



To: Whom it may concern

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TTM ISOLPAK ALU Weather Protection Film

Declaration of Compliance for Food Contact

There are some regulations that limit the manner in which the film may be used in food contact, which are described in the following sections of this declaration.

Food contact uses in Europe

The film complies with the applicable requirements of the EU “framework regulation” for food contact materials, (EC) 1935/2004 and the “good manufacturing practice regulation”, (EC) 2023/2006, as well as the German LFGB and *Bedarfsgegenständeverordnung*. Note that for the traceability required by these regulations, you must note the 10 digit roll numbers on the labels supplied with our film rolls. Other numbers are not suitable for rapid tracing.

We confirm that the composition of the plastic fulfils all the requirements of the new “plastics implementation measure, PIM”, Regulation (EU) 10/2011 (as amended by Regulation (EU) 321/2011), which is valid throughout the European Economic Area (EU, Iceland, Liechtenstein and Norway) as of 1 May 2011. It also fulfilled the requirements of the “plastics directive” 2002/72/EC (up to and including amendment 2011/8/EU) and its corresponding regulations in the Member States, which were replaced when Regulation (EU) 10/2011 came into force. It also fulfils the corresponding requirements in Switzerland. The polymer complies with the current requirements of BfR (German Federal Institute for Risk Assessment) Recommendation XVII.

The film does not contain post-consumer recycle nor “active or intelligent” components, so Regulations (EC) 282/2008 and 450/2009 are not applicable.

Beside normal compliance with migration limits and appropriate testing media, there are no particular limitations on the conditions of contact between product name and food in Europe. Both sides are permissible in food contact. Such limitations do exist in the United States, however.

Migration limits and testing

Regulation (EU) 10/2011 (like the previous Directive 2002/72/EC) limits the permissible overall migration to 10 mg/dm². The Union List also stipulates specific migration limits (SMLs, given in mg/kg food). The applicable SMLs for this film product are listed in a confidential appendix to this Declaration which is available on request. The appendix also describes when and which tests on the final food contact article are needed. As supplied, the film fulfils both the overall and the specific migration limits under the following test conditions:

<i>test conditions</i>		<i>applicable to</i>	
<i>simulant</i>	<i>time and temperature</i>	<i>food types</i>	<i>contact conditions</i>
3 wt.-% acetic acid	30 minutes at 130° C, then 10 days at 40° C	aqueous and/or acidic	heating for up to 30 minutes 130° C (sterilization) and long term storage at room temperature or below
10 vol.-% ethanol	10 days at 40° C	alcoholic	long term storage at room temperature or below
olive oil	10 days at 40° C	fatty (incl. cheese, but not other milk products)	long term storage at room temperature or below

For further details on testing conditions and permissible conditions of use (time, temperature, type of food), please refer to the current versions EU Directives 82/711/EEC and 85/572/EEC as well as the standard series EN 1186 and EN 13030. (Note that the conditions and simulants of 82/711/EEC and 85/572/EEC are mandatory until to 31 December 2012. Only after that date may or must the new conditions and simulants of Regulation (EU) 10/2011 be used.)

Specific migration values given in mg/kg food are converted to mg/dm² film surface by dividing by the standard conversion factor 6, since by definition 1 kg food is enclosed by 6 dm² film ("EU cube" conversion). Our determination of compliance relies on the "EU cube", but not on fat reduction factors (FRF).

Please note that it is the responsibility of both manufacturers of the food contact articles and industrial food packers to ensure that the finished articles are in actual compliance with the specific and overall migration limits. Please refer to the confidential appendix for further information on what migration testing, if any, may be required for your product. This confidential appendix is available on request.

Food contact uses in the United States (FDA conformance)

This 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 § 178.2010. The remainder of the components comply with requirements of 21 CFR §177.1630. 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. The film may also be used in applications where it is separated from food by a functional barrier consisting of metal.

Frequently asked questions about other regulations

We confirm that the heavy metals cadmium, mercury, lead and chromium6+ 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. The film also complies with the recoverability requirements set forth in Directive 94/62/EC.

The allergens for which Annex IIIa of Directive 2000/13/EC (including all amendments up to 596/2009) requires special food labelling are not used in the production of this film.

The film contains no substances that are derived from "bisphenol A" (2,2-Bis(4-hydroxyphenyl)propane), such as polycarbonate, "BADGE" (bisphenol A diglycidyl ether) or related compounds ("BFDGE" and "NOGE"), azodicarbonamide, vinyl chloride or 2,4,4'-trichloro-2'-hydroxydiphenyl ether (triclosan). Consequently, none of the following legislation is relevant: Directives 78/142/EEC, 80/766/EEC, 81/432/EEC, 2004/1/EC and 2011/8/EU, Regulation 1895/2005.

No plasticizing additives such as "phthalates" (esters of *ortho*-phthalic acid) or others are used in the formulation.

Under the REACH Regulation (1907/2006), the film is an "article". We confirm that it does not contain substances listed on the SVHC candidate list of 20 June 2011 in amounts above 0.1 weight-%. Accordingly, Article 33 of the regulation does not require any special communication about substances in the 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 the film is affected by such a change, we will inform you.

The 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). It is not classified as hazardous to water according to German regulations (no "WGK"). The formulation contains no substances forbidden or restricted by 76/769/EC and Annex XVII of REACH or subject to authorisation by Annex XIV of REACH. As waste, it does not form materials that require monitoring according to Directives 91/689/EEC and 91/156/EEC, *i.e.* it is not hazardous waste.

General

We have confirmed that this film complies with the legal requirements of regulations applicable to food contact materials. It is the responsibility of the user to test the suitability of our products for the intended packaging form and process, together with the intended foods. We recommend a practical test.

Consequently we accept no liability for losses arising from the inadequate suitability of our products for your packaging design or its inadequate suitability for a particular food.

This Declaration is intended for your company only and replaces previous Declarations of Compliance for Food Contact for European countries and the USA. It is valid only when signed by us, either manually or electronically. It will remain valid until 31 December 2014, unless:

- It is replaced by an updated Declaration, or
- No purchases occur for a period of more than 12 months, in which case it will not be valid for new deliveries. In this case, a new Declaration should be requested.

Within an ongoing business, we will inform you of any changes in the composition of the film which are relevant to food legislation or changes in legislation which affect its regulatory status by sending an update to the recipient of this Declaration, usually by e-mail.



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