

1 Manufacturer or importer plus issuer of this declaration of conformity

IBA Intermediate Bulk Alliance GmbH
Brägeler Ring 20, 49393 Lohne, Germany.

2 Identity of the plastic material or item

Trade name	Material type	Material number
Valve	Body: Polyketones, silicone seal	

3 General requirements

We confirm that the materials and items listed in Section 2 are suitable for contact with foodstuffs and meet the relevant requirements contained within the following regulations (including all supplements and as applicable at the time of submission of this declaration):

- Regulation (EC) No. 1935/2004 (Articles 3, 11 Sections 5, 15, 17)
- Regulation (EU) No 10/2011

Information on how compliance with applicable legislation has been established or verified can be found in Sections **Error! Reference source not found.** and 6 described in Section 5 Section 6 available in Section 3.2 in Section 6 as specified in section 5 listed in Section **Error! Reference source not found.**, as specified in Section REF_Ref466911961 \r \h 7, is ensured.

3.1.1 Primary aromatic amines (PAA)

According to the suppliers, levels of the primary aromatic amines listed in Table 1 of Annex I of Regulation (EU) No. 10/2011 released into foodstuffs or food simulants will not exceed the limit values.

According to supplier information and post-migration measurement checks, no detectable amounts of the following primary aromatic amines will be released into foodstuffs or food simulants:

- Substances listed in Appendix 8 to Annex XVII to Entry 43 of Regulation (EC) No. 1907/2006: Detection limit 0.002 mg/kg of foodstuff or food simulant
- Sum of primary aromatic amines: Detection limit 0.01 mg/kg of foodstuff or food simulant

3.2 Impurities and degradation products (NIAS - non intentionally added substances)

The specification of impurities and degradation products (NIAS - non intentionally added substances) is based on 10 ppb screenings with 95% by volume ethanol simulant, 10 days of test conditions at 60°C, measurement by GC-MS/FID

Substance (group)/ migration ^{*1} [mg of C13 equivalent / kg of foodstuff]	Rating
Isoalkanes (likely) Total < 0.01	Aliphatic saturated and unsaturated hydrocarbons (excluding 1-hexene, 1-octene, 1-decene, 1-dodecene, 1-tetradecene) are typical oligomers of polyolefins (POSH - polyolefin oligomeric saturated hydrocarbons). Using the worst-case surface area to volume ratio of one valve/250 L, migration is below the detection limit of 0.01 mg/kg of foodstuff for substances or groups of substances for which no migration is permitted and which are not classified as "mutagenic", "carcinogenic" or "toxic to reproduction" (cf. Regulation (EU) No. 10/2011, Art. 11, Paragraph 4)
Fatty amides (likely)/ Total < 0.01	Typical contamination of lubricants. Using the worst-case surface area to volume ratio of one valve/250 L, migration is below the detection limit of 0.01 mg/kg of foodstuff for substances or groups of substances for which no migration is permitted and which are not classified as "mutagenic", "carcinogenic" or "toxic to reproduction" (cf. Regulation (EU) No. 10/2011, Art. 11, Paragraph 4)
Di-tert-butylbenzene / < 0,01	Di-tert-butylbenzene is a degradation product of Irgafos 168 that is not listed in Regulation (EU) No. 10/2011. Using the worst-case surface area to volume ratio of one valve/250 L, migration is below the detection limit of 0.01 mg/kg

*1 converted using 1 valve/ min. 250 L of foodstuff

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Substance (group)/ migration *1 [mg of C13 equivalent / kg of foodstuff]	Rating
	of foodstuff for substances or groups of substances for which no migration is permitted and which are not classified as "mutagenic", "carcinogenic" or "toxic to reproduction" (cf. Regulation (EU) No. 10/2011, Art. 11, Paragraph 4)
Di-tert-butyl-p-benzoquinone (likely) / < 0,01	Di-tert-butylbenzoquinone is used as an oxidising agent and polymerisation catalyst. It can also be an impurity or a by-product from the oxidation of 2,6-di-t-butylphenol or BHT (butylated hydroxytoluene). Using the worst-case surface area to volume ratio of one valve/250 L, migration is below the detection limit of 0.01 mg/kg of foodstuff for substances or groups of substances for which no migration is permitted and which are not classified as "mutagenic", "carcinogenic" or "toxic to reproduction" (cf. Regulation (EU) No. 10/2011, Art. 11, Paragraph 4)
Siloxanes Total approx. 0.1	There is no specific European regulation for silicones (siloxanes) within the meaning of Article 5 of Framework Regulation (EC) No. 1935/2004. Silicones are regulated at national level using BfR Recommendation XV. Furthermore, polydimethylsiloxane (MW > 6800 Da) is listed in Plastics Regulation (EU) No. 10/2011 under FCM No. 575, Ref. No. 76721 with no limit value. Cyclic siloxanes can enter foodstuffs or food simulants both from crosslinked polydimethylsiloxanes (PDMS), which are used, for example, to coat baking papers and as baking moulds and utensils, and from non-crosslinked PDMS, which are used, for example, as defoamers, release agents or lubricants and in food production. Cyclic siloxanes, primarily D4 (octamethylcyclotetrasiloxane) and D5 (decamethylcyclopentasiloxane), were subject to intensive toxicological testing following ingestion via various exposure routes. The results of these studies show that siloxanes have very low acute oral, inhalative and dermal toxicity. Neither D4 nor D5 nor D6 are mutagenic or genotoxic. We do not have benchmark values for the assessment. For concentrations of or in excess of 0.1% (w/w) of substances, mixtures or articles containing the siloxanes D4, D5 and D6 (dodecamethylcyclohexasiloxane), classified as substances of very high concern (SVHC), information obligations must be taken into account. ECHA classification was based on existing or predicted environmentally-relevant properties (PBT and/or vPvB properties).
Unknown substances (possibly ketone oligomers)/ Total < 0.01	Ketones are not listed in Plastics Regulation (EU) 10/2011. Using the worst-case surface area to volume ratio of one valve/250 L, migration is below the detection limit of 0.01 mg/kg of foodstuff for substances or groups of substances for which no migration is permitted and which are not classified as "mutagenic", "carcinogenic" or "toxic to reproduction" (cf. Regulation (EU) No. 10/2011, Art. 11, Paragraph 4)

