

MATERIAL SPECIFICATION

| | |
|------------------------|--|
| Product: | Fungal nail 10ml |
| Packaging: | A bottle 5 ml packed in outer box, leaflet |
| Product code customer: | Art. Nr.: (PK Benelux BV) 040776 BULK |
| Product code supplier: | PK054 (rec.3352.08) |
| Expiry date: | 24 months after manufacturing |

Ingredients Fungal nail:

| Compounds | Function |
|---|----------------------|
| Aqua | Solvent |
| Ethoxydiglycol | Solvent |
| Urea | Active ingredient |
| Pentylene Glycol | Solvent |
| Alcohol Denat. | Solvent |
| Trideceth-9 | Emulsifying |
| PEG-40 Hydrogenated Castor Oil | Emulsifying |
| Benzyl Alcohol | Solvent |
| Melaleuca Alternifolia Leaf Oil | Antimicrobial |
| Limonene | Perfuming |
| Glycerin | Humectant |
| Sodium Caproyl\Lauroyl Lactylate (Natilact) | Antimicrobial |
| Propylene Glycol | Humectant |
| PVP | Film forming |
| Xanthan Gum | Emulsion stabilising |
| Eucalyptus Globulus Leaf Oil | Perfuming |
| Lavandula Hybrida Grosso Herb Oil | Perfuming |
| Lactic Acid | Active ingredient |
| Linalool | Perfuming |
| Dimethyl Isosorbide | Solvent |
| Citrus Aurantium Dulcis Oil | Masking |
| Pogostemon Cablin Leaf Oil | Perfuming |
| Disodium Phosphate | Buffering |
| Geraniol | Perfuming |
| Citral | Perfuming |
| Biotin | Skin conditioning |
| Coumarin | Perfuming |
| Citric Acid | Buffering |
| Farnesol | Perfuming |

Identification raw materials Fungal nail:

| Raw material | INCI | CAS Number |
|--------------------------------|---|--|
| Aqua demi | Aqua | 7732-18-5 |
| Transcutol CG | Ethoxydiglycol | 111-90-0 |
| Solubilizer | Trideceth-9 PEG-40 Hydrogenated Castor Oil, Aqua, Propylene Glycol | 24938-91-8 / 69011-36-5, 61788-85-0, 7732-18-5, 57-55-6 |
| Hydrolite 5 | Propylene Glycol | 5343-92-0 |
| Urea | Urea | 57-13-6 |
| Alcohol denat. | Alcohol denat. | not available |
| Benzyl Alcohol | Benzyl Alcohol | 100-51-6 |
| Tea-tree oil | Melaleuca Alternifolia Leaf Oil, Limonene, Linalool | 85085-48-9 / 8022-72-8 / 68647- 73-4, 138-86-3, 78-70-6 |
| Glycerine 1.26 | Glycerin | 56-81-5 |
| Dermosoft Decalact | Sodium Caproyl/Lauroyl Lactylate (Natilact) | 13557-74-9 / 13557-75-0 |
| Sinaasappel oil | Limonene, Citrus Aurantium Dulcis Oil, Linalool, Citral Farnesol | 138-86-3, 8008-57-9, 78-70-6 5392-40-5, 4602-84-0 |
| Propylene Glycol USP | Propylene Glycol | 57-55-6 |
| Kollidon 90 F | PVP | 9003-39-8 |
| Xanthan Gum CS | Xanthan Gum | 11138-66-2 |
| Eucalyptus oil | Eucalyptus Globulus Leaf Oil, Limonene, Linalool | 8000-48-4 / 84625-32-1, 138-86-3, 78-70-6 |
| Lavender oil (Lavandin grosso) | Lavandula Hybrida Grosso Herb Oil, Linalool, Limonene, Geraniol, Coumarin | 93455-97-1, 78-70-6, 138-86-3, 106- 24-1, 91-64-5 |
| Purac FCC 80 | Lactic Acid, Aqua | 50-21-5, 7732-18-5 |
| Arlasolve DMI | Dimethyl Isosorbide | 5306-85-4 |
| Patchouli oil | Pogostemon Cablin Leaf Oil, Limonene | 84238-39-1, 138-86-3 |
| RonaCare Biotin Plus | Urea, Disodium Phosphate, Biotin, Citric Acid | 57-13-6, 7558-79-4 / 7782-85-6 58-85-5, 77-92-9 / 5949-29-1 |

