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Dokument:

KE0700E

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Declaration of Compliance

You receive from us articles of the product group:

Monopack-products with colour batch, printed and unprinted

The article classification (number of article and article description applicable for the declaration of conformity) is available on our homepage in the download block.
<http://www.perga.de/index.php?id=64&L=1%27>

Material: Polyethylene medium and low density (LDPE + Coex)

The articles of this product group correspond with the following legal requirements or recommendations:

1. Generally:

- EU-Framework Regulation on materials and articles intended for food contact:(EC) No. 1935/2004
- Commission Regulation (EC) No 2023/2006 (GMP-Regulation) on good manufacturing practice for materials and articles intended to come into contact with food

2. Raw Materials / Composition

EU-regulations:

- Regulation (EU) No. 10/2011 and amendments
- Heavy metals according to EU-Directive 94/62/EC on Packaging and Packaging Waste

German regulations:

- § 30 und § 31 of the German Food and Feed Law
- Commodities Regulation of 10.04.1992 and amendments
- BfR-Recommendations (e.g. III for Polyethylene)

3. Conditions of use / Compliance with threshold values

Tested conditions of use

Leach of simulations	Time of contact	Contact temperature
A [Ethanol 10 % (v/v)]	10 days	40°C
B [Acetic acid 3 % (w/v)]	10 days	40°C
D2 Vegetable oil – olive oil	10 days	40°C

Ratio of the area of the food contact material to the volume used to determine the compliance of the plastic food contact material or article:	1 dm ² /160 ml and 1 dm ² /165 ml
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Migration testing according to Regulation (EU) No. 10/2011 “on plastic materials and articles intended to come into contact with food” and requirements of the standard EN 1186-1 ff. “Materials and articles in contact with foodstuffs – Plastic”.

The overall migration values, which were calculated, lie below the permitted limit for the selected simulants, contact times and contact temperatures.

The tests determine whether or not the item from the product group mentioned above is suitable for packaging the following foodstuffs or food groups for long term storage at room temperature or below. (According to the testing condition OM 2 which is indicated in the regulation (EU) Nr. 10/2011. The described “conditions of contact with food” for OM 1 and OM 3 are also included in the testing conditions of OM2.)

Reference number	Description of food
01	Beverages
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to 6 % vol.: A. Clear drinks: Water, ciders, clear fruit or vegetable juices of normal strength or concentrated, fruit nectars, lemonades, syrups, bitters, infusions, coffee, tea, beers, soft drinks, energy drinks and the like, flavoured water, liquid coffee extract B. cloudy drinks: juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate
01.02	Alcoholic beverages of an alcoholic strength of between 6 % vol and 20 %.
01.03	Alcoholic beverages of an alcoholic strength above 20 % and all cream liquors
01.04	Miscellaneous: undenaturated ethyl alcohol
02	Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares
02.01	Starches
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like)

Reference number	Description of food
02.03	Cereal flour and meal
02.04	Dry pasta e.g. macaroni, spaghetti and similar products and fresh pasta
02.05	Pastry, biscuits, cakes, bread, and other bakers' wares, dry: A. With fatty substances on the surface B. Other
02.06	Pastry, cakes, bread, dough and other bakers' wares, fresh: A. With fatty substances on the surface B. Other
03	Chocolate, sugar and products thereof
	Confectionery products
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes
03.02	Confectionery products: A. In solid form: I. With fatty substances on the surface II. Other B. In paste form: I. With fatty substances on the surface II. Moist
03.03	Sugar and sugar products A. In solid form: crystal or powder B. Molasses, sugar syrups, honey and the like
04	Fruit, vegetables and products thereof
04.01	Fruit, fresh or chilled: A. unpeeled and uncut B. peeled and/or cut
04.02	Processed fruit: A. Dried or dehydrated fruits, whole, sliced, flour or powder B. Fruit in the form of purée, preserves, pastes or in its own juice or in sugar syrup (jams, compote, and similar products) C. Fruit preserved in a liquid medium: I. In an oily medium II. In an alcoholic medium
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others): A. Shelled, dried, flaked or powdered B. Shelled and roasted C. In paste or cream form
04.04	Vegetables, fresh or chilled A. unpeeled and uncut B. peeled and/or cut
04.05	Processed vegetables: A. Dried or dehydrated vegetables whole, sliced or in the form of flour or powder C. Vegetables in the form of purée, preserves, pastes or in its own juice (including pickled and in brine) D. Preserved vegetables: I. In an oily medium II. In an alcoholic medium
05	Fats and oils
05.01	Animals and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified butter)
05.02	Margarine, butter and other fats and oils made from water emulsions in oil
06	Animal products and eggs
06.01	Fish: A. Fresh, chilled, processed, salted or smoked including fish eggs B. Preserved fish: I. In an oily medium II. In an aqueous medium

