
DECLARATION OF CONFORMITY

Article: Rhodoid rolls 100 m/roll, different widths

Customer: Bruyere

Customer art. ref.:

41605066	Col cello HT 45mm – ep 75 µm 100 m: RL
41605073	Col cello HT 50mm – ep 75 µm 100 m: RL
41605075	Col cello HT 60mm – ep 75 µm 100 m: RL
41605240	Col cello HT 40mm – ep 75 µm 100 m: RL

We hereby confirm that our product : is manufactured from Polyethyleneterephthalate (PET) polymers as identified with Code 1 in the list of Annexure 1 of Directive 97/129/EC in accordance with the procedure laid down in Article 1 of Directive 94/62/EC. The Above mentioned grade is manufactured with:

Δ Monomers/starting substances all listed in COMMISSION REGULATION (EU) 2023/1442 of 11 July 2023 amending Annex I to Regulation (EU) No 10/2011 relating to plastic materials and articles intended to come in contact with foodstuffs;

Δ All additives either listed in the plastic regulation (EU) 10/2011 amended till (EU) 2023/1442 of 11 July 2023. These additives also comply with the BFR (German federal Institute for Risk Assessment, previously known as BgVV & BGA) Recommendation XVII, Polyterephthalic acid diolesters.

Δ Above mentioned grade comply with the requirements of Directive 1935/2004/EC as amended till Commission Regulation (EC) No 450/2009.

Δ Above mentioned grade of comply with the requirements of regulation (EU) 10/2011 set out in article 19.

▶ Above mentioned grades meet the relevant requirements laid down in regulation (EC) 1935/2004 in article 3, 11, 15 and 17. In case of article 17, a roll number is mentioned on the roll labels supplied with our film rolls. In order to trace back any of these grades of films used by your organization properly, you have to note this roll no. for traceability.

▶ Directive 2004/1(EC) prohibits the use of azodicarbonamide as blowing agent from 2 August 2005. Above mentioned grade comply with this directive as azodicarbonamide is not used in their manufacture during any stage of production.

▶ Based on results obtained from specific migration test and declaration submitted to us by our supplier, Above mentioned grades do not contain epoxy derivatives as under and hence in compliance to regulation 1895/2005/EC amended to directives 2002/16/EC followed by 2004/13/EC.

- (a) Bisphenol A Di-Glycidyl Ether (“BADGE”)
- (b) 2,3-dihydroxypropyl ether (BADGE.H2O)
- © 2,3-dihydroxypropyl ether (BADGE.2H2O)
- (d) 3-chloro-2-hydroxypropyl glycidyl (BADGE.HCL)
- (e) (3-chloro-2-hydroxypropyl) – (2,3-dihydroxypropyl) ether {BADGE.H2O.HCL}
- (f) 3-chloro-2-hydroxypropyl ether (BADGE.2HCL)
- (g) Bis (4-hydroxyphenyl) methane (“BFDGE”),
- (h) Novolac glycidyl ethers (“NOGE”)

► Directive 2005/84/EC amending Directive 76/769/EEC which puts regulation on the use of Phthalates, (This Directive states that such phthalates “shall not be used as substances or constituents of preparations, at concentrations of greater than 0.1%by mass of the plasticized material.”).

Based on results obtained from specific migration test with reference to Commission Regulation (EU)No. 10/2011 and its amendments. Determination with ref. to EN ISO 18856:2005. Requirement have been referred from Regulation (EU) 2023/1442 amending Annex I to Regulation (EU) 10/2011 and declaration of raw material supplier, we confirm that Phthalates mentioned below meets the compliance requirement.

Parameter	CAS no.
Benzylbutylphthalate (BBP)	85-68-7
Diethylhexylphthalate (DEHP)	117-81-7
Dibutylphthalate (DBP)	84-74-2
Diisobutyl phthalates (DIBP)	84-69-5
Sum (BBP x 0.1 + DEHP x 1 + DBP x 5 + DIBP x 4)	
Diisononyl phthalate (DINP)	28553-12-0 68515-48-0
Diisodecyl phthalate (DIDP)	26761-40-0 68515-49-1
Sum (DINP + DIDP)	

►A new reduction Factor should be introduced in migration testing (FRF)for Lipophilic substances . The grade do not contain any substance falling under list of Lipophilic substances as given in regulation (EU) 10/2011& its amendments.

