

Biopack BV
Konijnenboslaan 21
B-8470 Gistel

Declaration of Compliance

Product code	BIODF9077-BIODF9078
Product description	Compostable fibre lids for 80 -90 mm diameter drinking cups
Material	Wood fiber

The manufacturer declares the following:

Comply with Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

Comply with Directive 2001/95/EC (General Product Safety).

Comply with Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Moreover, the products are in compliance with the (Foodstuffs, Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code – LFGB) §§ 30 and 31) and amendments as well as BfR Recommendation XXXVI “Paper and board for food contact”.

Comply with the Decreto Ministeriale del 21/03/1973 as subsequently amended and Supplemented. Comply with DPR 777/82 and subsequent modifications.

Comply with French regulations in force concerning materials and objects in contact with food, namely Decree No. 2007-766 of 10 May 2007, amended by Decrees No. 2008-1469 of 30 December 2008 - No. 2011-385 of 11 April 2011.

Comply with Fiche MCDA n°4 (V02 – 01/01/2019) - Aptitude au contact alimentaire des matériaux organiques à base de fibres végétales destinés à entrer en contact avec des denrées alimentaires as well as French law n° 2012-1442.

Comply with Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food.

Comply with Danish Order on food contact materials and on provisions for penalties for breaches of related EU legislation¹ (Bekendtgørelse nr. 681 af 25. maj 2020).

Comply with the requirements in FDA 21 CFR 176.170.

Comply with Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.



Wood Fiber lids' raw materials
100% Virgin wood pulp fibers FSC certified

The raw materials used in the manufacture of our lids comply with Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food as well as Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

- **Virgin wood pulp fibers**

For the purpose to achieve high chemical and microbiological purity, only virgin pulp fibers are used in the production of our lids:

Moreover, the virgin wood pulp fibers used are in compliance with:

- the (Foodstuffs, Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code – LFGB) in the version of the notification of 3 June 2013, (BGBl. P. 1426), last amendment by article 1 of the act of 30 June 2017 (BGBl. I p. 2147), §§ 30 and 31)
- BfR Recommendation XXXVI on paper and board for food contact
- BfR Recommendation XXXVI/1 on cooking papers, hot filter papers and filter layers
- BfR Recommendation XXXVI/2 on paper and paperboard for baking purposes
- BfR Recommendation XXXVI/3 on absorber pads based on cellulose fibres for food packaging.
- FDA, CFR Title 21 §186.1673 Pulp, as well as with the demands of the Code of Federal Regulations, Food and Drugs (FDA), 21 CFR Ch. I (1 April 2018 edition), §§ 176.170 and 176.180
- GB 9685-2016 Standard for Uses of Additives in Food Contact Materials and Articles
- Chinese Standard GB 4806.1-2016 – General safety requirements of food contact materials and articles
- Chinese Standard GB 4806.8-2022 – Food safety standard paper and paperboard in contact with foodstuffs

Directive (EU) 904/2019

We confirm that the raw materials used in the manufacture of our products are NOT covered by the definition of 'single-use plastic product' as defined in the Directive (EU) 904/2019. Therefore, our products are excluded from the scope of the Directive (EU) 904/2019.

EPOXY REGULATION

Our products do not contain any epoxy derivatives as part of its formulation, i.e. BADGE and its derivatives, NOGE and BFDGE as mentioned in the European Regulation (EC) No 1895/2005.



PACKAGING WASTE, TPCH

The heavy metal cadmium, lead, mercury and chromium^{VI} are not intentionally used in the manufacture of our products. The sum of heavy metals cadmium, lead, mercury and chromium^{VI} incidentally present is below 100ppm. Therefore, our lids comply with Directive 94/62/EC as amended, as well as the limit of US Model Toxics in Packaging Legislation by Toxics in Packaging Clearinghouse (TPCH), established by the Coalition of Northeastern Governors (CONEG).

CALIFORNIA PROPOSITION 65

We hereby confirm that our products do not contain any chemicals known to the State of California to cause cancer, birth defects or other forms of reproductive harm.

FSMA, CGMP

Our lids are manufactured in accordance with Food Safety Modernization Act (FSMA), and Final Rule 21 CFR 117 - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.

ALLERGENS

Our lids are manufactured without the intentional use of substances currently known to be or suspected of being food allergens. Furthermore, they are manufactured without the use of ingredients listed in Annex III LMKV.

Substances currently known as or suspected to be food allergens (listed in Annex II of Reg. (EU) No 1169/2011) are not being part of the raw materials used in their production, not used or intentionally added in their production process, not present in our factory and therefore, contamination from the processing equipment is also excluded.

GLUTEN

We confirm that our products are gluten free.

The raw materials used in their production are gluten free, are not obtained from mixtures of cereals containing gluten (ex wheat) and therefore no gluten is contained in any of our finished products.

No gluten containing materials are being handled at our facilities and therefore no potential for contamination of finished products exists.

