

Perga GmbH · Tiefenweg 25 · 74731 Walldürn-Altheim

#### Perga GmbH

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Document: **KE0700E** 

# **Declaration of Compliance**

You receive from us articles of the product group:

# Monopack-products with color 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.

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

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

#### 1. EU-regulations:

- 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
- Regulation (EU) No. 10/2011 and amendments
- Heavy metals according to Directive 2015/720 of the European Parliament and oft he Concil of 29 April 2015 amending Directive 94/62/EC as regards reducing the consumption of lightweight plastic carrier bags

#### 2. National regulations and recommendations:

### German regulations:

- § 30 und § 31 of the German Food and Feed Law
- Commodities Regulation of 10.04.1992 and amendments
- Applicable recommendation of the BfR III for Polyethylene

#### Other national regulations in Europe:

- -----

#### Non-EU-Vorschriften:

- -----



## 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	1,0 dm²/160 ml	
used to determine the compliance of the plastic food contact	and	
material or article:	1,0 dm²/165 ml	

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					



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Reference number	Description of tood					
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)					
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					



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Reference number	Description of food				
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				
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				



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Reference number	Description of food						
	C. Processed cheese (soft cheese, cottage cheese and similar)						
	D. Preserved cheese:						
	I. In an oily medium						
	II. In an aqueous medium (feta, mozarella, 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	lce-creams						
80.80	Dried foods:						
	A. With fatty substances on the surface						
00.00	B. Other						
08.09	Frozen or deep-frozen foods						
08.10	Concentrated extracts of an alcoholic strength equal to or exceeding 6 % vol.						
08.11	Cocoa:						
	<ul><li>A. Cocoa powder, including fat-reduced and highly fat reduced</li><li>B. Cocoa paste</li></ul>						
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						



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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	Ref. No	CAS No	E-No	Substance name
substance No				
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 geradzahliger Kohlenstoffkette (C14-C18) und mit aliphatischen ungesättigten geradkettigen Säuren mit geradzahliger Kohlenstoffkette (C16-C18)
69	74400			Tris(nonyl-und/oder dinonylphenyl)phosphit
95	95883			Weiße 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
282	18430	0000116-15-4		Hexafluorpropylen
356	18820	0000592-41-6		1-Hexen
395	41520	0001305-78-8	E529	Calciumoxid
402	96240	1314-13-2		Zink oxide
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



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FCM	Ref. No	CAS No	E-No	Substance name
substance No				
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
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-hydroxy- benzylphosphonat, 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
			E470a	Calciumstearat
			E530	Magnesiumoxid
			E172	Eisen(III)-oxid
			E173	Aluminium
				Eisen
				Kupfer
		0010213-78-2		Octadecylbis(2-hydroxyethyl)amine
				Aluminiumoxid
			470a	Kalziumsalze von Speisefettsäuren
				Bariumsulfat / Barium
				Eisen
			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)
				substances in raw materials of general known companys, which are subject to a secrecy agreement and may not be named

The delivered articles does not contain a functional barrier.



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#### 4. NIAS: Not Intentionally Added Substances

NIAS are always present, however, in many cases they are not problematic. The main part of NIAS are evaluated substances for which toxicological data are available.

For the raw materials / granulates used, we have declarations of conformity from the suppliers confirming that they comply with the requirements of Framework Regulation (EC) No. 1935/2004. Based on this, we assume that non-evaluated and/or non-intentionally added substances (NIAS), if relevant, have been evaluated by our suppliers, but we do not have explicit information on this. Accordingly, we cannot currently rule out the presence of NIAS in principle.

#### 5. Conclusion

In terms of EU-framework Directive (EC) No 1935/2004 there are no objections against the use of the product for the manufacture of articles intended for food contact.

The raw materials used comply with the demands of the Regulation (EU) No. 10/2011.

This declaration is valid for the product delivered by us as specified above. The Regulation (EU) No. 10/2011 provides guidelines for the selection of test conditions 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 shall verify himself that the product is suitable for the intended food to be packed beyond the stipulations of the Directives.

In particular it is emphasized that in case of printing material, no contact is allowed between the printing ink and food product.

This Declaration of conformity consequently does not represent a guarantee declaration.

sgd. sgd.

p.p. Ellen Metzger pro. Steffen Günther

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