Migration limits and testing:

The plastic materials are not fully inert and there are substances, which can transfer or migrate from the plastic packaging into the food and vice versa. This migration of substances is regulated by Directive (EU) 10/2011 until its latest amendment (EU) 2023/1442 of 11 July 2023 with two different migration limits:

A. Overall Migration Limit

Regulation (EU) 10/2011 limits the permissible overall migration limit i.e. the total quantity of substances released by the sample to 60 mg/kg or 10mg/dm² under the test conditions set out in Annex III in accordance with the rules set out in chapter 3, section 3.1 of Annex V.

S.NO	Test	Simulant used	Simulant used and Test condition
1.	Overall migration test	10% Ethanol	10 days at 40 °C 4 hrs at 100 °C
2.		3% Acetic acid	10 days at 40 °C 4 hrs at 100 °C
3		20% Ethanol	10 days at 40 °C 4 hrs at 100 °C
4		50% Ethanol	10 days at 40 °C 4 hrs at 100 °C
5		ISO OCTANE	10 days at 40 °C 10days at 60°C
6		95 % Ethanol	2 days at 20 °C 30minute at 60 °C

Above mentioned grades meet the overall migration limits accordingly.

B. Specific Migration Limits (SML)

Regulation (EU) 10/2011 until its latest amendment (EU) 2023/1442 of 11 July 2023 also stipulates specific migration limits (given in mg/kg food) for certain substance. Above mentioned grades meet the specific migration limits accordingly under the test conditions set out in Annex III in accordance with the rules set out in chapter 2, section 2.1 of Annex V. The required SML limits are met with surface-to-volume ratio of 6 dm²/Kg as per regulation (EU) 10/2011 and until its latest amendment (EU) 2023/1442 of 11 July 2023 Where simulants used for tests are A, B, C, D1 and D2 in accordance to Annex V point 2.1.4 (b) Testing for 10 days at 40 °C shall cover all storage times at refrigerated and frozen conditions including hot fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2[^]((T-70)/10) minutes. And point 2.1.4 (d) Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2[^]((T70)/10) minutes.

The following limitations apply under regulation (EU) 10/2011 as amended or as differently specified:

FCM No.	PM Ref.	CAS Nos.	Substances	Limitations
227	16990	000107-21-1	Ethylene glycol	SML(T)= 30 mg/kg (3)
785	24910	000100-21-0	Terephthalic acid	SML(T) = 7.5 mg/kg
398	35760	001309-64-4	Antimony trioxide	SML = 0.04 mg/kg (39) (expressed as antimony)

With regard to the results obtained from the testing of these film under the above mentioned test conditions for specific migration limits as well as overall migration, we hereby declare that above mentioned grades are complies with the regulation (EU) 10/2011 Annex I, table I until its latest amendment (EU) 2023/1442 of 11 July 2023

- Restriction on materials and articles: Regulation (EU) 10/2011 Annex II, imposes the limit for the use of heavy metals. It states that plastic materials and articles shall not release the following substances in quantities exceeding the specific migration limits below:

ELEMENT	RESULTS (mg/kg)	MAX. PERMISSIBLE LIMIT (mg/kg)
	1st Migration	
Barium (Ba)	<0.1	1.0
Cobalt (Co)	<0.030	0.05
Copper (Cu)	<1	5.0
Iron (Fe)	<5	48.0
Lithium (Li)	<0.1	0.6
Manganese (Mn)	<0.1	0.6
Zinc (Zn)	<1.0	5.0
Aluminium (Al)	<0.1	1.0
Nickel (Ni)	<0.01	0.02
Antimony (Sb)	<0.01	0.04
Arsenic (As)	<0.010	0.01
Cadmium (Cd)	<0.002	0.002
Chromium (Cr)	<0.01	0.01
Europium (Eu)	<0.01	0.05(sum)
Gadolinium (Gd)	<0.01	
Lanthanum (La)	<0.01	
Terbium (Tb)	<0.01	
Lead (Pb)	<0.01	0.01
Mercury (Hg)	<0.01	0.01

< = LESS THAN
mg/kg = MILLIGRAM PER KILOGRAM

Based on specific migration test results and suppliers declaration, we confirm that our above mentioned grades are complies with the specific migration limit of metals and are not detected in test limits mentioned above.

