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11.12.2014

Report No. 0003092165/30 AZ157380a/
0003123881/70 AZ186360a

Test item: Siliconelastomer sample

Identification: Zhermack - ZA 32 LT ROSSO
Zhermack product codes DT23026, DT23027 and DT23028

Condition at delivery: No claim

Date of delivery: 30.09.2013

Place of testing: Cologne

Test period: 16.10.2013 to 18.11.2013
22.09.2014 to 30.09.2014
24.10.2014 to 31.10.2014

Test scope: Critical parameters selected by test institute

Test specification: Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food, DGCCRF Information Notice 2004 / 64 on materials in contact with foodstuffs

Test result: Pass - According to the kind and extent of tests performed the test item meets the test specification.

Cologne, 11.12.2014



Staatl. gepr. LM-Chem. Andrea Collmann
(Expert)



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(Expert)

The test results exclusively refer to the samples examined.

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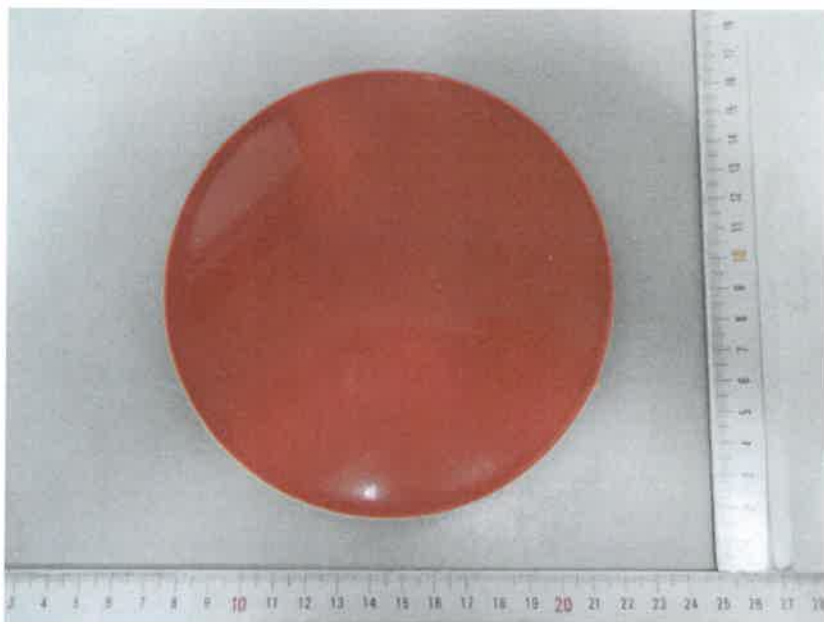
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1. Photo documentation

Picture 1: Silicon elastomere sample



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2. List of materials

Matlist.No.	Article	Article name
157380-1	1	Silicon sample room temperature (RT) ZA 32 LT ROSSO*
157380-4	2	Silicon sample room temperature (RT), delivery of 08.11.2013, ZA 32 LT ROSSO*
183560-1	3	Silicon sample room temperature (RT), delivery of 15.09.2014, ZA 32 LT ROSSO*
186360-1	4	Silicon sample room temperature (RT), delivery of 22.10.2014, ZA 32 LT ROSSO*

Mat.No.	Article	Component	Material	Colour
001	1	basic material	silicone	red
002	2	basic material	silicone	red
003	3	basic material	silicone	red
004	4	basic material	silicone	red

*Zhermack product codes: DT23026, DT23027 and DT23028

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3. Results

Sensory analysis

Sample No.	157380-002		
Sample composition	Mat. 001		
Unit	.		
Organoleptic test			
Contact medium	S/C		
Test conditions	2h/70°C		
Migration preparation			
Smell transfer	0		
Transfer of taste	0		

S/C

Chocolate

If the evaluation is between 0 to 2.5 no sensory deviation is indicated and the sample fulfils the requirements of § 31 LFGB respectively article 3 of the regulation (EC) 1935/2004 (61. Mitteilung Bundesgesundheitsbl. - Gesundheitsforsch - Gesundheitsschutz 46 (2003) 363).

