

September 23, 2024

Subject: ISOFlex Packaging Compliance Information – Absence Substances Statement

Dear Customer:

This letter will provide a statement on substances not present in all ISOFlex Films (hereinafter “the Products”). The information contained herein is based on the state of our actual knowledge (including information obtained from our raw material suppliers), and is neither part of a specification, nor may it be construed as a warranty, express or implied.

ALLERGENS

Allergens are not used in the Product. Note too that we do not test for them.

ANIMAL DERIVED MATERIALS

To the best of our knowledge, animal-derived materials are not intentionally added to either the Products or to any of the raw materials used to produce the Products, and no processing aids of animal origin are used during the production process. Good manufacturing practices (GMP) have been implemented in the production and warehouse areas.

LATEX

"Natural rubber latex", "dry natural rubber", "synthetic latex" or "rubber that contains natural rubber" are not used in the Products.

MINERAL OIL (also MOSH and MOAH)

Several suppliers report that trace quantities of mineral may be present in their products used by ISOFlex. However, these mineral oils would be of food grade quality as specified by FDA and EU. We do not test for mineral oil in the Product.

RECYCLED MATERIALS

Recycled materials are not used in the Products unless requested by customer(s).

CONEG

Our suppliers have assured us that lead, mercury, cadmium and hexavalent chromium are not used in the manufacture of the raw materials we use to make the Products. Furthermore, we do not intentionally use these metals in the manufacture of the Products. Based on these assurances and our good manufacturing practices, we believe that the total combined content of these metals is less than 100 parts per million (ppm). However, we do not test the Products for these metals.

NANOMATERIALS

There is currently no consensus regulatory definition for nanomaterials. However, we do not intentionally use nanomaterials in our Products. We do not test for presence.

CONFLICT MINERALS

Gold, tantalum, tin and tungsten based materials are not used in the Products. However, we do not test for them.

BISPHENOLS

BisPhenols and its derivatives are not used or intentionally added in the manufacture of the Products. However, we do not test the Product for bisphenols presence.

BUTYLATED HYDROXYTOLUENE (BHT)

BHT is not intentionally added to the Product. However, we do not test the Product for presence.

CHLORINE

Free chlorine is not used in the Products. We do not test for chlorine in the Products.

PHTHALATES

Phthalate plasticizers are not used in the Products. We do not test for phthalates presence.

EU SUBSTANCES OF VERY HIGH CONCERN (SVHC)

The Products do not contain any of the Annex XIV candidate chemicals listed as Substances of Very High Concern above the 0.1% threshold as stated in REACH (Article 57, Regulation No. 1907/2006) determined either through (i) non-use of the substance, (ii) mass balance calculation, (iii) specific testing, or (iv) supplier information. The current list of all SVHCs can be found at ECHA website link listed below:

<http://echa.europa.eu/web/guest/candidate-list-table>

EUROPEAN UNION (EU) DIRECTIVE - PACKAGING AND PACKAGING WASTE - 94/62/EC (AS AMENDED)

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RESTRICTION OF HAZARDOUS SUBSTANCES (RoHS)

Cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Di(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Di-n-butyl phthalate (DBP), or Diisobutyl phthalate (DIBP) are not used in the Products. Therefore, we believe the Products comply with RoHS requirements.

GENETICALLY MODIFIED ORGANISMS (GMO)

GMOs are not used in the Products.

OZONE DEPLETING CHEMICALS (ODCs)

Ozone depleting chemicals are not used in the Products. We do not test the Products for ODCs.

OTHER SUBSTANCES

Melamine, Trisnonylphenol phosphite (TNPP), titanium dioxide (TiO₂) and dioxins are not used in the Products. However, no testing for these substances is done.



101 ISO Parkway
Gray Court, SC 29645
864-724-8100
www.isoflexpackaging.com

Ultimately customers must make their own determination that their use of our product is safe, lawful (except as provided in the above certifications) and technically suitable in their intended applications. Because of possible changes in the law and in regulations, ISO Flex Packaging recommends that customers continuing to use our product verify status every year from the issue date of this letter.

Please contact Regulatory@ISOFlexpkg.com if you need additional information.

Sincerely,

Ranga Soundararajan

Dr. Ranga Soundararajan
Technical Director