- Based on our current manufacturing practice and information provided by our raw material suppliers, The above mentioned grade does not contain the additive (So called "dual-use additives")

or multiple function additives), which are covered by article 5 of regulation 2011/10/EU Annex-I.

We confirm that none of additives (known & unknown) used in above mentioned grade is subject to a migration/transfer their constituents into food in quantities having a technical effect on final food product.

► Directive 2001/18/EC and repealing council directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (GMO). Based on the supplier's information and knowledge of our production process, the above mentioned products do not contain GMO's.

Use of Food Packaging in the United States (FDA conformance)

Above mentioned grade comply with FDA regulations 21 CFR 177.1630 (a) (films made of Polyethylene terephthalate polymers) and specifications therein (e), (f) & (g) with regard to the results for net chloroform soluble fractions obtained from these films under the below mentioned conditions:

Dist. Water 120 deg F / 24 Hrs
n-heptane 120 deg F / 24 hrs 8
% ethanol 120 deg F/ 24 hrs
Dist. Water 250 deg F / 2 Hrs n-
heptane 150 deg F / 2 hrs
50 % ethanol 120 deg F/ 24 hrs

Thus the above mentioned grade films are suitable for food grade applications provided it is subject to limitations found in 21 CFR 177.1630 (e) & (g) where the non-coated side to be kept in direct contact with food and the films are used in accordance with the Good Manufacturing Practice -GMPregulations (defined in 21 CFR 174.5).

This film is a plain film (no coating is used) and the substances/additives used in the film production are as per 21CFR 177.1630 and its specifications.

► Effective from July 14, 2004, The Food and Drug Administration (FDA) has issued regulation 21 CFR Parts 189 and 700 to prohibit the use of certain cattle material, to address the potential risk of bovine spongiform encephalopathy (BSE) & Transmittable spongiform (TSE), in human food, including dietary supplements, and cosmetics. This action is consistent with the recent interim final rule issued by the U.S. Department of Agriculture (USDA) declaring specified risk materials and the carcasses and parts of nonambulatory disabled cattle to be inedible, unfit for human food, and prohibiting their use as human food and requiring that the entire small intestine be removed and disposed of as inedible.

We hereby certify that in the manufacture of above mentioned grade none of animal ingredients or its byproducts are being used. Thus these grade comply with the Food and Drug Administration (FDA) has issued regulation 21 CFR Parts 189 and 700 to prohibit the use of certain cattle material effective from July 14, 2004.

Other Regulations

► REACH-STATUS: On June 1, 2007, the European Commission's new regulatory system (EC 1907/2006) for the Registration, Evaluation, Authorization and restriction of Chemicals (REACH) went into effect.

SVHC substances list published in the Candidate List updated on 14 June 2023

To the best of current knowledge and according to supplier's declarations, we hereby declare that our films do not contain any of 235 specifically identified SVHCs substances at levels greater than

0.1 % (w/w).

► **ROHS:** Directive 2011/65/EU amending directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical & electronic component.

1. Mercury, Cadmium, Lead, Hexavalent Chromium
2. PBB (Polybrominated biphenyls)
3. PBDE (Polybrominated diphenyl ethers)

We confirm that in the manufacturing of above mentioned grades such heavy metals, PBBs or PBDEs as such and their compounds including DECA BDE are not used and thus comply with the RoHS regulations.

► **CONEG** (Coalition of Northeastern Governors) legislation – USA of 1989 : the sum of the concentrations of lead, cadmium, mercury and hexavalent chromium must not exceed 100 ppm. In April 2007 the state of Washington passed a law banning the manufacture, sale, and use of decaBDE in mattresses as of 2008.

We confirm that in the manufacturing of above mentioned grade such heavy metals, PBBs or PBDEs as such and their compounds including decaBDE are not used and thus comply with the above mentioned regulations.

► **The California proposition 65**, The Safe Drinking Water and Toxic Enforcement Act of 1986, was intended to protect California citizens and the State's drinking water sources from chemicals known to cause cancer, birth defects or other reproductive harm and to inform citizens about exposures to such chemicals. We certify that the composition for the above mentioned

grade does not contain such chemicals and thus comply with the above regulation.

