



PRO CLAD TEST REPORT (CLAD-FILM)

APPLICATION IN THE FOOD INDUSTRY



PAROC[®]

A. Applications with Food Contact in Europe

1. Compliance with applicable regulations

Clad-Film complies with the applicable requirements of EU "Framework Regulation" for food contact materials, (EC) 1935/2004, the "Food Contact Plastics Regulation" (EU) 10/2011 and the "Good Manufacturing Practice Regulation" (EC) 2023/2006, as well as the German Food and essential Commodities and Animal Feed Code, or LFGB for short, as well as the Essential Commodities Regulation as follows:

The monomers and additives used for Clad-Film are authorized under Regulation (EU) 10/2011 (as amended by (EU) 321/2011, 1282/2011, 1183/2012, 202/2014, 2015/174 and 2016/1416). Risk assessment of all other components of Clad-Film, including intentionally added components, such as catalysts, and non-intentionally added substances ("NIAS"), such as reaction and degradation products, according to §19 of (EU) 10/2011 has been performed. Thus the composition of Clad-Film complies with the legal requirements throughout the European Economic Area (EU, Iceland, Liechtenstein, and Norway). Clad-Film also fulfils the corresponding requirements in Switzerland. The film complies with the current requirements of BfR (German Federal Institute for Risk Assessment) Recommendation XVII.

Clad-Film complies with the overall migration limit, 10 mg/dm² under the standardized conditions for long term storage at room temperature and below, i.e.:

Simulant	Food type	Test designation	Time and Temperature
A - 10 Vol.-% ethanol	aqueous (hydrophilic)	OM2	10 d at 40°C
B - 3 wt.-% acetic acid	acidic (pH < 4.5)	OM2	10 d at 40°C
D2 - vegetable oil	fatty (lipophilic)	OM2	10 Cd at 40°C

Choice of simulants: According to (EU) 10/2011, Annex III point 4 overall migration testing in simulants A, B and D2 demonstrates compliance for **all types of food**.

Sensory testing with water and fat shows that Clad-Film complies with Para. 3 (1c) of (EC)1935/2004.

2. Substances subject to restrictions

The following substances or substance groups subject to specific migration limits (SMLs) were used to manufacture Clad-Film or could be released if it were hydrolysed:

Confidential				
Substance (group)	Food contact material No.	CAS no:	Limit (SML)	Tests*
terephthalic acid	785	100-21-0	7.5 mg/kg food	✓
ethylene glycol and diethylene glycol	227 and 263 (Group 2)	107-21-1 and 111-46-6	30 mg/kg food (group limit)	✓
2-(4,6-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)-phenol	770	147315-50-2	0.05 mg/kg food	*
manganese acetate	None (Item 1 of Appendix II of 10/2011)	2180-18-9	0.6 mg/kg food (expressed as manganese)	✓
zinc acetate	None (Item 1 of Appendix II of 10/2011)	557-34-6 or 5970-45-6	5 mg/kg food (expressed as zinc)	✓

You may only share this confidential information with customers, institutes, and enforcement authorities for the purpose of assessing compliance of Clad-Film and products containing it.

*Explanation of symbols in the "Tests" column:

✓	The migration of substances with this mark is not detectable in our tests because the substances are chemically bound, the amounts of the substances in the film are far below the SML (e.g. residual monomers), and/or the substances are not mobile in the plastic (e.g. salts). These substances can only be released under conditions that embrittle or destroy the film (hydrolysis under extreme heat, such as melting, or chemical attack).
*	Substances with this mark can migrate and are present in amounts that would exceed the SML. The film passes our migration tests because migration is very slow. We cannot rule out that interactions with plasticizers from other layers in the final product (plastics, adhesives, or printing inks) might accelerate the migration of these substances, particularly at high temperatures. Also note, that our tests for substances with this mark cannot confirm compliance for cases where the "EU cube" convention does not apply, i.e. packaging for infants and young children or packaging in the size range 500 millilitres or grams to 10 litres.

Therefore, for applications where Clad-Film is in intimate contact with materials that contain plasticizers or where the "EU cube" does not apply, the possible migration of the substances marked * should be **tested on the final product**, especially if high temperatures are applied and Clad-Film is the food contact surface.

3. “Dual use” additives

E551 and E650 are used in Clad-Film. These additives do not migrate out of Clad-Film at all, so they cannot cause technical effects or non-compliance of foodstuffs.

4. Permissible use conditions and specific migration test conditions

Specific migration testing confirms that Clad-Film may be used:

- For repeated use articles such as kitchen furniture or storage boxes in contact with all foods at room temperature and below.
- In single use articles such as food packaging, in contact with hydrophilic, acidic, and lipophilic (fatty) food types X/2, X/3, X/4 or X/5, for long term storage at room temperature (and below, including frozen storage).
- In single use articles in contact with X/1 fatty foods only refrigerated or frozen storage is permissible.
- At surface-volume ratios up to 6 dm²/kg food (standard “EU-cube”)

Clad-Film complies with applicable specific migration limits when:

Test conditions to confirm specific migration compliance according to (EU) 10/2011, Appendix V (New conditions of the 6th amendment, (EU) 2016/1416, permissible now and mandatory as of 14 September 2017)

Test conditions		Applicable to	
Simulant	Time and Temperature	Food types	Contact conditions
A - 10 Vol.-% ethanol	10 days at 60°C	hydrophilic (aqueous, alcoholic)	long-term storage (> 6 month) (and repeated use) at room temperature and below
B - 3 wt.-% acetic acid	10 days at 60°C	acidic (pH < 4.5)	
D2 - vegetable oil	10 days at 60°C	lipophilic (fatty) food types listed with X/2, X/3, X/4 or X/5 in D2 column in Annex III	
	10 days at 40°C	any lipophilic (fatty) food	
	3 x 10 days at 60°C	any lipophilic (fatty) food	repeated usage at room temperature or below

Notes:

Choice of simulants: According to (EU) 10/2011, Annex V item 2.1.2, testing in simulants A, B and D2 demonstrates compliance for all types of food.

