

1. Intended use / Indication

Lacquer for surface sealing of audiology devices fabricated from silicone.

2. Contraindication

otosil® SL-1 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. Patient Target Group

Persons for whom an earmold is to be created.

4. Intended Users

Earmold laboratory, ENT specialists, hearing aid acousticians

5. 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.

6. Application

Unscrew the cap of the otosil® SL-1 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.

7. 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.

8. 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.

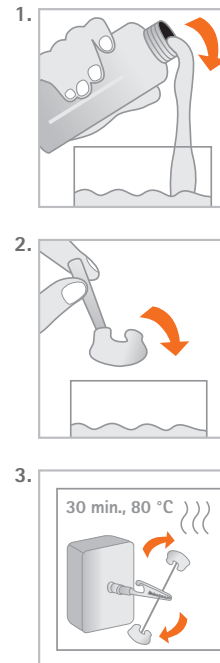
Caution: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground and bond container and receiving equipment. Use explosion-proof equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid release to the environment. Wear protective 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

Instructions for use



Physical properties*:

otosil® SL-1

- 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

100 g:
clear-transparent
REF: A0034151

250 g:
clear-transparent
REF: A0034150

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



This side up.
Diese Seite nach oben.
Ce côté vers le haut.
Este lado hacia arriba.
Questo lato in su.



Temperature limit
Temperaturgrenze
Limite de temperature
Limite de temperatura
Limite di temperature



CE mark
CE Zeichen
CE marca
CE marchio
CE marchio



Warning
Achtung
Attention
Atención
Attenzione



Do not use if package is damaged.
Nicht verwenden, wenn das Paket beschädigt ist.
Ne pas utiliser si l'emballage est endommagé.
No lo use si el paquete está dañado.
Non usare se il pacchetto è danneggiato.



Consult instructions for use.
Gebrauchsanweisung beachten.
Consulter le mode d'emploi.
Consultar instrucciones de uso.
Consultare le istruzioni per l'uso.



Keep dry.
Trocken aufbewahren.
Garder au sec.
Conservare all'asciutto.
Guardar en seco.

Rx only

QTY: 1EA



Medical Device
Medizinprodukt
Dispositif médical
Producto sanitario
Dispositivo medico



Use by date
Haltbarkeitsdatum
Utiliser par date
Utilizar por fecha
Usare entro la data



Catalogue number
Katalognummer
Número de catalogue
Número de catalogo
Numero di catalogo



Lot number
Chargennummer
Número de lote
Número de lote
Numero di lotto



Date of manufacture
Herstellungsdatum
Date de fabrication
Fecha de manufactura
Data di produzione



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