

# <u>Declaration of compliance</u> <u>Aluminium barrier film A30T, unprinted</u>

Composition 12 μ PET/12 μ Alu/95 μ LDPE

#### 1 Issuer of the Declaration of compliance

The company
Long Life for Art, Christoph Waller
Hauptstraße 47
79356 Eichstetten confirms based on the information available to us as following:

## 2 Identity of the plastic material or article

Tradename	Polymer type	Material no.
aluminium laminate film A30	laminate PET/Adh/AL/Adh/PE	
aluminium laminate film A30/4	laminate PET/Adh/AL/Adh/PE	

## 3 General provisions

We confirm, that the materials and articles listed in section 2 are suitable as food packaging and meet the relevant requirements laid down in the following Regulation (in each case including all amendments and in the version that is valid at the date of issue of this declaration)

- Regulation (EC) No 1935/2004 (article 3, 11 (5), 15 and 17)
- Regulation (EU) No 10/2011

Information about compliance testing with the applicable regulations are given in chapter 5 and 8. If necessary, tests are delegated, for which the user is responsible.

## 3.1 Transition period

Amendments of Regulation (EU) No 10/2011 are published regularly. Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation may be placed on the market until the end of a transition period which is usually mentioned in the amendment. During the transition period this Declaration of Compliance also relates to the valid version as applicable before the amendment.

#### 4 Plastics

#### We confirm

- that substances intentionally added to plastics, not subject to listing in the Union List comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 of the Plastics Regulation has been performed. If the risk assessment in accordance with Article 19 Plastics Regulation has not been completed in the previous stages, the identity of the substance together with relevant information for the risk assessment is provided in section 5
- that reaction intermediates, decomposition or reaction products in plastics comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 of the Plastics Regulation has been performed. If the risk assessment in accordance with Article 19 of the Plastics Regulation has not been completed in the previous stages, the identity of the substance together with relevant information for the risk assessment is provided in section 5
- that the complies with the overall migration limit (OML) of 10 mg/dm². Details on the test conditions used in this assessment and the simulant(s) are mentioned in section 8
- that the food contact material not yet in contact with food and intended for direct use by consumers complies with organoleptic requirements. Details on the test conditions used in this assessment and the simulant(s) are mentioned in section 8

Long Life for Art Christoph Waller Hauptstrasse 47 D - 79356 Eichstetten Fon: +49 (0)7663 60 89 9-0 Fax: +49 (0)7663 60 89 9-20

E-Mail: info@LLFA.de USt-IdNr.: DE142078540 Bankverbindung: Postbank Stuttgart Postfach, D – 70304 Stuttgart IBAN: DE74 6001 0070 0267 6737 01

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### 5 Substances with restrictions

We hereby confirm that the restrictions listed in the following sections are met for all substances that are marked as compliant (図) for the use specified in section 7.

The user of the finished material or article must ensure compliance with the limits or Article 19 of the Plastics Regulation for all substances which are not marked as compliant (X) when used differently.

If the material contains components which are not listed in the positive list of Regulation (EU) 10/2011 (e.g. (additives, solvents, catalysts, monomers, etc.), they comply with any national provisions applicable to these materials and articles e.g. the Federal Institute for Risk Assessment (BfR) recommendations or FDA regulations.