Reference number	Description of food
06.02	Crustaceans and molluscs (including oysters, mussels, snails) A. Fresh within the shell B. Shell removed, processed, preserved or cooked with the shell I. In an oily medium II. In an aqueous medium
06.03	Meat of all zoological species (including poultry and game): A. Fresh, chilled, salted, smoked B. Processed meat products (such as ham, salami, bacon, sausages, and other) or in the form of paste, creams C. Marinated meat products in an oily medium
06.04	Preserved meat: A. In an fatty or oily medium B. In an aqueous medium
06.05	Whole eggs, egg yolk, egg white A. Powdered or dried or frozen B. Liquid and cooked
07	Milk products
07.01	Milk A. Milk and milk based drinks whole, partly dried and skimmed or partly skimmed B. Milk powder including infant formula (based on whole milk powder)
07.02	Fermented milk such as yoghurt, buttermilk and similar products
07.03	Cream and sour cream
07.04	Cheeses: A. Whole, with not edible rind B. Natural cheese without rind or with edible rind (gouda, camembert, and the like) and melting cheese C. Processed cheese (soft cheese, cottage cheese and similar) D. Preserved cheese: I. In an oily medium II. In an aqueous medium (feta, mozzarella, and similar)
08	Miscellaneous products
08.01	Vinegar
08.02	Fried or roasted foods: A. Fried potatoes, fritters and the like B. Of animal origin
08.03	Preparations for soups, broths, sauces, in liquid, solid or powder form (extracts, concentrates); homogenised composite food preparations, prepared dishes including yeast and raising agents A. Powdered or dried: I. With fatty character II. Other B. any other form than powdered or dried: I. With fatty character II. Other
08.04	Sauces: A. With aqueous character B. With fatty character e.g. mayonnaise, sauces derived from mayonnaise, salad creams and other oil/water mixtures e.g. coconut based sauces
08.05	Mustard (except powdered mustard under heading 08.14)
08.06	Sandwiches, toasted bread pizza and the like containing any kind of foodstuff A. With fatty substances on the surface B. Other
08.07	Ice-creams
08.08	Dried foods: A. With fatty substances on the surface B. Other

Reference number	Description of food
08.09	Frozen or deep-frozen foods
08.10	Concentrated extracts of an alcoholic strength equal to or exceeding 6 % vol.
08.11	Cocoa: A. Cocoa powder, including fat-reduced and highly fat reduced B. Cocoa paste
08.12	Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered
08.13	Aromatic herbs and other herbs such as camomile, mallow, mint, tea, lime blossom and others
08.14	Spices and seasonings in the natural state such as cinnamon, cloves, powdered mustard, pepper, vanilla, saffron, salt and other
08.15	Spices and seasoning in oily medium such as pesto, curry paste

For the manufacture of our products, materials with limits (an SML or QM value and/or Dual Use Additives) are used. Compliance with the limits for the specified types of foodstuffs and conditions of use is confirmed. These statements are based on the documentation of the issuer of the declaration of compliance (supporting documents).

According to the information provided by our raw material suppliers, the following substances can be included in the articles of the above mentioned product group:

FCM substance No	Ref. No	CAS No	E-No	Substance name
9	30610	----	E470a	Monocarbonsäuren, C2-C24, aliphatische, geradkettige, aus natürlichen Fetten und Ölen, und deren Mono-, Di- und Triglycerinester (verzweigte Fettsäuren in natürlich vorkommenden Mengen sind eingeschlossen)
19	39090	----	----	N,N-Bis(2-hydroxyethyl)alkyl (C8-C18)amin
20	39120	----	----	N,N-Bis(2-hydroxyethyl)alkyl (C8-C18)aminhydrochloride
21	42500	----	E170	Kohlensäure, Salze
41	56486	----	E471	Ester von Glycerin mit aliphatischen gesättigten geradkettigen Säuren mit geradzahlig Kohlenstoffkette (C14-C18) und mit aliphatischen ungesättigten geradkettigen Säuren mit geradzahlig Kohlenstoffkette (C16-C18)
69	74400	----	----	Tris(nonyl-und/oder dinonylphenyl)phosphit
95	95883	----	----	Weiß Mineralöle, paraffinisch, gewonnen aus Kohlenwasserstoffen auf Erdölbasis
106	24550 89040	0000057-11-4	E470a	Stearinsäure [CA-salts; Ca-stearate (CAS 1592-23-0)]
125	16950	0000074-85-1	----	Ethylen
129	17020	0000075-21-8	----	Ethylenoxid
132	26140	0000075-38-7	----	Vinylidenfluorid
139	14680 44160	0000077-92-9	E330	Citronensäure
141	13380 25600 94960	0000077-99-6	----	1,1,1-Trimethylolpropan
227	16990 53650	0000107-21-1	----	Ethylenglykol
263	13326 15760	0000111-46-6	----	Diethylenglykol