Packaging: Bottle 5 ml packed in carton outer box; IFU

Physical analysis:

Appearance: Liquid

Odour: Characteristic

Colour: Cloudy Yellow

Density (g/cm³): 1.00 – 1.05

pH: 4.00 – 5.50

Viscosity: 250 – 1400 cP

(Brookfield DV-I Prime, Spindle LV-4/
Speed 20 rpm/ Temp 19.5-20.5°C):

Microbiology

Total Aerobic Microbial Counts: ≤100 CFU/g

Yeast: ≤10 CFU/g

Moulds: ≤10 CFU/g

Sampling:

Frequency: Every produced batch

Sampling size: ≥3 times (start, middle, end)

Method of analysis: Visual, physical en chemical

Certificate of Analysis: At delivery

DATA SHEET

1. PRODUCT IDENTIFICATION

| | |
|-----------------------|--|
| Product: | Anti-Fungal nail, 5 ml |
| Product category: | A topical antifungal product |
| Product Description: | A glass bottle containing 5 or 10 ml jelly like substance intended to be applied to nails of hands and feet. |
| Classification: | Non-invasive medical device, Class IIA. |
| Assessment procedure: | Medical Device Directive 93/42/EEC amended by 2007/47/EC, Annex V. |

2. DESIGN SPECIFICATION

Anti-Fungal nail ingredients:

| Filling agent INCI | Function | CAS No |
|---------------------------------|-------------------|-------------------------------------|
| Aqua | Solvent | 7732-18-5 |
| Ethoxydiglycol | Solvent | 111-90-01 |
| Urea | Active ingredient | 57-13-6 |
| Pentylene Glycol | Solvent | 5343-92-0 |
| Alcohol Denat. | Solvent | not available |
| Trideceth-9 | Emulsifying | 24938-91-8 / 69011-36-5 |
| PEG-40 Hydrogenated Castor Oil | Emulsifying | 61788-85-0 |
| Benzyl Alcohol | Solvent | 100-51-6 |
| Melaleuca Alternifolia Leaf Oil | Antimicrobial | 85085-48-9 / 8022-72-8 / 68647-73-4 |
| Limonene | Perfuming | 138-86-3 |
| Glycerin | Humectant | 56-81-5 |
| ... | ... | ... |

| Filling agent INCI | Function | CAS No |
|-----------------------------------|----------------------|-------------------------|
| Sodium Caproyl\Lauroyl Lactylate | Antimicrobial | 13557-74-9 / 13557-75-0 |
| Propylene Glycol | Humectant | 57-55-6 |
| PVP | Film forming | 9003-39-8 |
| Xanthan Gum | Emulsion stabilising | 11138-66-2 |
| Eucalyptus Globulus Leaf Oil | Perfuming | 8000-48-4 / 84625-32-1 |
| Lavandula Hybrida Grosso Herb Oil | Perfuming | 93455-97-1 |
| Lactic Acid | Active ingredient | 50-21-5 |
| Linalool | Perfuming | 78-70-6 |
| Dimethyl Isosorbide | Solvent | 5306-85-4 |
| Citrus Aurantium Dulcis Oil | Masking | 8008-57-9 |
| Pogostemon Cablin Leaf Oil | Perfuming | 84238-39-1 |
| Disodium Phosphate | Buffering | 7558-79-4 / 7782-85-6 |
| Geraniol | Perfuming | 106-24-1 |
| Citral | Perfuming | 5392-40-5 |
| Biotin | Skin conditioning | 58-85-5 |
| Coumarin | Perfuming | 91-64-5 |
| Citric Acid | Buffering | 77-92-9 / 5949-29-1 |
| Farnesol | Perfuming | 4602-84-0 |

