

Pumpen | Probenehmer | Laborbedarf für Labor, Industrie und Wissenschaft

Pumps | Sampling | Plastic Labware for Laboratory, Industry, Science



2327-0001 Packaging bucket 1 l 2327-0030 Packaging bucket 3 l 2327-0050 Packaging bucket 5 l 2327-0010 Packaging bucket 10 l

DECLARATION OF CONFORMITY

Declaration of conformity pursuant to Article 16 of Regulation (EC) No. 1935/2004 of the European Parliament and the Council dated 27 October 2004 "on materials and articles intended to come into contact with foodstuffs [...]" as well as pursuant to appendix IV and V of Regulation (EU) 10/2011* dated 14 January 2011 "on materials and articles made of plastics intended to come into contact with foodstuffs ".

Our supplier as producer and distributor of plastic packaging made of polypropylene hereby confirms that the articles mentioned below

comply with the statutory provisions of *Regulation (EC) No. 1935/2004* as well as of *Regulation (EU) No. 10/2011** and were produced in accordance with *GMP Regulation (EC) No. 2023/2006*.

Test conditions and field of application

As part of the migration test, the material used for the production was tested under worst foreseeable conditions of use on 10 days at $40\,^{\circ}$ C or rather 10 days at $60\,^{\circ}$ C. The anticipated food contact condition therefore corresponds to "any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/ or heating up to a temperature T where $70\,^{\circ}$ C \leq T \leq $100\,^{\circ}$ C for a maximum of t = $120/2^{\wedge}((T-70)/10)$ minutes".*

The values of specific and global migration are within the limits of *Regulation (EU) No. 10/2011** when used as specified. Thus, the mentioned articles are suitable for long-term storage and direct contact with all types of foodstuff.

Surfase volume ratio

The ratio of surface to volume, which forms the basis of assessment, is *6 dm2: kg*. For the test procedure, this has to be converted to the individual packaging.

Specific migration limits (SML) pursuant to appendix I of Regulation EU 10/2011*

Appendix I of **Regulation (EU) 10/2011*** defines specific migration values or other limits for below-mentioned materials which are used for the production of the products.

* Regulation (EU) No. 10/2011 including all valid amendments and additions

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Raw Material - Worst Case Scenario

RefNo.	CAS-No.	Substance	Restriction
39090		N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine	1,2 mg/kg
39815	182121-12-6	9,9-bis(methoxymethyl)fluorene	0,05 mg/kg
-	57-11-4	stearic acid	-
38560	7128-64-5	2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	0,6 mg/kg
66360	85209-91-2	2,2'-methylene bis(4,6-di-tertbutylphenyl) sodium phosphate	5 mg/kg
38550	0882073-43-0	bis(4-propylbenzylidene) propylsorbitol	5 mg/kg
95360	27676-62-6	1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6 (1H,3H,5H)-trione	5 mg/kg
45704	-	cis-1,2-cyclohexanedicarboxylic acid, salts	5 mg/kg
-	557-05-1	Zinc stearate	5 mg/kg (Zn)
55910	736150-63-3	glycerides, castor-oil mono-, hydrogenated, acetates	60 mg/kg
-	65-85-0	benzoic acid	-
-	-	Zinc	5 mg/kg
34650	151841-65-5	aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert-butylphenyl) phosphate]	5 mg/kg
38515	1533-45-5	4,4'-Bis(2-benzoxazolyl)stilben	0,05 mg/kg
39120		N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine hydrochlorides	1,2 mg/kg
46880	65140-91-2	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	6 mg/kg
68320	2082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	6 mg/kg
74880	84-74-2	phthalic acid, dibutyl ester	0,3 mg/kg
-	-	Aluminium	1 mg/kg
38507	-	cis-endo-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, salts	5 mg/kg

Color

RefNo.	CAS-No.	Substance	Restriction
-	-	Zinc	5 mg/kg

Dual Use Additives (DUAS)

The products contain the following materials, the use of which in foodstuffs is subject to limitation.

Raw Material - Worst Case Scenario

RefNo.	CAS-No.	E-No.	Substance
56585		-	glycerol, esters with stearic acid
92080	14807-96-6	553	b talc
37600	65-85-0	210	benzoic acid
-	31566-31-1	-	Glyceryl monostearate
89040	1592-23-0	470	a calcium stearate
-	-	471	Mono- and diglycerides of fatty acids
54450	-	-	fats and oils, from animal or vegetable food sources
-	57-11-4	-	stearic acid
-	532-32-1	211	Micronised Sodium Benzoate
90960	110-15-6	-	succinic acid
30960	-	475	acids, aliphatic, monocarboxylic (C6-C22), esters with polyglycerol

^{*} Regulation (EU) No. 10/2011 including all valid amendments and additions





Color

RefNo.	CAS-No.	E-No.	Substance
93440	13463-67-7	171	titanium dioxide
-	-	170	Calcium Carbonate

Appendix II of Regulation (EU) No. 10/2011*

The articles mentioned above do not release substances in such quantities exceeding the defined specific migration values pursuant to appendix II (1).

