: 007699
UN Number: None allocated
Dangerous Goods Class: None allocated Subsidiary Risk: None
Packaging Class: Not applicable
HAZCHEM Code: Not applicable
Poisons Schedule: S4

PRODUCT TYPE AND USE

A dental restorative agent for the rapid relief of pain associated with acute pulpal and periodontal inflammations.

PHYSICAL PROPERTIES

Description: .Fine cream coloured powder
Melting Point: No data
Boiling Point: No data
Vapour Pressure: No data
Density: No data
Solubility in Water: Miscible
Acidity or Alkalinity: No data
Flash Point: No data
Flammability Limits: No data

MATERIAL SAFETY DATA SHEET – Ledermix Powder (cement)

COMPOSITION

Ingredient	CAS No.	Proportion
Demeclocycline HCl	64-73-3	Low
Triamcinolone Acetonitrile	76-25-5	Low

Excipients: Zinc oxide, calcium hydroxide, Canada balsam,

Concentration guide: *Low (below 10%)* *Medium (10 to 60%)* *High (above 60%)*

HEALTH HAZARD DATA

LD₅₀ (rats): 2372 mg/kg for demeclocycline

Maximum allowable concentration in air: Not applicable

HEALTH EFFECTS

Swallowed: Repeated ingestion or swallowing large amounts may cause laboured breathing, nose bleeds and diarrhoea.

Eye: Direct contact may cause moderate irritation. Not hazardous if washed away promptly.

Inhaled: Not applicable

Skin: No significant irritation expected from a single short-term exposure. Repeated or prolonged contact may cause minimal irritation with possible phototoxicity.

FIRST AID

Swallowed: Do not induce vomiting. Drink a glass of water.

Eye: Immediately flush with water for several minutes. Get medical attention.

Inhaled: Remove to fresh air. Seek medical attention if ill effects persist.

Skin: Wash skin thoroughly with soap and water

REACTIVITY DATA

Stability: Store in a cool, dry place below 30°C.

Hazardous incompatibilities: No specific hazardous incompatibilities

Hazardous polymerisation: Will not occur

Spontaneous ignition: Will not occur

Fire fighting medium and protection: Not applicable

MATERIAL SAFETY DATA SHEET – Ledermix Powder (cement)

PRECAUTIONS IN USE

Personal Protection:

Respirator: Not required
Safety glasses/Face mask: Not required
Gloves: Recommended
Ventilation: Recommended

Flammability: Not flammable

Situations to be avoided: Avoid contact with oxidising materials

SAFE - HANDLING INFORMATION

Storage and Transport: Store below 30°C

Spills and Disposal: Wash area with copious amounts of water

Fire/Explosion Hazard: No hazard

DISCLAIMER

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