

Place, Date: Oberdiessbach, 07 September 2020
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General Declaration of Compliance

1. General Product Information

Name and Address of Producer:

Hoffmann Neopac AG
Burgdorfstrasse 22, CH-3672 Oberdiessbach, Switzerland
Neopac Hungary Ltd.
Hoffmann str. 1, 4031 Debrecen, Hungary

Name of Product(s):

PE Tubes including body, shoulder and cap for cosmetic and food packaging applications.

Description of Product(s):

Neopac articles:

PE Tubes Ø 30 x 110 mm, WS 0.5, 50 ml (Web shop TUBE 1 - 271705), Material specification: 200820-1
PE Tubes Ø 35 x 120 mm, WS 0.5, 75 ml (Web shop TUBE 2 - 271612), Material specification: 200820-2
PE Tubes Ø 40 x 135 mm, WS 0.5, 100 ml (Web shop TUBE 3 - 271613), Material specification: 200820-3
PE Tubes Ø 50 x 160 mm, WS 0.5, 200 ml (Web shop TUBE 4 - 271614), Material specification: 200820-4

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.

3. Compliance with Cosmetics Regulation

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. 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, BfR recommendation IX as well as with Directive 94/62/EC and CONEG (Coalition of Northeastern Governors).

5. Phthalates

It is well known that phthalates are used as minor component of most catalytic systems for polymerization of polypropylene resins, the catalysts typically containing very low levels of phthalates (< 15 parts per million). Testing of several polymer resins has resulted in the identification of the overall residual phthalate content no more than 10-15 parts per million. Further testing with food simulants (according to Regulation (EU) No.10/2011) has resulted in phthalates not detected at analytic detection limits of 20 parts per billion (0.02 ppm). Details on phthalate trace impurities in polypropylene raw materials are found in the materials regulatory certificates available to customers upon request.

6. 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.

7. Epoxy Derivatives

Epoxy derivatives Bisphenol A diglycidyl ether (BADGE), Bisphenol F diglycidyl ether, (BFDGE), Novolac glycidyl ether (NOGE), Bisphenol A (BPA) and Bisphenol F (BPF) are not used in the formulation of our polymer raw materials or the manufacturing of our products, in compliance with the requirements of Articles 2, 3 and 4 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 polymer materials or the final product for presence of epoxy derivatives not intentionally added into the formulation of the used raw materials.

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 and BPF.

8. 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 Directive 94/62/EC with all published amendments, as well as CONEG (Coalition of Northeastern Governors). However, determination of heavy metal concentration is not part of our quality control.

9. 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 production of tubes.

10. Halogenated Materials

We confirm that above tube references do not contain poly-vinyl-chloride materials (PVC or PVDC) or fluorinated hydrocarbons (PFC).

11. Materials of Animal Origin (BSE/TSE)

As declared by our suppliers, some plastics used in our tube production may contain tallow derived additives. These products (fatty acids, fatty alcohols, metallic soaps, fatty amines, fatty amides, fatty acid esters, glycerine) are incorporated into plastics as lubricants, slip agents, anti-static agents as well as emulsifiers, anti-oxidants or corrosion inhibitors. They are primarily extracted from tissues of ovine or bovine origin. The tallow derivatives used for the production of the plastics materials undergo a series of severe process steps during manufacture:

- Normally, pre-treatment of tallow and/or animal fat with strong acids
- Hydrolytic cleavage at temperatures above 200°C, under pressure, for more than 20 minutes, yielding glycerine and fatty acids
- Transesterification of the fatty acids with methanol at temperatures above 200 °C, under pressure, for more than 20 minutes, yielding fatty acid methyl ester
- Reduction of fatty acid methyl esters with hydrogen at temperatures above 200 °C, under pressure, for more than 20 minutes, yielding fatty alcohols

Tallow derived materials used in this product fulfill the requirements laid down in the Regulations (EC) No. 1069/2009 and 142/2011. Furthermore, during pelletization and conversion, the plastics are exposed to shear stress and to temperatures ranging from 180°C to 300°C during 20 seconds to a few minutes. These successive steps help to ensure the complete protection of people's health in respect of TSE for plastic materials used for food-contact, or similar, applications. No additives other than those present in the processed raw materials are added in our manufacturing. Tubes produced by Neopac are not tested for materials of animal origin.

12. Kosher and Halal

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

13. 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. Used recipes are not based on bisphenol A and hence are not subject to Regulation (EU) 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food.

14. 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. In case of non-compliance, an appropriate substitute will be identified by Neopac. 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.

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

Neopac Polyfoil and PE tubes can be stored over a period of 6 months after date of manufacturing without any loss of quality for subsequent filling & sealing processes, provided that the tubes are stored

- in normal temperature conditions (>10° C and < 35 ° C).
- in a place which is dry and protected against direct sunlight.
- in a clean place free of insects or other organic and inorganic substances and contaminations.
- in a way that the stacking of the cardboard boxes which contain the tubes does not lead to any squeezing of tubes.
- in their original transport packaging.

We cannot accept any liability for loss in original quality, for resulting processing problems during filling and sealing or for reduced shelf life of the packed product if above conditions are not fulfilled.

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).

Hoffmann Neopac AG



Oliver Künzi
(Head of Laboratory and Regulatory Affairs)