

Date of issue: April 03, 2024

DECLARATION OF COMPLIANCE

BOPA films are produced by OBEN HOLDING GROUP (OHG) in their transparent versions CAPRAN (PlainFilm), CAPRAN (SealFilm), OXYSHIELD (BarrierFilm) and metalized CAPRAN (MetalFilm), use in each manufacturing process homogeneous raw materials based on food grade polyamide 6 for food contact in all their production plants. These films are produced under an internal quality control system that guarantees the safety and compliance of the established specifications.

OHG is not responsible for failures that may arise as a result of improper handling and/or storage conditions outside the recommendations provided in the film Safety Data Sheets (SDS).

This declaration applies for the next manufacturing sites that produce and distribute BOPA films as previously mentioned:

- **Perú: OPP Film S.A**
Av. San Pedro Mz. B Lte. 48-A Urb. San Vicente, Lurín, Lima, Perú.
- **Argentina: Opp Film Argentina S.A.**
Calle 23 nro. 97, esquina Calle 9 - Parque Industrial Pilar, Argentina.
- **Portugal: Oben Portugal**
Parque Empresarial de Mogueiras lote B-5 / 4970-685 Arcos de Valdevez, Portugal.
- **Polonia: Oben Polonia**
ul.Parkowa 32 / 49-318 Skarbimierz- Osiedle, Polonia.
- **Ecuador: Bopp del Ecuador S.A**
Jaime Roldós E3-37, Carcelén Bajo, Quito, Ecuador.
- **Chile: BOPP Chile S.A**
Fresia 9341, Comuna Quilicura, Región Metropolitana, Chile.
- **Colombia: OPP Film Colombia S.AS.**
Km 114 Vía La Cordialidad, Zona Franca Zofia, Manzana 20, Bodega 318, Colombia.
- **El Salvador: OPP FILM El Salvador S.A de C.V**
Km 35.5 Carretera Quezaltepeque, Sitio del niño, Cantón Chanmico, San Juan Opico, La Libertad, El Salvador
- **México: OPP FILM México S.A de C.V**
Segunda Oriente 206, Parque Industrial Monterrey, Apodaca, Nuevo León CP 66603, México.

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I. FOOD CONTACT STATEMENT

OHG declares that its bioriented polyamide BOPA films are produced in accordance with regulations, legislations, and other established standards, and that they meet the following criteria for materials in contact with food:

I.1. GMP – GOOD MANUFACTURING PRACTICES

In order to prevent any contamination of their products, OHG has implemented policies and food safety procedures that ensure Good Manufacturing Practices (GMP) compliance in every production site. The established controls are based on good manufacturing practices as defined in Regulation (EC) 1935/2004 and their amendments, as well as the "GMP" Regulation (CE) 2023/2006 and their amendments, during the production and distribution processes of the films that OHG produces.

I.2. EUROPE

REACH

The chemical contaminants in the raw materials that are uniformly used in all of OHG's production facilities to produce films are registered by the ECHA (European Chemicals Agency), ensuring that none of the 240 restricted substances (last update: January 23, 2024 (D(2023)8585-DC), annex XIV of REACH regulation) above of 0.1% (threshold that refers to European Regulation (EC) No. 1907/2006/REACH Regulation, modified on 13 November 2023, Regulation (EU) 2023/2482) and Annex XVII of REACH updated on September 25, 2023 by Regulation (EU) 2023/2055.

EC/EU

The films produced in all OHG manufacturing sites are in compliance with Regulation No. 10/2011 and its subsequent amendments, including Nos. 321/2011, No. 1282/2011, No. 1183/2012, No. 202/2014, No. 865/2014, No. 174/2015, No. 1416/2016, No. 752/2017, No. 79/2018, No. 213/2018, No. 831/2018, No. 37/2019, No. 1338, No. 2023/1442, No. 2023/1627 (last update: August 10th, 2023).

HEAVY METALS

PACKAGING AND PACKAGING WASTE

The total amount of heavy metals, including lead, cadmium, mercury, and hexavalent chromium, is below 100 ppm by weight, as per Law 11/1997 on "Packaging and Packaging Waste," which includes Directive 94/62/EC (latest amended: Directive (EU) 2018/852). Regulations EN 13430 and EN 13431 were followed in the production of OHG's films.

RoHS

OHG's film complies with the requirements of Directive 2011/65/EU (latest amendment: (EU) 2024/232) regarding the limits of cadmium, lead, mercury, hexavalent chromium, Polybrominated Biphenyls (PBB), Polybrominated Diphenyl Ethers (PBDE), Bis(2-Ethylhexyl) Phthalate (DEHP), Butylbenzyl Phthalate (BBP), Dibutyl Phthalate (DBP) and Diisobutyl Phthalate (DIBP).