# 5.1 List of substances contained with restrictions and/or specifications according Regulation (EC) no 10/2011

Substance	FCM-No.	CAS-No.	limt	conform
terephthalic acid	785	0000100-21-0	7,5 [mg/kg food] (SML(T))	×
isophthalic acid	291	0000121-91-5	5 [mg/kg Food] (SML(T))	X
ethylene glycole	227	0000107-21-1	30 [mg/kg Food] (SML(T))	×
diethylene glycole (expressed as ethylene glycole)	263	0000111-46-6	30 [mg/kg Food] (SML(T))	X
antimony trioxide (expressed as antimony)	398	0001309-64-4	0,04 [mg/kg Food] (SML)	X
acrylic acid and their esters			6 [mg/kg Food] (SML)	(⊠)¹
methacrylic acid and their esters			6 [mg/kg Food] (SML)	(⊠)¹
acetaldehyde	128	0000075-07-0	6 [mg/kg Food] (SML(T))	×
confidential substances				<b>(⊠)</b> <sup>1</sup>
diphenylmethan-4,4'-diisocyanate	198	0000101-68-8	0,01 [mg/kg Food] (SML(T))	×
2,4-toluenediisocyanat e	354	0000584-84-9	0,01 [mg/kg Food] (SML(T))	×
hexamethylendiisocyanat e	372	0000822-06-0	0,01 [mg/kg Food] (SML(T))	×
1,1,1-trimethylolpropane	141	0000077-99-6	6 [mg/kg Food] (SML)	×
octadecyl-3-(3,5-di-ter-butyl-4-hydroxy- phenyl) propionate	433	0002082-79-3	6 [mg/kg Food] (SML)	×
2,6-di-tert-butyl-p-cresol (= BHT)	315	0000128-37-0	3 [mg/kg Food] (SML)	×

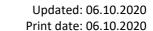
<sup>&</sup>lt;sup>1</sup> According to the supplier the calculation is based on "worst-case overall migration", by testing the overall migration or with tests of the specific migration on representative films; however, it is not clear from the declaration of conformity regarding SML whether all types of food are covered

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Substance	FCM-No.	CAS-No.	limt	conform
formaldehyde	98	0000050-00-0	15 [mg/kg Food] (SML(T))	×
2,4,6-Triamino-1,3,5-triazine	239	0000108-78-1	2,5 [mg/kg Food] (SML)	X
5-Sulfoisophthalic acid, salts	823	-	5 [mg/kg Food] (SML)	×
Dodecylbenzolsulfonic acids	658	0027176-87-0	30 [mg/kg Food] (SML)	×
zincstearate (expressed as zinc)	106	0000557-05-1	5 [mg/kg Food] (SML(T))	×
ethyleneoxide	129	0000075-21-8	1 [mg/kg Verpa- ckungsmaterial] (QM)	×
vinylidenefluoride	132	0000075-38-7	5 [mg/kg Food] (SML)	X
hexafluorpropylene	282	0000116-15-4	0,01 [mg/kg Food] (SML)	×
zincoxide (expressed as zinc)	402	0001314-13-2	5 [mg/kg Food] (SML(T))	×
aluminium (Al)	-	0007429-90-5	1 [mg/kg Food] (SML(T))	×

For the products listed in section 2, we use materials of different suppliers that contain various substances with limitations. These substances are fully included in the list. Since traceability is ensured at all times, on demand we will give you more information about the substances which are contained in the products supplied to you.

## 5.2 Substances that are subject to restrictions in national legislation

suibstance	Assessment	CAS-No.	limit	kon- form
propoxylated glycerol	Toxicological evaluation concerning its potential presence in food contact materials (1701091-0), Henkel AG & Co. KGaA, 13.12.2017	0025791- 96-2	no health risk fort he consumer is expected uot o 1mg /kg food, when cosuming 1 kg food	X
1,6-hexamethyl- enediisocyanate homopolymer	Swiss Regulation of EDI (SR 817.023.21)	0028182- 81-2	Part B, Annex 10, SR 817.023.21	$\mathbf{X}^2$

## 5.3 General restrictions on plastic materials and articles according to Annex II

Substances listed in Annex II (1) of the Plastics-Regulation or substances which can release primary aromatic amines (paA) mentioned in Annex II (2), are also listed in section 5.1 and, if applicable, marked as compliant ( $\boxtimes$ ) if the limits are met for the final use as specified in section 7.

<sup>&</sup>lt;sup>2</sup> tested as 1,6-hexamethylenediamine



5.4 Primary aromatic amines (PAA)

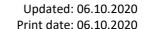
The limit value of 0.01 mg/kg food according to Annex II of the Plastics Regulation (EU) 10/2011 for the migration of primary aromatic amines, which may be formed from the isocyanates used for adhesives, is compliant when testing with acetic acid 3 % by weight, testing conditions 10d/60°C