Furthermore, no primary aromatic amines, except for those mentioned in Appendix I Table 1, are released in detectable amounts to foodstuffs or food simulants.

Liquid colours / Maserbatch (Pigments)

The liquid colours/ masterbatches used for colouring correspond to the requirements of Regulations (EC) No. 1935/2004 and (EU) No. 10/2011* as well as to Resolution AP (89)1 and the Recommendation IX of the BfR.

Note on heavy metals

Specified articles correspond to the requirements in *Article 11 (1)* of the *Guideline 94/62/EG* of the European Parliament and the Council dated 20 December 1994 "regarding packaging and packaging waste" as well as to the regulations mentioned in *Appendix II (1) of Regulation (EU) No. 10/2011**.

Undesirable substances

Following substances are no formulation components of above-mentioned product

• BBP

- DINP
- Bisphenol A
- DMEOB
- Bisphenol F
- DNOP
- Bisphenol S
- DNPPPVDC

DEPDIDOX

• PVC

NIAS (Non-Intentionally-Added Substances)

The product does not contain any non-intentionally added substances, which might change over to foodstuffs in such amounts which raise concern for human health under intended conditions of use.

For our production stage, there are no concerns about the use of the product as defined by § 30 and § 31 of the Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuches (LFGB/ German Food and Feed Code).

^{*} Regulation (EU) No. 10/2011 including all valid amendments and additions





Summary of the confirmation of conformity

Our supplier compliance with above-mentioned regulations and laws allows us to confirm that the articles listed on page 1 meet the food law regulations. Our supplier products are suitable for long-term storage at room temperature or below as well as for direct contact with food.

The user shall verify independently the product's suitability for the intended content given by the specifications and mentioned in the declaration of conformity.

Validity

A renewal of the declaration will take place in case of changes of the legal situation or substantial modifications in the composition or production - which lead to a change in the migration of materials or articles as well as the existence of new scientific findings.





2327-0020 Packaging bucket 2 l

DECLARATION OF CONFORMITY

Declaration of conformity pursuant to Article 16 of Regulation (EC) No. 1935/2004 of the European Parliament and the Council dated 27 October 2004 "on materials and articles intended to come into contact with foodstuffs [...]" as well as pursuant to appendix IV and V of Regulation (EU) 10/2011* dated 14 January 2011 "on materials and articles made of plastics intended to come into contact with foodstuffs ".

Our supplier as producer and distributor of plastic packaging made of polypropylene hereby confirms that the articles mentioned below

comply with the statutory provisions of *Regulation (EC) No. 1935/2004* as well as of *Regulation (EU) No. 10/2011** and were produced in accordance with *GMP Regulation (EC) No. 2023/2006*.

Test conditions and field of application

As part of the migration test, 1 dm2 of the packaging was tested in 100 ml food simulant on 10 days at 40°C and 10 days at 60°C. The anticipated food contact condition therefore corresponds to "any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/ or heating up to a temperature T where $70^{\circ}\text{C} \le T \le 100^{\circ}\text{C}$ for a maximum of $t = 120/2^{\circ}((T-70)/10)$ minutes".*

The values of specific and global migration are within the limits of *Regulation (EU) No. 10/2011** when used as specified. Thus, the mentioned articles are suitable for long-term storage and direct contact with all types of foodstuff.

Surfase volume ratio

The ratio of surface to volume, which forms the basis of assessment, is *6 dm2: kg*. For the test procedure, this has to be converted to the individual packaging.

Specific Migration Limits (SML):

In the manufacture of the products following materials could be used in which Annex I of Regulation (EU) no. 10/2011 specific migration limits or other restrictions are set. The migrations limits referred to in the legislation are not exceeded using the given contact condition at 10 days at 60 °C.