Packaging:

- A bottle 10 ml
- Outer box
- Leaflet with IFU

3. INTENDED USE

Anti-Fungal Nail is a topical antifungal medical device. The purpose of the gel is to support treatment of fungal nail infections (Onychomycosis) on hands and feet in adults through creating an unfavourable environment for the development of fungi.

4. MODE OF ACTION

Anti-Fungal Nail forms through a combination of ingredients a layer which creates an unfavourable environment for the development of fungi, serves a protective role by forming a physical barrier against spread of fungi. Urea enhances the penetration of the active ingredients into the nail plate. Lactic acid is offering acidic control and creates an antagonistic environment for fungi.

5. DOSAGE AND USE

Anti-Fungal Nail is for topical use. Apply the product on the affected area two or three times a day until the new nail has completely.

6. STORAGE CONDITION

Room temperature (5- 25°C) in a dry dark place in the original container.

7. USE DURING PREGNANCY OR BREAST FEEDING

In accordance with general medical practice, the product should not be used during pregnancy and lactation without medical advice (TCF 8).

8. POSSIBLE SIDE EFFECTS

May cause redness irritation and pruritus to the surrounding healthy skin if the product comes in contact with the normal skin in sensitive people.

9. CONTRAINDICATIONS

Allergies to ingredients of Anti-Fungal Nail.

10. CAUTIONS

- Keep out of reach of children.
- Not suitable for babies or infants.

11. RISK MANAGEMENT

Our manufacturer Benelux BV has established and will maintain throughout the life-cycle an ongoing process for identifying hazards associated with Anti-Fungal Nail and camouflage nail polish, estimating and evaluating the associated risks, controlling these risks and monitoring the effectiveness of the control. This process is based on ISO 14971: 2019 Medical devices – Applications of Risk Management to Medical Devices).

12. TEST REPORTS

a) Biocompatibility

The Biocompatibility of Anti-Fungal Nail has been evaluated. The evaluation and conclusions as to the biocompatibility of Anti-Fungal Nail is based on the assessment of risks and benefits of the material through compilation and assessment of the relevant published scientific literature of:

1. Toxicological evaluation on active ingredient
2. Toxicological evaluation on excipients.
3. Biocompatibility of individual components in relation to the combination in the formulation.

The rationale demonstrated the biocompatibility of Anti-Fungal Nail.

b) Microbiological Safety

Microbiological safety is demonstrated by stability testing based on real time aging and accelerated aging.

c) Clinical data

The active ingredients in the Anti-Fungal Nail are Tea tree oil, urea and lactic acid. A literature study has been performed and summarized based upon Meddev 2.7.1

d) Packaging integrity

TCF 6.4 Packaging Requirements Checklist has been established to ensure conformity with the NEN-EN 11607-1: 2020 standard which specifies the general requirements and test methods for all packaging materials and systems intended for use as packaging for medical devices which are to be terminally sterilized in their packaging. This standard does not apply to packaging materials and systems used for packaging aseptically manufactured products. As this is the only available standard with requirements regarding packaging of Medical Devices, also non-sterile Medical Devices have to follow this Standard, until a more appropriate standard is available. The requirements are based on NEN EN 11607-1: 2020. References to this ISO standard are made in this document.

e) Stability during shelf life

The stability of final product and packing is demonstrated for the shelf life (expiration date) by testing (a) accelerated aging and (b) real time aging.

A General Stability testing protocol and a Rationale of Stability testing NailMed© Gel & Camouflage Lacquer are provided in TCF 8.3. Based on shelf life reports the expiry date of Anti-Fungal Nail is 24 months after production date.