## 5.5 NIAS- non intentionally added substances

The declaration of impurities and degradation products (NIAS- non intentionally added substances) is based on a 10 ppb screening with simulant ethanol 95 vol%, test conditions 10 days at 60°C, measurement by GC/MS-FID

substance / Semiquantitative value after	comment
conversion (EU-Cube: 6dm²/kg food) [mg/kg food]	
Isoalkanes / approx. 0,1 mg/kg food	The alkanes undecane (CAS 0001120-21-4), dodecane (CAS 0000112-40-3), tetradecane (CAS 0000629-59-4), hexadecane (CAS 0000544-76-3) and octadecane (CAS 0000593-45-3) are not listed in Regulation (EU) No 10/2011 but listed in Annex 10, Part B of the Swiss Ordinance
saturated long chained al- kanes (C10 till C30) / approx. 2,3 mg/kg food	of the EDI on Requirements (SR 817.023.21). The substances listed in Part B of column 6 in Table 1 may be used only if they are not classified as mutagenic, carcinogenic or toxic to reproduction (CMR substances) and the migration of the substance is below 0.01 mg / kg food. The potential health risks posed by these substances in the finished material or article as non-intentionally added substances (NIAS) must be assessed by the manufacturer in accordance with internationally recognised scientific principles of risk assessment.  In our opinion, the assessment of non-intentionally added alkanes can be based on a summary by the Federal Institute for Risk Assessment (BfR) of questions and answers on mineral oil constituents in foodstuffs (Updated FAQ of the BfR of 12 December 2017), since these are saturated hydrocarbons which are chemically identical to mineral oil saturated hydrocarbons (MOSH). According to this publication, the following guideline values have been derived for solvents containing MOSH:  - carbon chain lengths from C10 to C16: 12 mg/kg food  - carbon chain lengths from C16 to C20: 4 mg/kg food
cyclic Polyesters (probabaly) approx 0,03 mg/kg food	Cyclic polyester oligomers are rearrangement products of polyesters which are e.g. used for polyurethane adhesives. According to today's knowledge, due to the ester functionality they are converted in the stomach (acidic milieu) and liver to the monomers (alcohols and acids). The momomers built are not carcinogenic, mutagenic or toxic to reproduction if they are evaluated by EFSA or listed in the positive list of the Plastics
	Regulation (EU) No 10/2011.  According to the present opinion on the food law evaluation of the adhesive used from the adhesive supplier, a risk assessment is available to evaluate the cyclic esters.
fatty acid amides (probably) approx 0,05 mg/kg food	The used slip agent (e.g. erucamide or oleamide) may be contaminated by homologues.  The quantified homologues (e.g. isomers compounds) of the used fatty acid amides are not listed in the Regulation 10/2011.

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substance / comment Semiquantitative value after conversion (EU-Cube: 6dm²/kg food) [mg/kg food] However, they are most likely impurities or degradation products of listed substances used in the product. The corresponding homologues fatty amides are usually metabolised from the body like their listed homo-logues. In accordance to that fact the limits of the listed substances can be adapted here. In the Union list the Regulation no. 10/2011, in addition to the most frequently used slipping agents erucamide (FCM 271) and oleamide (FCM 335) there are listed a several other substances which can be used as slipping agents: behenamide (FCM 458), stearamide (FCM 306), cis-11-eicosenamide (FCM 589), ethylene-N-palmitamide-N'stearamide (FCM 486), N, N'-ethylene-bis-palmitamide (FCM 488), N, N -ethylene-bis-stearamide (FCM 250) and N, N'-ethylene-bis-oleamide (FCM 251) listed with a general limit of 60 mg / kg Lebenmsittel. Only the two compounds octadecylerucamide (FCM 587) and oleylpalmitamide (FCM 622) are listed with an SML value of 5 mg / kg food, which can be used for the evaluation of contamination of fatty acid amides. Tris(2,4-di-tert-bu-Tris(2,4-di-tert-butylphenyl)phosphat is an oxidation product of Tris(2,4di-tert-butylphenyl)phosphit which is listed without limit in Regulation tylphenyl)phosphate / approx. 0,56 mg/kg food (EU) no. 10/2011. Phosphates are usually considered less critical than phosphites, since they are already in a higher oxidation state.

