

Perga GmbH · Tiefenweg 25 · 74731 Walldürn-Altheim









Seite 1 von 7

Document: I

GK

KE0800E

Declaration of Compliance

You receive from us articles of the product group:

Thermobags with coloring, 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 (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:

- -----

 Perga GmbH
 HRB

 Geschäftsführung Fabian Wilhelms
 Ustll

 Registergericht Mannheim
 Steur

HRB 460323 UstID-Nr. DE144447907 Steuer-Nr. 4000268420



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)	2 hours	100°C
B Acetic acid 3 % (w/v)	2 hours	100°C
D2 Vegetable oil – olive oil	2 hours	100°C

	0,5 dm² / 25 ml
Ratio of the area of the food contact material to the volume	resp.
used to determine the compliance of the plastic food contact	1,95 dm² / 100 ml
material or article:	resp.
	1,0 dm² / 50 ml

Migration testing accordning 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 high temperature applications at temperature up to 121°C. (According to the testing condition OM 5 which is indicated in the regulation (EU) Nr. 10/2011. The described "conditions of contact with food" for OM 1, OM 2, OM 3 and OM 4 are also included in the testing conditions of OM5.):

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				







Reference number						
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)					
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:					
	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					
04.04	Vegetables, fresh or chilled					
	A. unpeeled and uncut					
	B. peeled and/or cut					





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:					
	II. In an alcoholic medium					
05	Fats and oils					
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:					
	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					
	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					
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:					
	II. In an aqueous medium (feta, mozarella, and similar)					
08	Miscellaneous products					
08.01	Vinegar					







Reference number	Description of food				
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				
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				
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				

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
19	39090		19	N,N-Bis(2-hydroxyethyl)alkyl (C8-C18)amin
21	42500	0000471-34-1	21	Calciumcarbonat / Kohlensäure, Salze
41	56486		41	Ester von Glycerin mit aliphatischen gesättigten geradkettigen Säuren mit geradzahliger Kohlenstoffkette (C14-C18) und mit aliphatischen ungesättigten geradkettigen Säuren mit geradzahliger Kohlenstoffkette (C16-C18)
125	16950	0000074-85-1	125	Ethylen
132	26140	0000075-38-7	132	Vinylidenfluorid
141	13380 25600 94960	0000077-99-6	141	1,1,1-Trimethylolpropan
186	14020	0000098-54-4	186	4-tert-Butylphenol
222	13870	0000160-98-1	222	1-Buten
356	18820	0000592-41-6	356	1-Hexen
409	62240	0001332-37-2	409	Eisenoxid
410	62720	0001332-58-7	410	Kaolin
411	42080	0001333-86-4	411	Ruß
418	34720	0001344-28-1	418	Aluminiumoxid
433	68320	0002082-79-3	433	Octadecyl-3-(3,5-ditertbutyl-4- hydroxyphenyl) propionat
477	46720	0004130-42-1	477	2,6-Ditertbutyl-4-ethylphenol
504	86240	0007631-86-9	504	Siliciumdioxid
575	76721		575	Dimethylpolysiloxan
610	93440	0013463-67-7	610	Titandioxid
615	92080	0014807-96-6	615	Talkum
652	38820	0026741-53-7	652	Bis(2,4-di-tert-butylphenyl) pentaerythritoldiphosphit
715	46880	0065140-91-2	715	Monoethyl-3,5-ditertbutyl-4- hydroxybenzylphosphonat, Calciumsalz
760	83595	0119345-01-6	760	Phosphorous trichloride, reaction products with 1,1'- biphenyl and 2,4-bis(1,1-dimethylethyl)phenol
799	77708		799	Polyethylenglycolether (EO = 1-50) von linearen und verzweigten primären Alkoholen (C8-C22)
811	80077	0068441-17-8	811	oxidierte Polyethylenwachse
974	74050	0939402-02-5	974	Phosphorige Säure, gemischte 2,4-Bis(1,1- dimethylpropyl)phenyl- und 4-(1,1- Dimethylpropyl)phenyltriester
		0007429-90-5		Aluminium
		0007440-36-0		Antimon
				Arsen
				Bariumsulfat / Barium
				Blei
		0007440-43-9		Cadmium
		0007440-70-2		Calcium
		0001592-23-0		Calciumstearat / Calcium salts of fatty acids
		0007440-47-3		Chrom
		0007439-89-6		Eisen
				Kobalt
		0007440-50-8		Kupfer





FCM substance No	Ref. No	CAS No	E-No	Substance name
				Mangan
				Nickel
				Quecksilber
		0007440-66-6		Zink (Zn)
		0000557-05-1		Zinkstearat

The delivered articles does not contain a functional barrier.

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. p.p. Ellen Metzger sgd. pro. Steffen Günther

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