

MATERIAL SAFETY DATA SHEET

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Proprietary Name: Versatis

Generic Name: lidocaine 5% medicated plaster

Supplier Name: Teikoku Seiyaku Co., Ltd.

Address: 567 Sanbonmatsu, Higashikagawa, Kagawa 769-2695 Japan

Telephone number: +81-879-25-2221

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENS

Lidocaine 5% medicated plaster (hereafter referred to as Lidocaine plaster) is a medicinal drug product approved by MHRA and FDA, which is deemed safe for application to the skin for pain relief in certain types of neuralgia. Lidocaine plaster is comprised of an adhesive material, containing the active ingredient, which is uniformly applied to one side of a non-woven polyethylene terephthalate felt backing and covered with a polyethylene terephthalate film as a release-liner. The release-liner is removed prior to application of the plaster to the skin. The adhesive material is composed of the following ingredients.

<u>Ingredient</u>	<u>Purpose of Ingredient</u>
Lidocaine (5%)	Active ingredient
Water Purified	Diluent
Glycerol	Humectant
Sorbitol, Liquid (Crystallising)	Humectant
Polyacrylic acid solution 20%	Hydrophilic matrix component
Sodium Polyacrylate	Viscosity enhancing agent
Carmellose Sodium	Viscosity enhancing agent
Propylene Glycol	Solvent
Urea	Humectant
Kaolin, Heavy	Diluent
Tartaric acid	pH adjustment
Gelatin	Viscosity enhancing agent
Poly (Vinyl Alcohol)	Viscosity enhancing agent
Aluminum Glycinate	Hardening agent
Disodium edentate	Hardening retardant
Methyl Parahydroxybenzoate	Preservative
Propyl Parahydroxybenzoate	Preservative

All of the inactive excipients are commonly used in topical drugs and cosmetics. With the exceptions of polyacrylic acid 20% solution and sodium polyacrylate, all of the excipients are included in the current EP and USP/NF, and conform to EP and USP/NF specifications.

SECTION 3. HAZARDS IDENTIFICATION

Label Precautionary Measures

Lidocaine plaster is packaged in a hermetic envelope. If the product is exposed or damaged, then normal precautions should be taken to avoid contact with eyes. Contact with the skin is not harmful. All of the components which can leach out of the plaster are water soluble.

SECTION 4. FIRST AID MEASURES

In case of eye or skin contact, wash the area with cold water.

SECTION 5. FIRE FIGHTING MEASURES

Extinguishable media

Carbon dioxide, dry chemical powder or appropriate form

Special Firefighting Procedures

Wear self-contained breathing apparatus

Unusual Fire and Explosions Hazards

May emit toxic fumes under fire conditions

SECTION 6. ACCIDENTAL RELEASE MEASURES

None

SECTION 7. HANDLING AND STORAGE

No special precautions

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

In the absence of fire, no special exposure control is requested.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor

Lidocaine plaster is a cataplasm consisting of a white to light yellow polymeric adhesive mass with a faint characteristic odor, spread evenly on one side of a non-woven fabric, and covered with a plastic film. The plaster is packaged in a hermetic envelope.

SECTION 10. STABILITY AND REACTIVITY

Stability

Stable

Hazardous Combustion or Decomposition Product

Toxic fumes of:

Carbon monoxide, carbon dioxide

Nitrogen oxides

Hazardous Polymerization

Will not occur

SECTION 11. TOXICOLOGICAL INFORMATION

Acute Effects

May cause irritation with eye or skin contact

Skin or eye contact may result in local anesthesia

Target organs:

Skin

Toxicity Data

Human dermatologic studies for primary irritation contact sensitization, and photo-allergic potential were conducted. No irritation of any kind was observed in any of the test subjects (n=255).

Pharmacokinetic studies show that systemic levels of drug are negligible after 12 hours of continuous application of 3 plasters to the skin.

This product has been judged "safe" by the US FDA.

SECTION 12. ECOLOGICAL INFORMATION

Data not yet available

SECTION 13. DISPOSAL CONSIDERATIONS

This product is suitable for disposal by incineration, or landfill operations.

SECTION 14. TRANSPORT INFORMATIONS

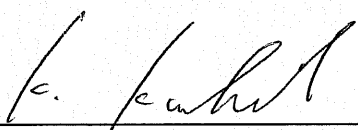
Recommended transport under controlled room temperature

SECTION 15. REGULATORY INFORMATION

Data not yet available

SECTION 16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Teikoku Seiyaku Co., Ltd. shall not be liable for any damage resulting from handling or from contact with the above product.

 2014. 11. 7

Kazuo Kushida

Quality Assurance Manager

Teikoku Seiyaku Co., Ltd.