

1. Intended use / Indication

Lacquer for surface sealing of audiology devices fabricated from silicone.

2. Contraindication

otosil® SL-1 | MSI is contraindicated if...

- ... if a patient is known to be allergic to any of the ingredients.
- ... for every application that is not part of the indication (see above).

3. Product Description

The audioprint® SL-1 | MSI lacquer includes a lactam-based, biomimetic solution for multi-species inhibition\*. This reduces the formation of undesirable biofilms on audio appliances without a microcidal effect.

\*c. albicans / s. mutans

4. Patient Target Group

Persons for whom an earmold is to be created.

5. Intended Users

Earmold laboratory, ENT specialists, hearing aid acousticians

6. Preparation

The surface of the to be lacquered silicone parts has to be roughed first. This can be done with sandpaper. Make sure that all the silicone parts are clean and free of any debris before applying the lacquer.

7. Application

Unscrew the cap of the otosil® SL-1 | MSI container and pour it into a dipping jar (see fig. 1).

Dip the silicone parts in the lacquer and make sure all surfaces are covered in the lacquer (watch out for trapped air bubbles) (see fig. 2).

Make sure the parts are moving to achieve an even coating thickness and prevent the lacquer from accumulating. To accelerate the curing, place the parts into an 80 °C oven and let them cure for 30 min. (see fig. 3).

After the curing, take the parts out of the oven and leave them to cool down.

8. Important working hints

Clean the bottles edge immediately after use, then close the bottle tightly. To ensure the quality of the lacquer, do not return residues of the lacquer back into the original bottle. Do not store in the refrigerator. During the application of the lacquer use a suction system.

9. Notice

Deviations from the described manufacturing processes or storing conditions may lead to different mechanical and optical properties of the material. According to the EU Medical Devices Regulation, users/patients are obliged to report serious events with a medical device to the manufacturer and to the competent authority of the country in which they occurred.

**Caution:** Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground and bond container and receiving equipment. Use explosion-proof equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. In case of fire: Use carbon dioxide to extinguish. Collect spillage. Store in a well-ventilated place. Keep cool.

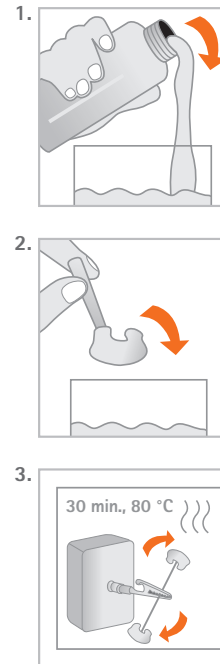
10. Hazard statements

Highly flammable liquid and vapour. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

Lacquer SL-1 | MSI

UMDNS 11-375

Instructions for use



Physical properties\*:

otosil® SL-1 | MSI

- Viscosity: ≤ 0.5 Pas
- Curing time: 30 min. at 80 °C (176 °F)
- Application: at 23 °C ± 2 °C, (73 °F ± 36 °F)
- Storage: 18 °C - 28 °C (64 °F - 82 °F)

Ordering information:

otosil® SL-1 | MSI

250 g;  
clear-transparent  
REF: A0034160

\* These data come from measurements of a representative sample that was determined as part of our quality assurance.

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