Old test conditions according to EU Directives 82/711/EEC and 85/572/EEC: May no longer be used.

5. “Functional barrier” status

Clad-Film does not require a functional barrier. Direct contact with food is permissible on both sides.

B. Food contact use in the USA (FDA approval)

Clad-Film is not approved for direct food contact in the United States of America.

All of the components of the film are covered by FDA regulations. However, one additive is used in a higher concentration than would be permissible for direct food contact under the requirements of 21 CFR 178.210 [Code of Federal Regulations Para.178.210, title 21]. The remainder of the components comply with requirements of 21 CFR Art177.1630 for thermoplastic resin and film. As this additive is not volatile it will not be transferred to food via the air, so its use in the proximity of food is permissible as long as it does not directly contact the food surface.

C. Frequently asked questions about other regulations and certain substances

The film does not contain post-consumer recycle or “active or intelligent” components, so Regulations (EC) 282/2008 and 450/2009 are not applicable.

We hereby confirm that the heavy metals cadmium, mercury, lead, and chromium(VI) as such and their compounds are not used in the production of the film. The sum of these heavy metals from possible contaminations is below 100 ppm (DIN 38 406) and complies with Article 11 of EU Directive 94/62/EC (Packaging and packaging waste) as well as with the CONEG Legislation in the USA. Clad-Film also complies with the recoverability requirements set forth in Directive 94/62/EC.

Allergens for which Annex IIIa of Directive 2000/13/EC and Annex II of Regulation (EU) 1169/2011 requires special food labelling are not used in the production of the film.

The formulation of the film does not contain any substance, that derives from “bisphenol A” (2,2-bis(4-hydroxy-phenyl)-propane), such as polycarbonate for example, “BADGE” (bisphenol A diglycidyl ether) or related compounds (“BFDGE” and “NOGE”), azodicarbonamide, vinyl chloride, perfluorooctylsulphonate (“PFOS”), perfluorooctanoic acid (“PFOA”) or 2,4,4'- trichloro-2'-hydroxydiphenyl ether (triclosan). Consequently, none of the following legislation is (or was) relevant: Directives 78/142/EEC, 80/766/EEC, 81/432/EEC, 2004/1/EC and 2011/8/EU, Regulation 1895/2005, 17th amendment of the German Bedarfsgegenständeverordnung.

No plasticizing additives such as “phthalates” (esters of ortho-phthalic acid) or others are used in the formulation of the Clad-Film. Further, the formulation does not include benzophenone, alkyl phenols such as nonyl or octyl phenol, or derivatives thereof.

Clad-Film is no “nanomaterial” as defined in Commission Recommendation 2011/696/EU and is consequently not subject to reporting to the French ANSES agency. Similarly, no reports are required for Clad-Film to the Danish nanomaterial registry.

Under the REACH Regulation (1907/2006), Clad-Film is an “article”. We confirm that it was manufactured in accordance with applicable REACH requirements and that it does not contain substances listed on the SVHC candidate list of 20 June 2016 in amounts above 0.1 weight-%. Accordingly, Article 33 of the regulation does not require any special communication about substances in Clad-Film along the supply chain or to consumers. It is not necessary to request updates every time the SVHC candidate list is changed. In the unlikely event that Clad-Film is affected by such a change, we will inform you.

The Clad-Film is not subject to labelling as a hazardous chemical or mixture according to 67/548/EEC, 1999/45/EC and 1272/2008 (GHS Regulation) and, according to German provisions not classed hazardous to water (no “WGK” - Water Hazard Class). The formulation contains no substances forbidden or restricted by Annex XVII of REACH and 76/769/EEC or subject to authorization by Annex XIV of REACH. As waste, Clad-Film does not form materials that require monitoring according to Directives 91/689/EEC and 91/156/EEC, i.e. it is not hazardous waste.



DURABLE

PAROC® stands for energy-efficient and fire safe insulation solutions of stone wool for new and renovated buildings, marine and offshore, acoustics and other industrial applications. Behind those products, there is an 80-year history of stone wool production knowhow backed with technical insulation expertise and innovation.



REUSABLE

Building Insulation offering covers a wide range of products and solutions for all traditional building insulation. The building insulation products are mainly used for the thermal, fire and sound insulation of exterior walls, roofs, floors and basements, intermediate floors and partitions. Sound absorbing ceilings and wall panels for interior acoustic control, as well as industrial noise control products, are available in the range.



**SOUND
REDUCING**

Technical Insulation offering includes thermal, fire and sound insulation in HVAC systems, industrial processes and pipework, industrial equipment as well as shipbuilding and offshore industry.

For more information please visit www.paroc.co.uk



FIRE PROOF



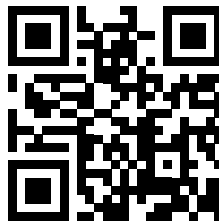
**MOISTURE
PROOF**



SAFE



**ENERGY
EFFICIENT**



Technical information contained herein is furnished without charge or obligation and is given and accepted at recipient's sole risk. Because conditions of use may vary and are beyond our control, Paroc makes no representation about, and is not responsible or liable for the accuracy or reliability of data associated with particular uses of any product described herein. Paroc reserves the right to modify this document without prior notice.