

Place, Date: Oberdiessbach, 14 December 2021
Your contact: Oliver Künzi
E-Mail: oliver.kuenzi@neopac.com
Created by: Lukas Stettler

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):

COEX (PE/tie/EVOH/tie/PE) tubes including body, shoulder and cap for cosmetic packaging applications, containing EU and/or US food grade rHDPE and LDPE recycling materials in the tube body, and US food grade rHDPE recycling material in the tube shoulder.

Description of Product(s):

PE-COEX Tubes Ø 30 x 110 mm, WS 0.35, 50 ml (Web shop TUBE - 277269), Material specification: 211214-1
PE-COEX Tubes Ø 35 x 120 mm, WS 0.35, 75 ml (Web shop TUBE - 277311), Material specification: 211214-2
PE-COEX Tubes Ø 40 x 125 mm, WS 0.35, 100 ml (Web shop TUBE - 277316), Material specification: 211214-3
PE-COEX Tubes Ø 50 x 160 mm, WS 0.35, 200 ml (Web shop TUBE - 277317), Material specification: 211214-4

2. Compliance with international food contact regulations

The used PE and PP virgin as well as the rLDPE (PIRLDPE) raw materials comply with the applicable requirements of 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.

The rHDPE recycling material used in the inner layer of the tube body and the tube shoulder does not comply with European requirements of Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food, but does fulfil the US requirements on recycled materials used for articles or components of articles intended to come into contact with food according to letter of no objection from FDA. The material has been registered and complies to REACH and SVHC limitations according to the candidate list. The material complies to CONEG (Coalition of Northeastern Governors).

Specifically, the rHDPE material used in the tube body and shoulder is made from clear food-grade HDPE containers and has been evaluated for suitability for food contact under FDA rules, while the rLDPE material is made from separately collected unmixed LDPE food grade granulate from tube extrusion lamination processes at our tube laminate supplier.

3. Compliance with Commission Regulation (EU) No 10/2011 (Plastics regulation)

3.1 rLDPE (PIR) contained in tube body

The rLDPE material is unmixed production foil based mono-material waste of a well-defined original LDPE food grade granulate raw material originating from extrusion lamination processes during tube laminate production at our tube laminate supplier. The food grade LDPE waste foil material is collected unmixed and marked, and then prepared for re-use by a re-granulation and packing step on a pre-cleaned compounding machine at our tube laminate supplier's. Based on an unmixed production waste collection and re-granulation step without any added substances or additives, the original food contact compliance according to (EU) No 10/2011 and all published amendments to date of the virgin granulate raw material applies to this rLDPE material. By using this high quality post-industrial-recycling material for new tube manufacturing instead of processing into down-cycling as has been done in the past, production waste is prevented at the very beginning of the life-cycle of the final packaging material, addressing the two highest priority orders for waste prevention according to Article 4 of Directive 2008/98/EC: (a) prevention, (b) preparing for re-use.

3.2 Virgin plastic materials used in tube body and cap

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.

4. Compliance with FDA 21 CFR requirements

4.1 rHDPE (PCR) contained in tube body and tube shoulder

According to FDA letter of no objection, the recycling process is effective in reducing potential contaminants from rHDPE (PCR) to levels that do not migrate to food at a dietary concentration of exceeding 0.5 ppb, FDA's threshold of regulatory concern. Therefore, the rHDPE (PCR) material may be used at levels of up to 100% recycled content in the fabrication of articles that contact all food types at room temperature and below, (*i.e.*, Conditions of Use E-G). This determination covers the use of rHDPE (PCR) derived from the feedstock that consists of clear food-grade HDPE containers (*e.g.*, those that hold milk, water and juice), complying with all applicable authorizations. The feedstock excludes industrial/chemical containers.

The rHDPE (PCR) complies with all other applicable authorizations, including 21 CFR § 174.5 - General provisions applicable to indirect food additives. In particular, in accordance with section 402(a)(3) of the Federal Food, Drug and Cosmetic Act, use of the recycled material should not impart odor or taste to food rendering it unfit for human consumption.

5. Compliance with Commission Regulation (EC) No 282/2008 regarding recycled plastic materials

The rLDPE (PIRLDPE) material is from separately collected unmixed tube laminate production waste prepared for re-use with no required cleaning step. Our supplier operates a suitable quality assurance system in accordance with Regulation (EC) No 2023/2006.

6. 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 food contact compliant packaging materials are suitable for cosmetic packaging. Regarding food contact compliance please refer to chapters 2 and 3.

7. 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).

8. 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).

9. 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.

10. Heavy Metals

According to our suppliers the raw materials for our tube 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.

11. Halogenated Materials

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

12. Materials of Animal Origin (BSE/TSE)

As declared by our suppliers, some plastics used in our tube production may contain tallow derivated 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.

13. Kosher and Halal

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

14. 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.

15. REACH

According to up-stream supplier information, pre-registration and registration of all article components are confirmed. The materials do not contain more than 0.1% (w/w) of any SVHC present in the "candidate list" as of the date of this declaration.

16. Recycling

This tube product can be recycled within the normal plastic waste collection.

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

Neopac Polyfoil and PE tubes can be stored over a period of 12 months after date of manufacturing without any loss of quality for subsequent filling & sealing processes, according to the recommendation of the European Tube Manufacturing Association (ETMA), provided that the tubes are stored

- in normal temperature conditions ($>10^{\circ}\text{C}$ and $<35^{\circ}\text{C}$).
- 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)