FCM substance No	Ref. No	CAS No	E-No	Substance name
282	18430	0000116-15-4	----	Hexafluorpropylen
356	18820	0000592-41-6	----	1-Hexen
395	41520	0001305-78-8	E529	Calciumoxid
402	96240	0001314-13-2	----	Zinkoxid
409	62240	001332-37-2	E172	Eisenoxid
411	42080	0001333-86-4	----	Kohlenstoffschwarz
433	68320	0002082-79-3	----	Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionat
483	68860	0004724-48-5	----	n-Octylphosphonsäure
499	19965 65020	0006915-15-7	E296	Apfelsäure
504	86240	0007631-86-9	E551	Siliciumdioxid
568	79040	0009005-64-5	----	Polyethylenglykolsorbitanmonolaurat
571	79280	0009005-67-8	----	Polyethylenglykolsorbitanmonostearat
610	93440	0013463-67-7	E171	Titandioxid
615	92080	0014807-96-6	E553b	Talkum
638	23590 76960	0025322-68-3	E1521	Polyethylenglykol
652	38820	0026741-53-7	----	Bis(2,4-di-tert-butylphenyl) pentaerythritoldiphosphit
661	95360	27676-62-6	----	1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazin-2,4,6(1H,3H,5H)-trion
689	95280	0040601-76-1	----	1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazin-2,4,6 (1H,3H,5H)-trion
715	46880	0065140-91-2	----	Monoethyl-3,5-di-tert-butyl-4-hydroxybenzylphosphonat, Calciumsalz
716	60800	65447-77-0	----	1-(2-hydroxyethyle)-4-hydroxy-2,2,6,6-tetramethyl
779	39815	182121-12-6	----	9,9-Bis(methoxymethyl)fluoren
792	92475	0203255-81-6	----	3,3',5,5'-Tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclischer Ester mit [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl] oxyphosphonsäure
793	94000	0000102-71-6	----	Triethanolamin
923	39150	0000120-40-1	----	N,N-Bis(2-hydroxyethyl)dodecanamid (Diethanolamin)
----	----	----	E170	Calciumcarbonat
----	----	----	E530	Magnesiumoxid
----	----	----	E172	Eisen(III)-oxid
----	----	----	E173	Aluminium
----	----	----	----	Eisen
----	----	----	----	Kupfer
---	---	0010213-78-2	----	Octadecylbis(2-hydroxyethyl)amine
----	----	1592-23-0	E470a	Calciumstearat
----	----	----	----	Aluminiumoxid
----	----	----	470a	Kalziumsalze von Speisefettsäuren
----	----	----	----	Aluminium Compound
----	----	----	----	Bariumsulfat / Barium
-----	-----	557-05-1	----	Zinc stearate
----	----	----	E471	Mono- and diglycerides of fatty acids
----	----	----	E470a	calcium salts of fatty acids
----	----	557-05-1	----	Zinc stearate [Group SML = 5 mg/kg (expressed as Zn)]
----	----	----	E504	Magnesiumcarbonat
----	----	----	----	Silica
----	----	000557-05-01	----	Zinc (Zn)
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The delivered articles does not contain a functional barrier.

General indication

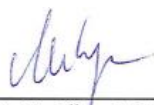
For our diverse and very extensive product range measurements are not possible in each individual cases. In a defined procedure (worst-case-procedure) we measure on different articles on a random basis the global migration. Furthermore we assure, that generally we only use raw materials for the production of films with food contact which have a certificate according to the current law for food approval.

4. 4. Conclusion

In terms of EU-framework Directive (EC) No 1935/2004 and §§ 30 and 31 LFGB, published in the Bundesgesetzblatt (Federal Law Gazette) No 55 of 6.09.2005 there are no objections against the use of the product for the manufacture of articles intended for food contact.

This declaration is valid for the product delivered by us as specified above. The Regulation (EU) Nr. 10/2011 "on plastic materials and articles intended to come into contact with food" and the requirements of the standard EN 1186-1 ff. „Materials and articles in contact with foodstuffs - plastics" provide a guideline for the selection of test conditions that has to be used for various food products. According to that and under consideration of the food contact conditions stated, the product complies with the stipulations of these Regulations regarding the packaging of food products to be packed. The user has to verify himself if the product is suitable for the intended food to be packed beyond the stipulations of the Directives.

It is expressly pointed out that any contact between printing ink and food must be avoided. This Declaration of conformity consequently does not represent a guarantee declaration.



i. V. Ellen Metzger
- QMR /BRC-representative

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