

VERPACKUNGSZERTIFIKAT

Artikelbeschreibung

Datum: 13.06.2023

Chargen Nr.: 2315524
(337/2019)

Artikelnummer: 301504

Artikelbezeichnung: Minituben 1 ml natur, sterilisiert

Verpackungsdaten

Menge pro VE: 2.500

Verpackt in:

50 Stück in einem Beutel;

50 x 50 Stk. in einem Umbeutel

1 Umbeutel in einem Karton + Etikette + Sterilindikator

keim- und partikelarm verpackt lt. DIN EN ISO 15378:2017

Bildein, 13.06.2023
Ort, Datum

Elpack Packaging GmbH Lager
Paracelsusweg 1
7521 Bildein

BESTRAHLUNGSZERTIFIKAT

Lieferscheinnr.: 20233171

Lieferdatum: 16.06.2023

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PCN	PCN Datum	Produktnr.	Lot Nr.	Dnom [kGy]	Dmin [kGy]	Dmax [kGy]	Pakete Stk
Kundenanlieferschein.: 23-0018							
202308236	16.06.2023	EL301504	2315524	25,0 - 50,0	30,4	37,8	4

Die Behandlung der Produkte erfolgte mittels E-Beam nach EN ISO 13485 sowie ISO 11137.

Die Dosiskontrolle wird durchgeführt. Die Kalibrierung der Dosimeter ist rückverfolgbar auf einen NPL-Standard.

16.06.2023



(Shift Coordinator)



P.IVA/C.F. 02070460239
Cap. Soc. € 10.400,00 i.v.
Reg. Imp. di Verona n. T41441594
REA: VR 216428

www.discos.it



Art. Nr. **301500**

DISCOS srl

SEDE LEGALE

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DECLARATION

This Declaration is used as a document for the assessment of the product safety of cosmetic products in accordance with the EC Cosmetics Regulation 1223/2009. It is used for packaging/packaging materials which are in direct contact with the filling.

Furthermore, this declaration serves for the documentation of compliance with the provisions of Directive 94/62/EC on packaging and packaging waste and the REACH Regulation 1907/2006.

1. Basic data

Date of the Declaration: **22/04/2022** Version No.: 01

Author of the document (packaging manufacturer):

DISCOS SRL - OPPEANO, VERONA - ITALY

Recipient and user of the document (packaging user):

ELPACK PACKAGING GmbH - AUSTRIA

Description of the packaging/packaging part/packaging material:

Specification: **STRIP PP TRANSPARENT 5X1 ML- lot 337/2019**

Data sheets: **ATTACHED FILES (Adflex X 500 F)**

2. Application history

The packaging/packaging part/packaging material specified above is already

- used for cosmetic products yes/ no
- used for foods yes/ no

If necessary, state the product categories (cosmetic products/foods):

3. Declarations of conformity

It is hereby declared that the packaging/packaging part/packaging material complies with the provisions of the following regulations, rules and/or recommendations:

Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food; in conjunction with Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food.

The specific migration limits stated in Regulation (EU) No. 10/2011 Annex I are complied with.

For metal packaging: Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food

German Commodities Regulation based on the Food, Commodities and Feed Code – Section 5

Recommendations of the Federal Institute for Risk Assessment (BfR) for materials in contact with food

For colorants: *CoE Resolution AP (89) 1 "On the use of colorants in plastic materials coming into contact with food"* and Recommendation No. IX of BfR "Colorants for the colouring of plastics and other polymers for commodities" (Status: 01.01.2010)

4. Declaration of substances/additives which are added for the purpose of special functions and/or during manufacturing (e.g. lubricants, antistatic agents)

Substance type: _____ CAS No.: _____

Substance amount: _____

Substance data sheet/safety data sheet as an Annex

Substance type: _____ CAS No.: _____

Substance amount: _____

~~Substance data sheet/safety data sheet as an Annex~~

5. Declaration about the use of biocidal active substances in accordance with Regulation (EU) No. 528/2012 (Biocidal Products Regulation)

Substance type: _____ CAS No.: _____

Substance amount: _____

~~Substance data sheet/safety data sheet as an Annex~~

Substance type: _____ CAS No.: _____

Substance amount: _____

~~Substance data sheet/safety data sheet as an Annex~~

6. Declaration about the use of CMR substances (substances which are classified as carcinogenic, mutagenic or toxic for reproduction in accordance with Annex VI of Regulation (EC) No. 1272/2008)

Substance type: _____ CAS No.: _____

Substance amount: _____

~~Substance data sheet/safety data sheet as an Annex~~

7. Declaration/exclusion of special substance groups

Does not contain / Contains

Substances of Very High Concern (SVHC in accordance with the REACH Regulation 1907/2006)

> 0.1 % per substance (if necessary, specify below).

Substance type: _____ CAS No.: _____

Substance amount: _____

~~Substance data sheet/safety data sheet as an Annex~~

Contains altogether < 100 ppm of the substances Pb, Cd, Hg, Cr (VI) and hence complies with the provisions of Directive 94/62/EC on packaging and packaging waste.

8. Exclusion/restriction of specially declared substances

For the packaging/packaging part/packaging material specified above it is hereby declared that no substances are contained in the packaging/packaging part/packaging material which appear in the following list and/or that their specific migration limit value is complied with:

Substance: _____	CAS No.: _____
Substance: _____	CAS No.: _____
Substance: _____	CAS No.: _____
Substance: _____	CAS No.: _____
Substance: _____	CAS No.: _____
Substance: _____	CAS No.: _____

Name of the author of the document: MRS SPERANZA ELENA

Function of the author of the document: QUALITY ASSURANCE

Date: 22/04/2022

Signature: _____


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