

Declaration of Compliance

created:	13.08.2018
revised:	29.08.2018
from:	
printed:	
file:	BA 21965-1 DRAFT_DOC_Dosen- weiß_ENG

1 Manufacturer or importer and issuer of the Declaration of compliance

Filthaus plastics GmbH
Werner-Battenfeld-Str. 6
58540 Meinerzhagen

2 Identity of the plastic material or article

Tradename	Polymer type	Material no.
Screw lid tins 90 ml, 130 ml, 150 ml, 200 ml, 200 ml, 275 ml, 300 ml, 325 ml, 325 ml, 350 ml, 400 ml, 500 ml, 600 ml, 650 ml, 750 ml, 1000 ml, 1200 ml, 1400 ml, 1500 ml, 1700 ml, 2000 ml, 2500 ml	PP white colored	Borealis BD310MO Borealis RJ377MO Ineos 300CA06 Ineos 200CA40
Cream tins 125 ml, 150 ml, 200 ml, 250 ml, 500 ml	PP white colored	"
Cream tins 50 ml Doppelwand, 50 ml Einwand	PP white colored	"

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, 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.

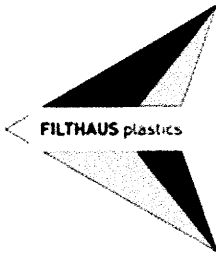
3.1 Transition period

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 the plastics which are not separated from the food by a functional barrier are manufactured only with monomers, other starting substances and additives that are authorised under the Plastics Regulation.
- 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



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- 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 material 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

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 (☒) for the use specified in section 7.

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

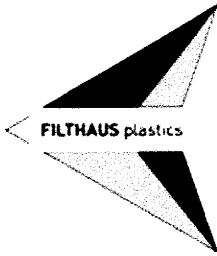
5.1 List of substances contained with restrictions and/or specifications according Regulation (EC) no 10/2011

Substance name	FCM substance no.	CAS no.	Limit	compliant
Aluminium (Al)		0007429-90-5	1,0 [mg/kg food] (SML(T))	☒
Confidential substances 2.272-10.215 und 2.271-10.210				☒

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 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 (☒) if the limits are met for the final use as specified in section 7.



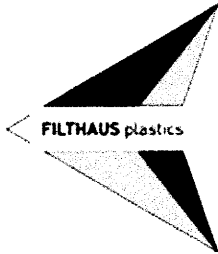
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5.3 NIAS- non intentionally added substances

The list of contaminants and degradation products (NIAS- non intentionally added substances) is based on a 10 ppb Screening with simulant ethanol 95% (v/v), testing conditions 10 days at 60°C, detection and quantification by GC/MS-FID

Substance/ Quantity after conversion with O/V of max. 6.7 dm ² /kg	evaluation
Isoalkanes (probably) / 11-34 mg/kg food	Aliphatic saturated and unsaturated hydrocarbons (except 1-hexene, 1-octene, 1-decene, 1-dodecene, 1-tetradecene) are not listed in the Plastic Regulation (EU) No. 10/2011. As oligomers of polyolefins (POSH- polyolefin oligomeric saturated hydrocarbons) they are usually accepted. The migration of saturated hydrocarbons currently is assessed by the legislature, and we expect that a lower limit than the overall migration limit is adopted. We don't know if this limit will also apply for oligomers.
tris(2,4-di-tert-butylphenyl) phosphate/ 0,2 - 1,5 mg/kg food	Tris(2,4-di-tert-butylphenyl)phosphat is an oxidation product of Tris(2,4-di-tert-butylphenyl)phosphit which is listed without limit in Regulation (EU) no. 10/2011. Phosphates are usually considered less critical than phosphites, since they are already in a higher oxidation state
fatty acid amide (probably) 1,6 - 3,5 mg/kg food (by overlaying with isoalkane one measured value approx. 5.5) (possibly C14-C18 alkana- mide) 4,0 to 5,5 mg/kg food (possibly stearamide) < 5 mg/kg food (Alkanamides not to be as- signed)	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. 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 homologues. 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 Lebensmittel. 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.