GMO

We hereby confirm that Genetically Modified Organisms (GMO) are not intentionally added in the production of our product.



ANIMAL ORIGIN

We hereby confirm that additives of animal origin are not intentionally added in the production of our products.

NANOPARTICLES

We confirm that our products do not release nanoparticles or any additive in nanoparticle form.

RADIOLOGICAL HAZARDS - HAZARD ANALYSIS

We confirm that radiological hazards have been taken into account in our Hazard Analysis, investigating the geographical location and history of the country-of-origin for each component-raw material, ingredients, and packaging material of the final packaging.

IRRITATED FCMS - IRRADIATION AND IRRADIATED MATERIALS

We declare the **Nonuse** of irritated FCMs, taking into account the main radiation sources, including ionizing, radiofrequency, ultraviolet and pulsed light radiation. Our products do not contain residues of radioactive contamination. They have not been treated with ionizing radiation and have not been produced from raw materials treated with ionizing radiation. The products do not contain any ionized or irradiated components.

SUBSTANCES WITH RESTRICTION, DUAL USE ADDITIVES - ADDITIVES CHEMICALLY IDENTICAL WITH A FOOD ADDITIVE OR FLAVOURING:

FCM no.	CAS no.	Name	SML / Limitation	DUAL USE /additive Chemically identical with a food additive or flavouring	NIAS / BY - PRODUCTS
451	2682-20-4	2-Methyl-4-isothiazolin-3-one	SML = 0.5 mg/kg / 80 µg/dm ² (BfR XXXVI)	NO	NO
-	26172-55-4	5-Chloro-2-methyl-4-isothiazolin-3-one	25 µg/dm ² (BfR XXXVI)	NO	NO

The SML / Limitations of substances in the table above are not exceeded based on migration analysis or are covered by the worst-case calculation and are not exceeded under the conditions of use, therefore, specific monitoring is not required.



RISK MANAGEMENT

All raw materials used in the manufacture of our lids have been evaluated and the risk assessment for finished product food contact suitability has been carried out in accordance with the applicable legal provisions and CEPI food contact guidelines 2019.

MINERAL OILS

Mineral oil hydrocarbons (MOH) are not used as raw materials in our production. The NIAS case has also been examined (through our raw materials suppliers) without identifying these chemicals. Recycled fibers are not used in the production of our products and therefore there is less risk of non-intentionally added substances (NIAS) such as traces of printing inks or mineral oils. Mineral oil saturated hydrocarbons (MOSH) or mineral oil aromatic hydrocarbons (MOAH) are not being part of the formulation of our products and the raw materials used in the manufacture of our products do not contain any substance than can degrade into or be capable of releasing any of the above-mentioned restricted substances / compounds as NIAS. Furthermore, Mineral oil saturated hydrocarbons (MOSH) or mineral oil aromatic hydrocarbons (MOAH) are not presented as contaminants in our products in any stage of the production since we have established a quality and food safety management system constantly following Good Hygiene and Manufacturing Practices and we can confirm their absence from our products.

OTHER SUBSTANCES

We also declare that substances such as phthalates, BPA, Bisphenols F and S, Bisphenol derivatives, glycol ethers, PVC-PVDC, Primary Aromatic Amines, Alkylphenols, APEO's, NPEO's, or any other endocrine disrupting chemicals, Fluorosurfactants, PFAS, PFOA/ PFOS, PBBs, PCB's, PAHs, PBDE's, photoinitiators, benzophenones, benzoates, 1- hydroxycycloheptylketone, 2- ethylantraquinone, isopropylthioxanthone, 2-ethylhexyl-4- (dimethylamino)benzoate (EHDAB), ethyl-4-(diethylamino)benzoate (EDAB), Quaternary ammonium salts, Didecylidimethylammonium chloride (DDAC), Benzalkonium chloride (BAC) are not used, not being a part of the production of our products, not presented in our products and the raw materials used do not contain any substance than can degrade into or be capable of releasing any of the above-mentioned restricted substances ensuring products' compliance with European Framework Regulation (EC) no 1935/2004.

Furthermore, we declare the following for our lids:

The concentration of Cadmium (Cd) is < 0.002 mg/dm², the concentration of Lead (Pb) is < 0.003 mg/dm², the concentration of Mercury (Hg) is < 0.002 mg/dm² and the concentration of Pentachlorophenol (PCP) is < 0.1 mg/kg.

OBAs, FWAs, FBAs

Optical brightening agents (OBAs), or fluorescent whitening agents (FWAs), or fluorescent brightening agents (FBAs) are not intentionally added to the raw materials used in the manufacture of our products and we confirm their absence from our products.



NIAS SCREENING ANALYSIS

The results of the screening analysis for not intentionally added substances (NIAS) gave no indication for any objections. Consequently, the results of the NIAS screening comply with the requirements in (EC) 1935/2004 article 3.