Raw Material - Worst Case Scenario

RefNo.	CAS-No.	Substance Restriction	
39090		N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine	1,2 mg/kg
39815	182121-12-6	9,9-bis(methoxymethyl)fluorene	0,05 mg/kg

^{*} Regulation (EU) No. 10/2011 including all valid amendments and additions

¹Regulation (EU) No. 10/2011 from 14th of January 2011; page L 12/86; table 3 Standardized test conditions OM2





-	57-11-4	stearic acid	-
38560	7128-64-5	2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	0,6 mg/kg
66360	85209-91-2	2,2'-methylene bis(4,6-di-tertbutylphenyl) sodium phosphate	5 mg/kg
38550	0882073-43-0	bis(4-propylbenzylidene) propylsorbitol	5 mg/kg
95360	27676-62-6	1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6 (1H,3H,5H)-trione	5 mg/kg
45704	-	cis-1,2-cyclohexanedicarboxylic acid, salts	5 mg/kg
-	557-05-1	Zinc stearate	5 mg/kg (Zn)
55910	736150-63-3	glycerides, castor-oil mono-, hydrogenated, acetates	60 mg/kg
-	65-85-0	benzoic acid	-
-	-	Zinc	5 mg/kg
34650	151841-65-5	aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert-butylphenyl) phosphate]	5 mg/kg
38515	1533-45-5	4,4'-Bis(2-benzoxazolyl)stilben	0,05 mg/kg
39120		N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine hydrochlorides	1,2 mg/kg
46880	65140-91-2	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	6 mg/kg
68320	2082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	6 mg/kg
74880	84-74-2	phthalic acid, dibutyl ester	0,3 mg/kg
-	-	Aluminium	1 mg/kg
38507	-	cis-endo-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, salts	5 mg/kg

Color

RefNo.	CAS-No.	Substance	Restriction
68320	2082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	6 mg/kg
-	57-11-4	stearic acid	-
-	77-99-6	1,1,1-trimethylolpropane	6 mg/kg

Dual Use Additives (DUAS)

In the product the following substances could be used which are subject to a restriction on their use in food:

Raw Material - Worst Case Scenario

RefNo.	CAS-No.	E-No.	Substance
56585		-	glycerol, esters with stearic acid
92080	14807-96-6	553	b talc
37600	65-85-0	210	benzoic acid
-	31566-31-1	-	Glyceryl monostearate
89040	1592-23-0	470	a calcium stearate
-	-	471	Mono- and diglycerides of fatty acids
54450	-	-	fats and oils, from animal or vegetable food sources
-	57-11-4	-	stearic acid
-	532-32-1	211	Micronised Sodium Benzoate
90960	110-15-6	-	succinic acid
30960	-	475	acids, aliphatic, monocarboxylic (C6-C22), esters with polyglycerol

ERegulation (EU) No. 10/2011 including all valid amendments and additions

¹Regulation (EU) No. 10/2011 from 14th of January 2011; page L 12/86; table 3 Standardized test conditions OM2Á





Color

RefNo.	CAS-No.	E-No.	Substance
93440	13463-67-7	171	titanium dioxide
89040	1592-23-0	470	a calcium stearate

Appendix II of Regulation (EU) No. 10/2011*

The articles mentioned above do not release substances in such quantities exceeding the defined specific migration values pursuant to appendix II (1).

Furthermore, no primary aromatic amines, except for those mentioned in Appendix I Table 1, are released in detectable amounts to foodstuffs or food simulants.

Liquid colours / Maserbatch (Pigments)

The liquid colours/ masterbatches used for colouring correspond to the requirements of Regulations (EC) No. 1935/2004 and (EU) No. 10/2011* as well as to Resolution AP (89)1 and the Recommendation IX of the BfR.

Undesirable substances

Following substances are no formulation components of above-mentioned product

BBP
Bisphenol A
Bisphenol F
DNOP

Bisphenol SDEPDIDOXDNPPPVDC

NIAS (Non-Intentionally-Added Substances)

The product does not contain any non-intentionally added substances, which might change over to foodstuffs in such amounts which raise concern for human health under intended conditions of use.

Summary of the confirmation of conformity

Our supplier compliance with above-mentioned regulations and laws allows us to confirm that the articles listed on page 1 meet the food law regulations. Our supplier products are suitable for long-term storage at room temperature or below as well as for direct contact with food.¹

The user shall verify independently the product's suitability for the intended content given by the specifications and mentioned in the declaration of conformity.

^{*} Regulation (EU) No. 10/2011 including all valid amendments and additions

¹Regulation (EU) No. 10/2011 from 14th of January 2011; page L 12/86; table 3 Standardized test conditions OM2





Validity

A renewal of the declaration will take place in case of changes of the legal situation or substantial modifications in the composition or production - which lead to a change in the migration of materials or articles as well as the existence of new scientific findings.

The declaration is based on our current state of knowledge and information provided by our supplier at the time that the document was drawn up. The supplier – Bürkle GmbH in Bad Bellingen/Germany – is certified according to the standard DIN EN ISO 9001 by the DQS (German Society for Quality Assurance) since 1995. The number of certificate is 2284-08.

15. November 2017

Bürkle GmbH, Bad Bellingen,

Martin Saint-Denis, Managing Director