Evaluation scheme:

0 = no discernible deviation

1 = barely discernible deviation

2 = weak deviation

3 = clear deviation

4 = strong deviation

Sensory analysis

Sample No.	157380-001		
Sample composition	Mat. 001		
Unit	.		
Baking test			
Smell transfer	0		
Transfer of taste	0		
Test conditions	20 min/220°C		

If the evaluation is between 0 to 2.5 no sensory deviation is indicated. The sample fulfils the requirements of § 31 LFGB

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Overall migration, Tenax

Sample No.	157380-013		
Sample composition	Mat. 002		
Unit	mg/dm ²		
Conditions of migration, Tenax	2h / 70°C		
Migration preparation	0,42dm ² /1,6841g		
Overall migration	3,1		

Limit value for products in contact with foodstuffs according to the German Commodity Goods Ordinance respectively Regulation (EU) No 10/2011 and if applicable amendments:

Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm² of food contact surface (mg/dm²).

By derogation from this, plastic materials and articles intended to be brought into contact with food intended for infants and young children, as defined by Commission Directives 2006/141/EC and 2006/125/EC, shall not transfer their constituents to food simulants in quantities exceeding 60 milligrams of total of constituents released per kg of food simulant.

Primary aromatic amines (photometric), migration

Sample No.	157380-008		
Sample composition	Mat. 001		
Unit	mg/kg food simulant		
Migration solution	3% HAC		
Conditions of migration	2h/10°C		
Migration preparation	1,4dm ² /230ml		
Primary aromatic amines	<0,01		

3% HAC

3% acetic acid

Limit value for products in contact with foodstuffs according to the German Commodity Goods Ordinance respectively Regulation (EU) No 10/2011 and if applicable amendments:

Plastic materials and articles shall not release primary aromatic amines, excluding those appearing in Table 1 of Annex 1, in a detectable quantity into food or food simulant. The detection limit is 0,01 mg of substance per kg of food or food simulant. The detection limit applies to the sum of primary aromatic amines released.

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Color migration of pigmented plastics

Sample No.	157380-007		
Sample composition	Mat. 001		
Unit	.		
Colour fastness			
Water	pass		
2% Acetic acid	pass		
10% Ethanol	pass		
Coconut oil	pass		

According to the recommendation of the BfR part IX " Farbstoffe zum Einfärben von Kunststoffen und anderen Polymeren für Bedarfsgegenstände", "Kunststoffe im Lebensmittelverkehr" (synthetic material in contact with food), no traces of colour may migrate into the food simulant.

*at silicone vegetable oil

Extractable substances, silicone

Sample No.	157380-004		
Sample composition	Mat. 001		
Unit	%		
Extractable components			
3% - acetic acid	<0,05		
10% Ethanol	<0,05		

Requirements according to the recommendation of the BfR part XV "Silicones": Limit value 0,5 %

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Metals, total plastics

Sample No.	157380-010		
Sample composition	Mat. 001		
Unit	mg/kg		
Cadmium	<5		
Lead	<10		

Legal limit value for cadmium according to Ordinance on Banned Chemicals, Article 18, Annex to § 1 respectively Regulation (EC) No. 1907/2006 Annex XVII incl. amendment by Regulation (EU) No. 494/2011:
100 mg/kg.

Platinum, total content

Sample No.	157380-006		
Sample composition	Mat. 001		
Unit	mg/kg		
Platinum	21		

Requirements according to the recommendation of the BfR part XV "Silicones": 50 mg/kg in end product

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Polycyclic aromatic hydrocarbons (PAH)

Sample No.	157380-009		
Sample composition	Mat. 001		
Unit	mg/kg		
Category *	1		
Naphthalene	<0,2		
Acenaphthylene	<0,2		
Acenaphthene	<0,2		
Fluorene	<0,2		
Phenanthrene	<0,2		
Anthracene	<0,2		
Fluoranthene	<0,2		
Pyrene	<0,2		
Benzo(a)anthracene	<0,2		
Chrysene	<0,2		
Benzo(b)fluoranthene	<0,2		
Benzo(j+k)fluoranthene	<0,2		
Benzo(e)pyrene	<0,2		
Benzo(a)pyrene	<0,2		
Indeno(1,2,3-cd)pyrene	<0,2		
Dibenz(ah)anthracene	<0,2		
Benzo(ghi)perylene	<0,2		
Total PAH	n.n.		
n.n.	not detectable		

* Assessment of the results according to ZEK 01.4-08

Category 1 - Materials intended to be put in mouth and toys for children aged < 36 months intended to come into contact with the skin. Requirement for total PAH: < 0.2 mg/kg**.

Category 2 - Materials not covered by category 1 with foreseeable contact to skin for longer than 30 seconds (long term skin contact). Limit for total PAH: 10 mg/kg respectively limit for benzo(a)pyrene: 1 mg/kg.

Category 3 - Materials not covered by category 1 or 2 with foreseeable contact to skin up to 30 seconds (short term skin contact) or without skin contact. Limit for total PAH: 200 mg/kg respectively the limit for benzo(a)pyrene: 20 mg/kg.