REACH REGULATION (EC) 1907/2006

The products do not contain:

- Substances included on the Candidate List of SVHCs (incl. Annex XIV, Authorization) in a concentration above 0.1%
- Substances included in Annex XVII

MIGRATION / TEST REPORTS

BfR XXXVI, FRENCH DGCCRF, (EU) 10/2001, (EC) 1935/2004

TYPE OF ANALYSIS	CONCLUSION	REGULATION OR PROTOCOL
Cold water extraction analysis	Pass	BfR XXXVI & FRENCH DGCCRF
Sensory analysis	Pass	Regulation (EC) No 1935/2004 article 3
Inhibition test	Pass	BfR XXXVI & FRENCH DGCCRF
Fastness of Optical brighteners	Pass	BfR XXXVI & FRENCH DGCCRF
Specific migration of PAA	Pass	BfR XXXVI & FRENCH DGCCRF
Specific migration	Pass	(EU) No 10/2011
Specific migration of mineral oils	Pass	German mineral oil ordinance
Screening of NIAS	Pass (no indication for any objection – No peak to report)	Regulation (EC) No 1935/2004 article 3c.
Specific migration of Metals	Pass	FRENCH DGCCRF



Specific migration of Photoinitiators	Pass	FRENCH DGCCRF
Specific migration of Phthalates	Pass	FRENCH DGCCRF
Specific migration of PAHs	Pass	FRENCH DGCCRF
Content analysis of Bisphenol A	Pass	FRENCH DGCCRF
Content analysis of Pentachlorophenol (PCP)	Pass	FRENCH DGCCRF
Specific migration of PFOA	Pass	FRENCH DGCCRF
Overall migration	Pass	FRENCH DGCCRF

EXTRACTION ANALYSIS (FDA 176.170)

TEST REQUESTED	RESULT
176.170 extractives in 50% alcohol	Pass
176.170 extractives in 8% alcohol	Pass
176.170 extractives in n-heptane	Pass
176.170 extractives in water	Pass

GB 4806.8-2016 MIGRATION ANALYSIS

TEST	LIMIT	RESULT
overall migration into 4% acetic acid (2 hours / 70° C)	10 mg/dm ²	PASS
overall migration into 50% Ethanol (2 hours / 70° C)	10 mg/dm ²	PASS



ITALIAN DM 21.3.73 TEST REPORT

TYPE OF ANALYSIS	CONCLUSION
Fibrous Materials content	Pass
Residue (ash content)	Pass
Auxiliary substances determination	Pass
Insoluble nitrogenous substances determination	Pass
Polychlorobiphenyls content	Pass
Specific migration of formaldehyde	Pass

Moisture, starches, Rosin and derivatives analyses have also been conducted.

PFAS TEST REPORT

TYPE OF ANALYSIS	CONCLUSION	REGULATION OR PROTOCOL
Specific migration of PFASs	Pass	FRENCH DGCCRF (limit of PFOA as a reference)
Content of PFAS	Pass	(EU) 2019/1021

TOF ANALYSIS

TYPE OF ANALYSIS	CONCLUSION	REGULATION OR PROTOCOL
Total Organic Fluor (TOF)	Pass	Danish Guide indicator value

Full details based on the testing and direct comparison with limit values are available upon request.



Specification of the intended use or limitations:

- Type(s) of food intended to come into contact with the product:
 - o All aqueous, acidic and alcoholic foods and milk products, coffee, tea, chocolate, etc...
- Duration and temperature of treatment and storage while in contact with the food:
 - o From 0°C - 70 °C for up to 2 hours, including hot-fill and/or heating up to a temperature T where $70\text{ °C} \leq T \leq 90\text{ °C}$ for maximum of $t = 120/2^{((T-70)/10)}$ minutes, which are not followed by long term room temperature or refrigerated storage.
- Ratio of the area of food contact material to the volume used to determine the compliance of the food contact material or article:
 - o mg/kg: for the EU-convention of 6 dm² packaging for 1 kg food
- Storage:
 - o Storage conditions: from 0° C up to 45°C, protect against moisture.
- Recommended Shelf life:
 - o 24 months

Under FDA:

- o The product has been tested under conditions of use C as described in table 2 of CFR 21 §176.170(c) and may be used in contact with the food types I., II., III., IVA., IVB., VI-A, VI-B and VI-C as described in table 1 of CFR 21 §176.170(c).
- o Product use: at temperatures up to 194°F

Traceability of the products is ensured according to Regulation (EC) No 1935/2004 via the number of the production lot and the date of production displayed in the production carton.

Biopack BV is a trader and does not alter the product.

The information provided is stated on the declaration by the manufacturer of the product.

This declaration is valid from 14/10/2024 and replaces all previous declarations. This declaration may be modified without prior notice. A recent version can always be retrieved.

Gistel, 22/05/2025



Eline Kimpe
Biopack BV

