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Place, Date: Oberdiessbach, 21 April 2026
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Declaration of Compliance

1. General Product Information

Name and Address of Producer:

Hoffmann Neopac AG
Burgdorfstrasse 22
3672 Oberdiessbach
Switzerland

Name of Product(s):

Polyfoil MMB Tubes produced in Oberdiessbach according to ISO 9001, ISO 14001, ISCC PLUS and ISO 15378 including body, shoulder and closure for pharmaceutical, cosmetic and food packaging applications.

Description of Product(s):

Neopac article number: 293718

Materials Registration: MR03010.00

Customer reference: NASANFIT

2. Compliance with General Food Contact Legislation

Neopac confirms that the product(s) covered by this declaration comply(ies) with the applicable requirements of EU “Framework” Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food and with Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.
All polymer raw materials comply with current regulations for materials in contact with foodstuff according to European Regulation (EU) No. 10/2011 and all published amendments made to Regulation (EU) No. 10/2011 and FDA 21 CFR.

3. Compliance with Cosmetics Regulation

Neopac tubes are in compliance with Art. 17 and Annex I, Part A, Point 4) of the cosmetics regulation (EC) No. 1223/2009. Concerning phthalates please refer to chapter “Phthalates”. Concerning SVHC substances, please refer to chapter “REACh”.

Regarding requirements from Cosmetic Europe, substances of concern such as mentioned in Annex II and III (>10 ppm) of Regulation (EC) No. 1223/2009, substances classified as CMR 1A, 1B and 2 (>10 ppm) according to CLP regulation (EC) No. 1272/2008 as well as skin sensitizers Cat1A (>100 ppm), Cat1 and 1B (>1000 ppm) of group H317 according to CLP regulation (EC) No. 1272/2008 including all amendments to date are

not intentionally added in the formulation of the plastic raw materials used as contact materials for the product(s).

The Cosmetic regulation (EC) No. 1223/2009 refers principally to the cosmetic formulation and not to the packaging thereof, and is not specific regarding the requirement of cosmetic packaging. Due to this lack of clarity, today it is widely accepted that compliance of packaging for food contact also implies compliance for cosmetic packaging.

4. NIAS (Not intentionally added substances)

Substances used in the manufacture of plastic materials or articles may contain impurities originating from their manufacturing or extraction process. These impurities are non-intentionally added together with the substance in the manufacture of the plastic material (non-intentionally added substance- NIAS). Based on the assessment of the raw materials used and the data / test results available so far, our suppliers confirm that the product meets the relevant requirements of Article 3 of Regulation (EC) 1935/2004 and Article 19 of Regulation (EC) 10/2011.

5. Recycled Plastic Materials

The product(s) do(es) not contain recycled plastic materials as defined by and subject to Regulation (EU) 2022/1616.

6. Color masterbatches

The color masterbatches used in the plastic layer(s) comply with (EU) No. 10/2011 and all published amendments made to date, AP (89) 1 on colorants in plastic materials and with BfR recommendation IX.

Details on FDA 21 CFR compliance are available in raw materials regulatory certificates available to customers upon request and justification for need.

7. Adhesives

The starting substances are listed in Regulation (EU) No. 10/2011 and FDA 21 CFR §175.105.

The adhesive contained in the tube body laminate is cured such that, when tested at time and temperature conditions that are recognize as being at least as severe as the actual conditions of use, the delivered product does not release primary aromatic amines (PAAs) to the food or food simulant in quantities at or above the detection limit as required in Annex II of Regulation (EU) No 10/2011.

8. Printing Inks and Lacquers

Lacquers/varnishes and inks used for tube decoration on the outside of tube bodies (no contact with inside of tubes) are compliant to (EC) No. 1895/2005. Moreover, we can exclude direct set-off from outside to inside layers because the used tube body laminate is not pre-printed and the tube body is printed after shaping in its cylindrical form. Used recipes are not based on bisphenol A and hence are not subject to Regulation (EU) 2024/3190.

Inks and lacquers are in compliance with the EuPIA ”Exclusion Policy for Printing Inks and Related Products” and are formulated and manufactured in accordance with the EuPIA “Good Manufacturing Practice (GMP) Printing Inks for Food Contact Materials” and the EuPIA “Guideline on Printing Inks applied to the non-food contact surface of food packaging”.