Additionally, all films produced by OHG are in compliance with:

- Italian Statement D.P.R. 777/82 y D.M. 21/03/1973 and subsequent changes to Italian law until the present date Presidential Decree 777/82 and subsequent updates and changes.
- German Consumer Goods Regulation, Be darfsgegenständeverordnung (BedGgstV) and their amendments
- BFR recommendations on materials in contact with food The respective amendments are announced in the Bundesgesundheitsblatt-Gedankenforschung-Gedankenschutz (a monthly federal publication on health, health research and health protection).
- Swiss Ordinance on materials and articles in contact with food, SR 817.023.21.

I.3. USA

FDA/CFR

All films produced at OHG manufacturing sites may be used for food contact material, according to Title 21 of the Code of Federal Regulations of the United States Food and Drug Administration (FDA). Furthermore, they can be used in contact with all types of foods from "I-IX" as described in Table 1 of 21 CFR 176.170(c) and under the conditions of use of "A-H" as described in Table 2 of 21 CFR 176.170(c). The raw materials used to manufacture films at OHG are authorized under 21 CFR 170-189 by specific citation and are Generally Recognized As Safe (GRAS).

Proposition 65 - OEHHA

OHG declares that its film compositions do not contain any substances listed in Proposition 65 of California State and amendments (latest update: December 29, 2023).

TPCH/CONEG

The total amount of heavy metals, including lead, cadmium, mercury, and hexavalent chromium, is below 100 ppm total, as per Toxics in Packaging Clearing House (TPCH) (formerly known as CONEG).

EPA

OHG complies with the requirements stipulated by the Toxic Substances Control Act (TSCA) Inventory Reporting (Section 8(b)), with updates in compliance with the Chemical Data Reporting (CDR), formerly known as the Inventory Update Reporting (IUR).

I.4. CANADA

OHG films comply with the requirements of the Canadian Food Inspection Agency (CFIA), concordant with the Domestic Substances List (DSL) of the Canadian Environmental Protection Act, 1999 (CEPA) came into force on March 31, 2000 and has been updated to include all amendments, Division 23 of the Canadian Food and Drug Regulations (FDR): Regulation CAN / CGSB: 32.310-2020, items 8.1.6 and 1.4 (b1 and b2).

OHG has a "No Objection to Use" letter issued by Health Canada.

I.5. MERCOSUR

OHG films meet the requirements listed in:

- MERCOSUR / GMC / RES: No. 03/92; No. 32/10; No. 11/20; No. 19/21; No. 20/21.

Implicitly, it is in compliance with the following resolutions of Brazil (ANVISA):

- RDC RESOLUTION: No. 51/10; No. 589/21; No. 326/19.

I.6. OTHERS

I.6.1. PERÚ

OHG films meet the requirements according to NTP 399.163-1.2017. Plastic containers and accessories in contact with food, Chapter 1: General provisions and requirements.

I.6.2. COLOMBIA

All materials and/or raw materials used are in accordance with the requirements listed in:

- **RESOLUTION No 000683** of 2012 of the Ministry of Health and Social Protection, on sanitary requirements of materials, objects, containers and equipment intended to come into contact with food and beverages for human consumption.
- **RESOLUTION No 004143** of 2012 of the Ministry of Health and Social Protection, on the technical regulation through which the sanitary requirements of materials, objects, packaging and plastic, elastomeric equipment and its additives intended to come into contact with food are indicated and drinks for human consumption.
- **RESOLUTION No 2014022808** of 2014 of the National Institute for Drug and Food Surveillance through which migration tests are established and verification of compliance with the limits of total and specific migration.

I.6.3. JAPAN

OHG's film complies with the requirements Japan Food Sanitation Act of 1947(included Japan Notification No. 196 of 2020 as published on April 28, 2020 by MHLW (Japan Ministry of Health, Labour and Welfare)) and subsequent amendments.

II. DECLARATION OF COMPOSITION

II.1. GLOBAL MIGRATION

Global migration tests performed on films produced by OHG reveal that the Global Migration Limit (LMG) is below 10 mg/dm², in compliance with section 1 of article 12 of regulation (EU) No 10/2011; MERCOSUR GMC Resolution No. 56/92; and NTP 399.163-1.2017.

II.2. SPECIFIC MIGRATION

In accordance with NTP 399.163-16:2017, Annex I of Regulation (EU) No. 10/2011, and MERCOSUR GMC Resolution Nos. 19/21 and 11/20:

Specific Migration Limit (SML)			
Chemical substance	Ref. N°	Limit (mg/kg)	Observation
Caprolactam	-	15	4

- (1) The calculated concentration of the substance does not exceed one tenth of the restriction in the final article.
 (2) The calculated concentration of the substance does not exceed one quarter of the restriction in the final article.
 (3) The calculated concentration of the substance does not exceed half of the restriction in the final article.
 (4) The calculated concentration of the substance does not exceed the end article restriction.
 (5) The calculated concentration of the substance exceeds the restriction.

