MATERIAL SPECIFICATION

Product:	Athlete’s foot spray, 25 ml
Packaging:	HDPE bottle packed in outer box, leaflet
Product code manufacturer:	Art. Nr.: 4010088
Product code supplier:	Pk047 (rec. 5333-03)
Batch code:	---
Expiry date:	24 months after manufacturing

Raw materials:

Active raw materials	**Specification / active compound**
Urea	Urea
Purac FCC 80	Lactic acid
Additives / Non-active compounds	**Specification / functionality**
Aqua demi	Solvent
Alcohol Denat.	Astringent
Glycerine	Humectant
Dermosoft Decalact	Surfactant
Euxyl PE 9010	Antimicrobial, Deodorant
Kamfer	Denaturant, Fragnance
Menthol	Denaturant, Fragnance
Origanol	Fragrance

Packaging:
- 25 ml in 30ml HDPE bottle with sprayer; with label;
- packed inouter box; with IFU

Physical analysis:

Appearance:	Clear liquid
Odor:	Menthol
Density (g/cm3) (Temp. 20 °C):	0.935-0.940
pH:	4.80-5.50

Microbiology

Total Aerobic Microbial Counts:	≤100 CFU/g
Yeast:	≤10 CFU/g
Moulds:	≤10 CFU/g

Final product:

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:	WeFix Athlete‘s Foot Spray, 25ml
Product category:	Topical antifungal medical device
Product Description:	A liquid substance consisting of urea, lactic acid and excipients.
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

Filling agent INCI	Function	CAS No
Alcohol Denat.	astringent	64-17-5
Aqua	solvent	7732-18-5
Glycerin	humectant	56-81-5
Urea	active ingredient	57-13-6
Sodium Caproyl/Lauroyl Lactylate	surfactant	not available
Phenoxyethanol	antimicrobial	122-99-6
Ethylhexylglycerin	deodorant	70445-33-9
Camphor	denaturant, fragrance component	76-22-2 / 464-49-3 / 21368-68-3
Menthol	denaturant, fragrance component	1490-04-6/2116-51-5/ 89-78-1/15356-70-4
Lactic Acid	active ingredient	50-21-5
4-Terpineol	fragrance	562-74-3

Packaging:

- HDPE bottle with label containing 25 ml
- Outer box
- Leaflet with IFU

3. INTENDED USE

Athlete’s foot spray is a medical device for support the treating fungal infections of the skin of toes and feet (tinea pedis, athlet’s foot).

4. MODE OF ACTION

Athlete’s foot spray mixture forms through a combination of ingredients a persistent barrier (a barrier layer) offering acid pH control, thus creating an unfavourable environment for the development of fungi. It serves a protective role by forming a physical barrier against spread of fungi and helps prevent secondary infection and soothes itch and redness. The product supports the natural production of new healthy skin cells skin repair.
Growth inhibition of pathogenic fungi by Athlete’s foot spray is postulated,
due to several mechanisms:

- Keratolytic activity
- Moisturizing the horny layer
- Acidification of the stratum corneum

5. DOSAGE AND USE

Athlete’s foot spray is for topical use.
Clean and dry affected area, spray the product 2 times per day until the fungus is gone (10-14 days).
Continue to apply for two weeks after symptoms cease.

6. STORAGE CONDITION

Ambient temperature (15- 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

- skin dryness;
- pruritus;
- stinging;
- burning;
- redness.

9. CONTRAINDICATIONS

Allergies to ingredients of Athlete’s foot spray.

10. CAUTIONS

Keep out of reach of children.

11. RISK MANAGEMENT

PK Benelux BV has established and will maintain throughout the life-cycle an ongoing process for identifying hazards associated with Athlete’s foot spray, 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 Athlete’s foot spray has been evaluated.
The evaluation and conclusions as to the biocompatibility of Athlete’s foot spray 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 Athlete’s foot spray.

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 Athlete’s foot spray are urea and lactic acid. A literature study has been performed and summarized based upon Meddev 2.7.1

d) Packaging integrity

TCF 6.2 Packaging Requirements Checklist has been established to ensure conformity with the NEN-EN-ISO 11607-1:2009 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-ISO 11607-1:2009 References to this ISO standard are made in this document.