Substances that are not listed in (EU) No. 10/2011 comply with Article 3 of Regulation (EC) No. 1935/2004.

All substances used in the manufacturing of the inks are listed in the Swiss Ordinance 817.023.21 Annex 2 and/ or 10.

9. Epoxy Derivatives

Epoxy derivatives Bisphenol A diglycidyl ether (BADGE), Bisphenol F diglycidyl ether, (BFDGE), Novolac glycidyl ether (NOGE), Bisphenol A (BPA), Bisphenol F (BPF) and Bisphenol S (BPS) are not used in the formulation of our polymer raw materials or the manufacturing of our products, in compliance with Regulation (EU) 2024/3190, with the requirements set out in Articles 3, 15 and 17 of Regulation (EC) No 1935/2004 and with the requirements of 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. However, nor our suppliers nor Neopac do test the used raw materials for presence of epoxy derivatives not intentionally added into the formulation.

Lacquers used for tube decoration on the outside of tube bodies (no contact with inside of tubes) are compliant to (EC) No.1895/2005. The recipes are free of BADGE, BFDGE, NOGE, BPA, BPF and BPS.

Performed worst case migration tests with representative tube samples according to Plastics Regulation (EU) 10/2011 under direct analysis and test conditions of 60°C for 10 days in 95% ethanol, we hereby declare that different bisphenols as e.g. BPA, BPF or BPS are not found in migration testing within detection limits which are lower than acceptable levels according above mentioned regulation(s).

10. Statement on Mineral Oil Hydrocarbons (MOH)

Based on supplier information, we confirm that the inks and lacquer specifications used for the tubes, are receptively free of Mineral Oil Aromatic Hydrocarbons (MOAH) and Mineral Oil Saturated Hydrocarbons (MOSH).

We conclude, that the tubes therefore are compliant with article 112 of France Law n° 2020-105 of February 10, 2020 (Loi AGEC) – Decree 2020-1725 of December 29, 2020.

Performed worst case migration tests with representative tube samples according to Plastics Regulation (EU) 10/2011 under direct analysis and test conditions of 60°C for 10 days in 95% ethanol, we hereby declare that mineral oil Hydrocarbons and mineral oil Satured Hydrocarbons (MOAH/MOSH) are not found in migration testing within detection limits which are lower than acceptable levels according above mentioned decree.

11. Phthalates

Based on raw material supplier information, we hereby declare that the tube specifications are manufactured with raw materials where Phthalates are not intentionally used in the manufacture or formulation of the raw materials respectively tubes.

However, Neopac does not test the products for these chemical substances.

12. Active and Intelligent Packaging

The product(s) do(es) not contain active and intelligent materials or articles as defined by and subject to Regulation (EC) No. 450/2009.

13. Heavy Metals

According to our suppliers the raw materials for our manufacturing do not contain heavy metals such as lead, cadmium, mercury, hexavalent chromium or chemical compounds of such elements as part of our recipe, above the level of 100 ppm. Neither are heavy metals added in our own manufacturing process.

For this reason, our final products contain less than the allowed limit of 100 ppm of heavy metals and meet the requirements of Article 5(4) of Regulation (EU) 2025/40 (“PPWR”), as well as CONEG (Coalition of Northeastern Governors).

Based on performed representative worst case migration tests with representative tube samples according to Plastics Regulation (EU) 10/2011 and test conditions of 60°C for 10 days in simulant B, we hereby declare that Cadmium, Chromium, Lead and Mercury, are not found in migration testing within detection limits.

14. Rubber Latex

Natural rubber latex is not used in the manufacturing of the used raw materials for the product(s). During manufacturing of Polyfoil- and Polyethylene tubes at Neopac, no latex in any form is added to the final product(s). However, no analytical measurements for latex presence are performed at Neopac.

15. Genetically Modified Substances (GMO)

Based on the knowledge of the raw materials as well as of the manufacturing process, we are able to confirm that no GMO's (Genetically Modified Organisms) are used in the raw materials for our product(s).

16. Halogenated Materials

Based on raw material supplier information and performed representative worst case tests with representative tube samples under direct analysis (alkaline methanol, 2h/60°C), we hereby declare that Perfluoro- and Polyfluoroalkyl Substances (PFAS) are either not intentionally added and/or not found in testing within detection limits.