► **GMP:** The above mentioned packaging films are being produced under the ISO 22000 – Food Safety & Hygiene certifications covering the Good Manufacturer's Practice – GMP regulations (under the provisions of LFGB § 30 and § 31, EC-regulation 2023/2006/EC as well as US FDA 21 CFR § 174.5 within a quality management system, certified as per ISO 9001:2015) and HACCP (Hazard and Critical Control Points). The film manufacturing also complies with the requirements of ISO 14001:2015 – Environment Management Systems.

► **Mineral oils MOSH, POSH and MOAH** This is to confirm that mentioned substances are not used as a raw material, nor, they added intentionally in any stage of manufacturing process of above mentioned products. We have no reason to expect the presence of above material in our polyester film.

► **Allergenic substances:** During production of the above mentioned films no allergenic substances (Wheat, Crustaceans, Egg, Fish, Peanuts, Soybeans, Milk, Tree Nuts, Mustard, Sesame, Lupin and their products thereof) are used, for which a special food labelling is required by directive 2003/13/EC and amendment 2003/89/EC.

This is to confirm, that all allergens listed according to Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations 2000/13/EC, are not present in our product:

► **Other Substances:** To the best of our knowledge below mentioned substances are not used as raw material, nor intentionally added at any stage of manufacturing of grade films.

Ozone Depletion Substances	Polvaromatic Hydrocarbons (PAH)	Conflict Minerals	Halogen containing substances
Acetylacetone	Biocides	PVC/PVDC	Nanoparticles

Acrylamide	Organotin compounds	ITX	Nonylphenol and nonylphenol ethoxylate
Aromatic amines	CMR substances	Latex	Brominated substances
Asbestos	Dioxins and furans	Triclosan	TNPP antioxidant
Azocolorants	ESBO	PFOA/PFOS /PFAS	N-nitrosamines
Bisphenol	Gylmo glyeo	Endocrine disruptors	GMO , Phthalates

► Specifications on use:

- a) Types of food intended to come into contact with the material: The film can be used for packaging, transporting and holding all type of foods and beverages as per 21CFR177.1630 (g).
- b) Duration and temperature of treatment and storage while in contact with food: 10 days at 60°C tested.
- c) Ratio of the area of the food contact material to the volume used to determine the compliance: 6 dm²/Kg

Info about 2023/1442 + 2023/1627:

Commission Regulation (EU) N^o2023/1442 and Commission Regulation (EU) N^o2023/1627 amending and correcting Regulation (EU) N^o 10/2011 on plastic materials and articles intended to come into contact with food has been published on July 11, 2023 & August 10, 2023.

Based on our suppliers' declarations, we hereby confirm that Commission Regulation (EU) N^o2023/1442 & Commission Regulation (EU) N^o2023/1627 does not impact the current food-contact compliance statements sent to our customers. they still can be considered valid for aboe mentioned grade

However, the products have been not tested for compliances against above regulation.

This statement does not cover: -

- any modification of the products by any addition of any other product to it,
- any modification of the products resulting from processing of the product, or
- an inadequate us and/or storage of the products or the finished articles by the end user.

Responsibilities:

Please note that it is the responsibility of both the manufacturer of the finished food contact articles as well as the industrial food packer to ensure that the finished articles are in actual compliance with the specific and overall migration limits. Our test on film cannot replace migration test on the finished articles, especially if the film is combined with other materials.

By following the above mentioned regulations we have fulfilled our duty of care regarding the conformance of the film we supply with legislation governing food contact applications. It is the responsibility of the user to test the suitability of our products for the intended application. We accept no liability for losses arising from inadequate suitability of our products for the food medium being used by you.

We will inform you of any changes in the composition of our above mentioned grade that are

relevant to food legislation or changes in legislation, which affects their regulatory status. We moreover recommend that you verify on a regular basis, with our marketing representative, the latest contact status of our product.

Cardboard disclaimer:

Roll material: If the product is wound on rolls with cardboard cores, the 5 last windings closest to the core are to be discarded. The outside 2 windings of the rolls are to be discarded as well.

Sheet material: If the product has cardboard supports the 5 sheets closest to the cardboard are to be discarded.

Date of issue: 26-9-23

Name: Ralph Uyttersprot, Quality Manager

A handwritten signature in blue ink, consisting of several loops and a long horizontal stroke extending to the right.