## 6 Dual use additive(s)

Substance name	FCM substance no.	CAS no.	E- or FL-no
polyethyleneglycole	638	0025322-68-3	E1521
kaolin	410	0001332-58-7	E559
titandioxide	610	0013463-67-7	E171
calciumacetat e	115	0000062-54-4	E263
potassiumhydroxide	399	0001310-58-3	E525
phosphoric acid	509	0007664-38-2	E338
2,6-di-tert-butyl-p-cresole	315	0000128-37-0	E321
aluminium (Al)		0007429-90-5	E173
siliciumdioxide	504	0007631-86-9	E551
talc	615	0014807-96-6	E553b

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## 7 Information related to the final use

Use as packaging film

Filling all kind of foodstuff

RefNr. LM-Kat. nach VO (EU) 10/2011 different

Filling temperature [°C] ambient temperature

**Heat treatment [°C / min]** 70 °C  $\leq$  T  $\leq$  100 °C, contact time max. t = 120/2^((T-70)/10)

min

Storage temperature [°C]

room temperature

Shelf life

long term storage

not provided

Preparation with packaging Contact area /volume- ratio

unknown (Assessment with EU-Cube 6dm²/kg Food)

#### 8 Tests

## 8.1 Overall migration (OM)

food simulant	test conditions (time/temperature)	tested	note
A (Ethanol 10 % (v/v))	OM2: 10d / 40°C	×	-
B (Acetic Acid 3% (w/v))	OM2: 10d / 40°C	X	-
D2 (Vegetable oil)	OM2: 10d / 40°C	×	-

In particular cases worst case test conditions compared to the test conditions given above or screening approaches could be accepted for compliance testing in accordance with Annex V of Plastic Regulation (EC) No 10/2011.

#### 8.2 Specific migration

food simulant	test conditions (time/temperature)	tested	note
A (Ethanol 10 % (v/v))	10d / 60°C	×	-
B (Acetic Acid 3% (w/v))	10d / 60°C	×	-
D2 (Vegetable oil)	10d / 60°C C	×	-

In particular cases worst case test conditions compared to the test conditions given above or screening approaches could be accepted for compliance testing in accordance with Annex V of Plastic Regulation (EC) No 10/2011.

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#### 8.3 Organoleptic

The odour and taste deviation according to DIN 10955 (simulant: still water, storage: 22 +/-2 hours/ at 23°C) is below grade of 2.5.

As foodstuffs can vary in their composition, we would like to point out that the manufacturer of the finished food contact material or article must verify that the finished material or article does not modify the organoleptic properties of the food.

## 9 Supporting documents

This Declaration of Conformity is based on the information disclosed for the test, evaluation, tests or calculations carried out, and the declarations of conformity of the raw material suppliers.

Report	Date	Titel	
BA 22537	28.08.2018	Test Report, Innoform GmbH	
BA 22782	20.12.2018	conformity status, Innoform GmbH	
18-14678/1	09.11.2018	Test Report, Henkel AG & Co. KGaA	

## 10 Further Regulation

This confirmation applies to the product delivered by us as described. Regulation (EU) No. 10/2011 provides a guideline for the selection of test conditions for various foodstuffs. Accordingly, the product fulfils the requirements of this regulation for the packaging of the food specified, provided that the specified food contact conditions are observed. The user has to convince himself of the suitability of the product for the intended use which goes beyond the specifications of the regulation.

#### **Adhesives**

- Plastics Regulation (EU) 10/2011
- XXVIII Recommendation of the BfR "Cross-Linked Polyurethanes as Adhesive Layers for Food Packaging Materials

#### Aluminium

- Council of Europe practical guide (2013) on metals and alloys used in food contact materials and articles prepared by the Committee of Experts on Packaging Materials for Food and Pharmaceutical Products (P-SC-EMB)
- DIN EN 602

#### **Processing Aids:**

CFR 21 § 178.3910 "Surface lubricants used in the manufacture of metallic articles

#### General

This declaration is valid for the product delivered by us as specified above. The user is responsible for the examiniation of the suitability of the packaging both for the planned filling good/foodstuff and kind of application. Furthermore we are not responsible for possible quality changes of the filling good/foodstuff as a result of interactions with the packaging or parts of it.

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