4 Dual-use additives

Substance name	FCM No.	CAS No.	E or FL number
Calcium phosphate tribasic (=hydroxyapatite) (Ca salt from polyphosphoric acids)	534	012167-74-7	E341 / E451/ E452
Calcium phosphate (Ca salt from phosphoric acid)	509	0007758-87-4	E341
Titanium dioxide	610	0013463-67-7	E171

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Aluminium (Al)		0007429-90-5	E173
Silicon dioxide	504	0007631-86-9	E551

5 Final use information

Use as	Valve
Filling material	all types of foodstuffs
Ref. no. Food category according to Regulation (EU) 10/2011	different
Filling temperature [°C]	70°C ≤ T ≤ 100°C, max. duration t = 120/2 ^Δ ((T-70)/10) min
Heat treatment [°C / min]	70°C ≤ T ≤ 100°C, max. duration t = 120/2 ^Δ ((T-70)/10) min
Storage temperature [°C]	Room temperature
Shelf life / storage time	Long-term storage
Preparation within the package	not intended
Surface/volume ratio	SML substances: Assessment with max. 6 dm ² /kg of foodstuff NIAS: Assessment with 1 valve/min. 250 L of foodstuff

6 Tests

In some cases, stricter test conditions than those listed here and/or screening procedures in accordance with Annex V of the Plastics Regulation (EU) No. 10/2011 were used to check conformity.

6.1 Overall Migration (OM)

Food simulant	Test conditions (time/temperature)	carried out	Comment
A (ethanol 10% by volume)	OM2: 10d / 40°C	<input checked="" type="checkbox"/>	-
B (acetic acid 3% by weight)	OM2: 10d / 40°C	<input checked="" type="checkbox"/>	-
D2 (vegetable oil)	OM2: 10d / 40°C	<input checked="" type="checkbox"/>	-

6.2 Specific migration

Food simulant	Test conditions (time/temperature)	carried out	Comment
A (ethanol 10% by volume)	10d / 60°C	<input checked="" type="checkbox"/>	-
B (acetic acid 3% by weight)	10d / 60°C	<input checked="" type="checkbox"/>	-
D2 (vegetable oil)	10d / 60°C	<input checked="" type="checkbox"/>	-

6.3 Sensors

The transition from sensory substances to still water (the test foodstuff) in accordance with DIN 10955 (test conditions 1 day at 23°C) falls below grade 2.

Since foodstuffs can differ greatly in their composition, we would like to highlight that the packer must ensure that the foodstuff's organoleptic properties are not impaired by the finished material or item.

6.4 Colour fastness

Coloured plastic materials experienced no discernable fading in accordance with BfR Chapter IX, Part B II (test liquids: dist. water, 2% acetic acid, 10% ethanol, peanut oil).

7 Documentation

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This declaration of conformity is based on the information made available for testing and evaluation, the tests or calculations carried out, as well as the declarations of conformity from the raw material suppliers.

Report	Date	Title
BA 32058-1	12/05/2023	Conformity status, Innoform GmbH
BA 31725	12/05/2023	Test report, Innoform GmbH

8 Further legislation

We certify that the materials and items listed in Section 2 comply with the relevant requirements of the following regulations (including all amendments and as applicable at the time of making this declaration):

Coloured plastics

- BfR Recommendation IX. Colourants for colouring plastics and other polymers for consumer goods
- Council of Europe Resolution AP (89) 1 on the use of colourants in plastics in contact with foodstuffs

Silicones

- BfR Recommendation XV. Silicones

This confirmation applies as described to the product delivered by us. Regulation (EU) No. 10/2011 provides guidance on selecting test conditions to be applied to different foodstuffs. Thereafter, the product meets the requirements of this regulation for contact with the specified filling materials if the specified food contact conditions are observed. It is the user's responsibility to ensure the product's suitability for all intended filling materials beyond the requirements of the regulation.