

MATERIAL SAFETY DATA SHEET LMX4®

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1. Identification of the Product and Company

Product Name:	LMX4®
Product Code:	LMX02943F
Other Names:	None allocated
Use:	Topical anaesthetic.
Company Name & Contact Details	<p>Medical and Regulatory Information Dermocosmetica Pty Ltd ABN 52152881019 Unit 8, 14-16 Lens Street, Coburg North VIC 3058 Australia P.O. Box. 285, Batman VIC 3058 Freecall: 1800 317 534 Email: lmx4@dermocosmetica.com.au; Websites: www.lmx4.com.au; www.dermocosmetica.com.au</p>

Other Information All reasonable care has been taken to ensure information and advice contained in this data sheet is accurate at time of printing. However, Orion accepts no liability for any loss or damages suffered as a consequence of reliance on the information contained herein.

2. Hazards Identification

Hazard Classification	This product is not hazardous or dangerous.
Risk phrase(s)	No component is present at sufficient concentration to require a hazardous classification
Safety phrase(s)	Do not apply near eyes. Not to be used on broken skin.

3. Composition/Information on Ingredients

Chemical Entity	CAS No:	Proportion
Lignocaine	137-58-6	<4% w/w
Benzyl Alcohol	100-51-6	<5% w/w
Phospholipon® 80H	97281-48-6	<10% w/w
Propylene Glycol	57-55-6	<10% w/w
Ingredients determined not to be hazardous	-	to 100% w/w

4. First Aid Measures

Inhalation:	Remove to fresh air immediately. If not breathing, give artificial respiration. Get medical attention immediately.
Ingestion:	Wash out mouth with water if conscious. Do NOT induce vomiting. Obtain medical attention immediately. Components of this product are rapidly absorbed from the gastrointestinal tract.
Skin:	Flush skin thoroughly with water. Seek medical if symptoms persist or occur after washing. Local anaesthesia is expected to last approximately 5 hours.
Eye:	Flush eyes with gently running water for at least 15 minutes. If irritation and/or stinging persist, seek medical attention immediately. Continue to rinse.
Advice to Doctor:	Treat symptomatically.

5. Fire Fighting Measures

Extinguishing Media	Not flammable.
Hazards from Combustion products	On burning, gases hazardous to health may be formed. (CO, CO ₂).
Precautions & Equipment for Fire Fighters	Fire fighters should wear protective clothing, including breathing apparatus, in case of emissions of hazardous gases by combustion products
Hazchem Code	None allocated

6. Accidental Release Measure

In case of spillage: Cleanup personnel to avoid contact with skin. Collect and seal in properly labelled containers for disposal. Wash area down with excess water.
Waste material may be incinerated under controlled conditions where permitted. Refer to local Waste Management Authority Regulations for other approved methods.

7. Handling and Storage

Safe Handling Practices	Wash hands after use. Note that contact with skin will produce transient local anaesthesia which may last up to 5 hours.
Storage	Store below 25°C

8. Exposure Controls; Personal Protection

Exposure Limits:	Not ascertained.
Engineering Controls	No special requirements necessary. Use with adequate ventilation at all times.
Personal Protection	Avoid contact with eyes. When handling large quantities of cream (such as spill clean-up), use chemical resistant gloves and appropriate eye protection. Wash hands after use. Do not smoke, eat or drink while handling this product. Approved barrier creams and chemical resistant gloves may prove useful when prolonged skin contact is unavoidable.

9. Physical and Chemical Properties

Appearance:	White to off-white yellowish cream.		
Odour:	Characteristic	Boiling Point:	Not known
pH:	8 - 10	Freezing/Melting Point:	Not known
Vapour Pressure:	Not known	Solubility:	Slightly in water.
Vapour Density:	Not known	Specific Gravity or Density:	Not known
Flash Point:	> 205°C		

10. Chemical Stability and Reactivity Information

Stability:	Stable under normal ambient and anticipated storage and handling conditions of temperature and pressure. Components are hygroscopic.
Conditions to Avoid:	Avoid exposure to moisture and high temperatures.
Materials to Avoid:	Avoid contact with strong oxidising agents, mineral acids, strong acids, caustics, aliphatic amines and isocyanates.
Hazardous Decomposition Products:	Emits toxic fumes under fire conditions. Combustion can yield carbon dioxide, carbon monoxide and other oxides.
Hazardous Polymerisation:	Will not occur.

11. Toxicological Information

Inhalation:	May be harmful if inhaled. May cause irritation.
Ingestion:	May be harmful if swallowed. May cause abdominal cramps and diarrhoea.
Skin:	Repeated and prolonged contact may cause irritation.
Eye:	May cause irritation.
LD50/LC50	Lidocaine/Lignocaine: Oral rat: 317mg/kg; Oral mouse: 220mg/kg Benzyl Alcohol: Oral rat: 1230mg/kg; Dermal rabbit: 2000mg/kg Propylene Glycol: Skin rabbit: > 100mg/kg; Oral rat: 20g/kg; Oral mouse: 22g/kg
Irritancy Data:	Benzyl Alcohol: Rabbit/skin: skin irritation – 24h Propylene Glycol: Rabbit/eye: mild; Human/skin: mild, moderate
Other Carcinogenicity Data:	Metabolites of lidocaine/lignocaine have been shown to be carcinogenic in laboratory animals.
Reproductive Effects:	Studies in animals have not shown that lidocaine/lignocaine causes adverse events on the foetus. It has been used as a local anaesthetic during delivery. The Centre for the Evaluation of Risks to Human Reproduction concluded that propylene glycol is not a reproductive or developmental toxicant in animals, and that human developmental or reproductive risks are of negligible concern.
Mutagenicity:	Lidocaine/lignocaine hydrochloride was not shown to be mutagenic in the <i>Salmonella</i> /mammalian microsome test not clastogenic in chromosome aberration assay with human lymphocytes and mouse micronucleus test. Propylene glycol was found to cause DNA inhibition and was positive in cytogenic studies in mice and hamster fibroblasts. It has been negative in the Ames <i>Salmonella</i> assay.

12. Ecological Information

Low toxicity to aquatic organisms. Low potential for bioaccumulation. Prevent spilled material from entering sewers, storm drains, other unauthorised draining systems and natural waterways.

13. Disposal Considerations

Disposal Methods & Containers:	Collect and seal in properly labelled containers for disposal. Wash area down with excess water. In case of large spills, clean-up personnel should wear protective clothing and gloves.
Special Disposal for Landfill or Incineration:	Waste material may be incinerated under controlled conditions where permitted. Refer to local Waste Management Authority Regulations for other approved methods.

14. Transport Information

UN Number:	None allocated
UN Proper Shipping Name:	None allocated
DG Class & Subsidiary Risk:	None allocated
Packing Group:	None allocated
Hazchem Code:	None allocated

15. Regulatory Information

Australia

Classified as a Pharmacy Medicine S2, using the criteria for the Uniform Scheduling of Medicines and Poisons (SUSMP).

TGA Registration No. AUST R 126095; AUST R 208815 (with dressings)

NZ

Classified as Pharmacy Only medicine.

Medsafe registration number:TT50-9285

END OF MSDS