In accordance with reference to Article 11, item 3 of Regulation (EU) 10/2011: Regulation (EU) No. 1333/2008 and its amendments (EU) No. 1129/2011 and (EU) No. 380/2012 on Food Additives, Annex II, "Union List of Food Additives Authorized for Use in Foods, and Conditions of Use", the films produced by OHG may contain the following additives that are considered dual use:

Dual use additives	
Aluminum	E173
Monoglycerides and diglycerides of fatty acids	E471

II.3. TYPES OF FOODS AND INTENDED CONDITIONS OF USE

All types of food may come into contact with the films produced by OHG. This was successfully examined through migration tests, using the food simulants A (Ethanol at 10% (v/v)), B (Acetic acid at 3% (w/v)), and D2 (Vegetable Oil).

The following test circumstances were used to analyze:

- Global migration test (LMG): 10 days at 40 degrees.
- Specific migration tests (SML): 10 days at 60 degrees.

Note: for the conducted migration tests, the area of the material in contact with food to the volume utilized to measure the compliance of the plastic material in contact with food was 6 dm² /Kg. Also, consider the maximum 'referential' thickness for BOPA films is 25µm respectively

III. DECLARATION OF ABSENCE

To the best of our knowledge and according to the results of the internal controls, the following substances and their derivatives are not part of the raw materials and are not present during the formulation and manufacturing processes of their products:

III.1. PERFLUORO-ALKYLATED AND POLYFLUORO-ALKYLATED SUBSTANCES

In compliance with current regulations in Europe, Canada, and the USA.

III.2. PHTHALATES

Phthalates listed on the Federal Register 83 FR 56750, which was published on May 20, 2022, as well as the substances under Regulation (EU) 2018/2005, which amends Annex XVII of Regulation (EC) 1907/2006, and Annex to Directive 2005/84/EC, which amends Directive 76/769/EEC

III.3. BISPHENOLS

Bisphenols included on the State of California Proposition 65 List and the Candidate List of Substances of Very High Concern in the REACH authorization procedure are not intentionally included in the production and formulation of their films.

III.4. MOSH/POSH/PAO and MOAH

MOSH (Mineral Oil Saturated Hydrocarbons), MOAH (Mineral Oil Aromatic Hydrocarbons), POSH (Polyolefin Oligomeric Saturated Hydrocarbons) and PAO (Polyalphaolefin).

III.5. EPOXY DERIVATIVES

BADGE, NOGE and BFDGE mentioned in regulation (CE) No. 1895/2005.

III.6. MGM and GMO

Genetically modified materials (MGM- Genetically Modified Microorganism), GMO (Genetically Modified Organism), natural rubber, natural rubber latex, dry natural rubber, synthetic latex, among others, are not intentionally added during the production of OHG's films

III.7. ALLERGENS

None of the known or potential allergens listed in Annex II of Regulation (EU) No. 1169/2011 are present during the manufacture of their products.

III.8. OTHERS

Animal derivatives:

According to the information of OHG's suppliers, the raw materials used to manufacture films are free of contaminants that could cause diseases including bovine spongiform encephalopathy (BSE), transmissible spongiform encephalopathies (EETs), and other substances obtained from animals.

Recycled content:

All Films comply with Regulation (EC) 2023/2006 and do not contain any external or post-consumer recycling materials, thus Regulation (EC) No 282/2008 does not apply.

Films produced at OHG can be recycled according to industry standards.

Conflict Minerals:

To the best of our knowledge none of the substances listed in Annex I of Regulation (EU) 2017/821 are present in the raw materials or during the production or composition of the films.

Biocides:

In compliance with regulation (EU) No 528/2012, neither OHG's production process nor its films include any biocides.

This declaration of compliance is subject to revision if, among other considerations, regulations are changed. The declaration excludes any modifications to the product brought about by the inclusion of other kinds of substances (such as adhesives and adhesion boosters, printing inks, pigments and dyes, solvents, etc.), or by the use of the finished product under inappropriate circumstances, contemplated in the specification of the intended use.

This declaration of conformity was issued in accordance with EU law, the aforementioned regulations applicable to products and materials intended to come into contact with food, the declarations of conformity from our raw material suppliers, and the results of product testing.

It is the responsibility of the user to perform the necessary tests following any conversion and/or packaging process to ensure adequate functionality in accordance with the planned usage of the film.

We confirm that the information mentioned in this declaration is accurate and consistent with our production processes.

Technical Direction

For additional information, please contact the OHG technical department, through the following email:
asistenciatecnica@obengroup.com