Further, we confirm that the product(s) do not contain poly-vinyl-chloride materials (PVC or PVDC) or fluorinated hydrocarbons (PFC) as listed in annex I of Regulation (EU) 2024/590.

However, the determination of PFAS, PVC, PVDC or PFC is not part of our quality control.

17. Allergens

According to our raw materials suppliers the food ingredients listed in Annex II of Regulation (EU) No. 1169/2011 are not used in the manufacture or formulation of the polymeric raw materials for tube production. However, Neopac tubes have not been tested for these substances.

18. Kosher and Halal

The polymeric raw materials cannot be certified to be Kosher/Halal or certified to be in compliance with Kosher/Halal requirements.

19. REACh

As a „downstream user", we know about our responsibilities and are constantly in contact with our suppliers. According to up-stream supplier information, pre-registration and registration of all article components are confirmed. Neopac complies with Art. 33, 1907/2006 and, up to raw materials supplier data sheets, our tubes do not contain any SVHC substances (Art. 57, 1907/2006) at concentration levels >0.1% in weight.

20. Recycling

In general, Polyfoil PE-MMB Tubes are fully compatible with the current European HDPE recycling stream as certified by RecyClass for a semifinished product. As certified by APR (Association of Plastic Recyclers) Polyfoil MMB Tubes with or without thin film metallization are meeting or exceeding the most strict APR HDPE Critical Guidance criteria.

For a final recyclability assessment, the whole tube including the closure/applicator material(s) and dimension (size sorting) need to be taken into consideration. The customer must assess the recyclability of the filled packaging, rated differently depending on the formulation (rate of restitution).

21. Storage and Shelf-Life prior to Filling & Sealing

In agreement with the European Tube Manufacturing Association (ETMA), Neopac declares a shelf-life of 12 months for Polyfoil, PE-Coex and Polyethylene Tubes between tube production date until filling & end-sealing process. Neopac Polyfoil, PE-Coex and Polyethylene Tubes can be stored without any loss of quality over a period of 12 months after date of manufacturing, provided that the tubes are stored

- In normal temperature conditions (>10°C and < 35°C)
- in a place which has a humidity of 40-60% and which is protected against direct sunlight
- in a clean place free of contaminations
- in a way that the stacking of the cardboard boxes which contain the tubes does not lead to any deformation of tubes
- in their original transport packaging

The main reason for shelf-life limitation to 12 months in empty state until filling and end-sealing operation, due to unavoidable ageing processes going on in plastics materials in contact with the atmosphere (surface oxidation etc.), is that the obtained seal strength after end-sealing operation may start to decrease with extended storage times of empty tubes.
As filling and end-sealing operation is under responsibility of our customers, performed and validated with equipment and processing parameters defined by our customers, we highly recommend that customers are putting special attention to end-seal strength obtained with tubes having exceeded Neopac's shelf-life statement prior to filling operation.

For tubes disregarding our shelf-life statement and storage conditions Neopac cannot accept any claims or liability for loss in original quality, for resulting processing problems during filling and sealing or for reduced shelf life of the filled product.

22. Supporting documents

In accordance with Article 16 of the Plastics Regulation, Neopac retains appropriate documentation including supplier DoC's, migration test results, calculations and other evidence on the safety or reasoning demonstrating compliance. Such information is not intended to be passed along the supply chain and will only be shown to competent authorities, on request.

23. Disclaimer

Parts of the product(s) supplied by the customer himself are not covered by this declaration.

This declaration of compliance describes the status of the product(s) specified under "general product information". The user of the product(s), or downstream user if applicable, is responsible for ensuring that the finished tube package complies with applicable migration limits under actual conditions of use with the packed formulation. Furthermore, the user of the product is responsible for verifying possible interactions of the product(s) or its components with the filled formulation (e.g. modification of odour, taste, consistency, migration, change of materials properties etc.), or any possible interaction of the formulation with the product leading to a failure of the packaging, which are to be checked prior to use and in function of the end-uses.

This declaration replaces all previous declarations for the same specification/ product(s). It remains valid until a change in the legislation or new scientific information changes the legal status. If, during this period, Neopac changes the product formulation such that this declaration is no longer accurate, Neopac will notify the customer.

Please do not hesitate to contact your Neopac sales representative for any additional information.

Hoffmann Neopac AG

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