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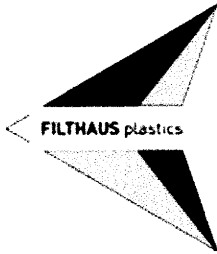
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6 Dual use additive(s)

Substance name	FCM sub- stance no.	CAS no.	E- or FL-no
calcium carbonate (carbonic acid, salts)	21	0000471-34-1	E170
titanium dioxide	610	0013463-67-7	E171
aluminium (Al)		0007429-90-5	E173
sodium benzoate		0000532-32-1	E211
sodium, potassium and calcium salts of fatty acids		E470a	E470a
mono- or diglyceride of fatty acids (Acids C2-C24 aliphatic, linear, monocarboxylic, from natural oils and fats or synthetic and their mono-, di- and triglycerol esters)	9/10	E471	E471
calcium oxide	395	0001305-78-8	E529
talc	615	0014807-96-6	E553b
calcium stearate	106	0001592-23-0	E572

7 Information related to the final use

Use as	packaging material
Filling	all kind of foodstuff
Reference no food category acc. Regulation (EU) No. 10/2011	different
Filling temperature [°C]	ambient temperature
Heat treatment [°C / min]	$70\text{ °C} \leq T \leq 100\text{ °C}$, contact time max. $t = 120/2^{(T-70)/10}$ min
Storage temperature [°C]	room temperature
Shelf life	long term storage
Preparation with packaging	not provided
Contact area /Volume- ratio	max. 6,7 dm ² /kg food



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8 Tests

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.

8.1 Overall migration (OM)

food simulant	test conditions (time/temperature)	tested	note
A (Ethanol 10% (v/v))	OM2: 10d / 40 °C	<input checked="" type="checkbox"/>	
B (Acetic acid 3% (w/v))	OM2: 10d / 40 °C	<input checked="" type="checkbox"/>	
D2 (vegetable oil) If technically not feasible, test with alternative simulants: - Ethanol 95 % (v/v) 10d/40°C - Iso octane, 2d/20°C	OM2: 10d / 40 °C	<input checked="" type="checkbox"/>	

8.2 Specific migration

food simulant	test conditions (time/temperature)	tested	note
A (Ethanol 10% (v/v))	10d / 60 °C	<input checked="" type="checkbox"/>	
B (Acetic acid 3% (w/v))	10d / 60 °C	<input checked="" type="checkbox"/>	
D2 (vegetable oil) If technically not feasible, test with alternative simulants: - Ethanol 95 % (v/v) 10d/40°C - Iso octane, 2d/20°C	10d / 60 °C	<input checked="" type="checkbox"/>	

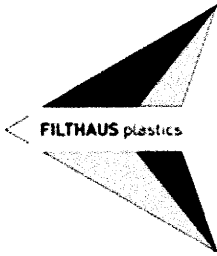
8.3 Organoleptic

The odour and taste deviance according to DIN 10955 (food simulant still water, storage 22h/23°C) is lower than grade 2,5.

Since food can differ widely in its composition we remind you 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.

8.4 Colourfastness of dyes of plastic materials

There is no colour migration recognizable according to BfR Chapter IX, Part B II (testing media: water, 2% acetic acid, 10% ethanol, ground-nut oil) of coloured plastic materials.



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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	Title
1519425/2	10.09.2015	Prüfbericht, Dr. Graner & Partner GmbH
1519424/2	14.09.2015	Prüfbericht, Dr. Graner & Partner GmbH
1535013	29.12.2015	Prüfbericht, Dr. Graner & Partner GmbH
BA 20600-2	22.05.2018	Prüfbericht, Innoform GmbH
BA 21965-1	29.08.2018	Prüfbericht, Innoform GmbH
BA 21965-1	13.08.2018	Konformitätsstatus, Innoform GmbH

10 Further regulation

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):

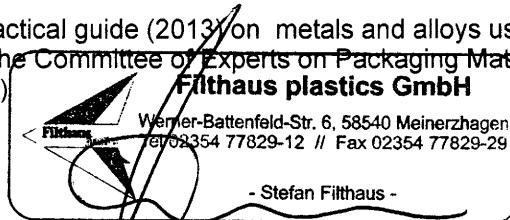
coloured plastics

- BfR Recommendation IX. Colorants for Plastics and other Polymers Used in Commodities
- Council of Europe Resolution AP (89)1 On the Use of Colourants in Plastic Materials Coming into Contact with Food
- 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)

05.09.2018

Datum

Unterschrift



- Stefan Filthaus -

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.