** If the limits of category 1 are surpassed but the limits of category 2 still met, the confirmation of suitability of contact with the oral mucosa can be verified by an additional specific migration test of the PAH components according to EN 1186, ff. and BVL B 80.30-1. The results of the migration test shall be evaluated according to law criteria for foodstuff.

Limit for 8 EU-PAHs (grey indicated substances) in rubber or plastic components of articles according to Regulation (EC) No. 1907/2006, Annex XVII, (effective from 27.12.2015):

- 1 mg/kg per substance for parts of articles that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use
- 0.5 mg/kg per substance for toys and childcare articles

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Volatile organic compounds

Sample No.	157380-014	186360-001	
Sample composition	Mat. 002	Mat. 004	
Unit	%	%	
Test conditions	2h / 70°C	4h / 200°C	
Volatile organic compounds	<0,1	0,3	

Requirements according to the recommendation of the BfR part XV "Silicones": Limit value 0,5 %

Sample No.	183560-001		
Sample composition	Mat. 003		
Unit	mg/kg food simulant		
Migration solution	3% HAC		
Conditions of migration	2h / 100°C		
Migration preparation	3,7dm ² /620ml		
Tin	<0,02		

Limit value according to "Resolution RESAP (2004) 5 on silicones used for food contact applications": SML 0,02 mg/kg food simulant

----End of results----

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4. Summary of methods

Sensory analysis	Standard: DIN 10955	Issue date: 01.06.04
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Method description:
Sensory analysis - Testing of container materials and containers for food products (Commodities)

Sensory analysis	Standard: DIN 10955	Issue date: 01.06.04
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Method description:
According to: Sensory analysis - Testing of container materials and containers for food products

Notes:
Dough according to DIN 10955, article 11.2.5.4
It is examined to what extent food simulant, which comes into contact with the product, undergoes detectable changes in taste and smell. For this purpose the food simulant is stored in the product for the mentioned time and temperature. After this time the food simulant is examined by an appropriate number of tasters with regard to any divergence in smell and taste. Another test sample, which is used as a reference, is treated the same way except that it has no contact with the product to be tested.

Evaluation scheme:
0 = no discernible deviation
1 = barely discernible deviation
2 = weak deviation
3 = clear deviation
4 = strong deviation

Overall migration, Tenax	Standard: DIN EN 1186-13	Issue date: 01.12.02
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Method description:
Materials and articles in contact with foodstuffs - Plastics - Part 13: Test methods for overall migration after repeat determination at high temperatures, Tenax method

Primary aromatic amines (photometric), migration	Standard: BVL L 00.00-6	Issue date: 01.12.02
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Method description:
Determination of primary aromatic amines in plastics according to: Examination of foodstuff - Determination of primary aromatic amines as aniline-hydrochloride in an aqueous extract of foodstuff

Color migration of pigmented plastics	Standard: BGESUNDHBL 15 (1972): 285	Issue date: 01.07.72
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Method description:
Examination of plastics - 24. Recommendation of the BfR commission for plastics: Testing of colour fastness of coloured commodities made of plastics and other polymers

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Date: 11.12.2014

Extractable substances, silicone	Standard: BGESUNDHBL 4 (12): 189	Issue date: 16.06.61
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Method description:
Examination of plastics - 1. Recommendation: Examination of plastics used as commodities according to food law

Metals, total plastics	Standard: DIN EN 1122	Issue date: 01.02.02
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Method description:
According to: plastics - determination of cadmium - decomposition by microwave HNO₃:H₂O₂

Platinum, total content	Standard: DIN EN ISO 11885	Issue date: 01.09.09
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Method description:
According to: Water quality - Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES), silicone

Polycyclic aromatic hydrocarbons (PAH)	Standard: ZEK 01.4-08	Issue date: 25.11.11
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Method description:
Harmonized Method for Determination of Polycyclic Aromatic Hydrocarbons (PAH) in plastic sampling, gas chromatographic method with mass spectrometric detection. Limit of determination 0,2 mg/kg per component

Notes:
Single components with an amount of < 0.2 mg/kg were not considered by the calculation of the sum. In the case of all 18 PAH were not detected, the result is stated n.n. (not detectable).
Benzo(j)fluoranthene and Benzo(k)fluoranthene are reported together.

Volatile organic compounds	Standard: BGESUNDHBL 46 (2003) 362	Issue date: 01.04.03
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Method description:
Examination of plastics - 61. Report: Determination of commodities made of silicones