wipf
Innovative Packaging Solutions

TO WHOM IT MAY CONCERN

Volketswil, 14.02.2022

Declaration of Conformity

WICOVALVE® type W006

Valve body HDPE - Silicone oil - Membrane PET - Membrane holder brown HDPE

For our aroma protection / pressure relief valve we confirm:

1. General

Our products are produced in conformity to the good manufacturing practice (EC) No. 2023/2006 for the usage in direct contact to food and meet the applicable requirements of EU "Framework" Regulation (EC) No. 1935/2004 (Article 3, 11(5), 15 and 17).
Wipf AG is a producer of flexible packaging materials for food applications. We are certified according to ISO 9001 and BRCGS Packaging. Our valves are additionally certified to ISO 22000.

2. Application

WICOVALVE® type W006 can be used for dry, non-aggressive filling goods. The valve is suitable for any long-term storage at room temperature or below. Thermal after treatments are not allowed.

3. Raw materials

Based on the declarations we got from our suppliers, the raw materials used are in conformity with the following regulations and directives:

3.1 Plastics (valve body, membrane and membrane holder)

EU	Regulation (EC) No. 1935/2004	
	Regulation (EU) No. 10/2011	
FDA	PET:	Vol. 21 CFR 177.1630
	HDPE:	Vol. 21 CFR 177.1520 – Paragraph (c) 2.1

3.2 Masterbatch (colorants for membrane holder)

EU	Colorants:	AP (89) 1
	Polymers:	Regulation (EU) No. 10/2011
DE		BfR-Recommendation IX
FDA	Colorants:	Vol. 21 CFR 178.3297
	Polymers and additives:	Vol. 21 CFR 177.1520

3.3 Silicone oil (sealing oil)

EU	Regulation (EC) No. 1935/2004
	Regulation (EU) No. 10/2011
DE	BfR Recommendation XV
FDA	Vol. 21 CFR 173.340, 175.105, 175.300, 176.170, 176.180, 176.200, 176.210, 177.1210, 177.1640, 177.2260, 177.2600, 178.3120, 178.3910

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4. Specific migration

Substances with specific migration limits (SML) do not migrate above their limit per valve. This has been verified by tests according to the rules laid down in Regulation (EC) No. 10/2011 and their amendments or is given by calculation or by statements of our suppliers. The confirmation applies to the scope of application mentioned in point 2.
The compliance with the restriction for the final packaging including the valve is in the responsibility of the distributor.

4.1 Monomers and additives with restriction from plastics

Monomers and additives	REF-No.	CAS-No.	Restriction
Acetaldehyde NIAS: Non-intentionally added substance. Traces possible	10060	0000075-07-0	SML 6 mg/kg
Acetic acid, manganese salt	30180; 10090; 30000	0002180-18-9	SML 0.6 mg/kg
Antimony trioxide	35760	0001309-64-4	SML 0.04 mg/kg
Diethyleneglycol	13326; 15760; 39160; 47680	0000111-46-6	SML 30 mg/kg
Ethyleneglycol	16990; 16778; 53650	0000107-21-1	SML 30 mg/kg
Iron (Fe) from iron compounds			SML 48 mg/kg
Terephthalic acid	24910	0000100-21-0	SML 7.5 mg/kg
ZINC ACETATE	10090; 30000	0000557-34-6	SML 5 mg/kg
Zinc (Zn) from zinc compounds			SML 5 mg/kg
Zinc acetate, dihydrate	10090; 30000	0005970-45-6	SML 5 mg/kg

5. Dual use additives

Based on the information of our suppliers following food additives were used:

Substances	REF-No.	CAS-No.	E-No.
CALCIUM ACETATE	10090; 30000	0000062-54-4	E 263
PHOSPHORIC ACID	23170; 72640	0007664-38-2	E 338
POLYDIMETHYLSILOXANE OIL (Polymer)	23547; 76720; 76721; 86300	0063148-62-9	E 900
POTASSIUM HYDROXIDE	81600	0001310-58-3	E 525
SILICON DIOXIDE	86240; 85580	0007631-86-9	E 551
TITANIUM DIOXIDE (TiO2)	93440	0013463-67-7	E 171
ZINC ACETATE	10090; 30000	0000557-34-6	E 650

The food additives cannot migrate in amounts causing a technical effect in the food.

6. Overall migration

For the overall migration analysis, all plastic parts of the valve were entirely inserted into the simulant.

Test conditions	Simulants	Results
10 days / 40°C	Acetic acid 3%	< 2 mg/item
10 days / 40°C	Olive oil	< 2 mg/item
10 days / 40°C	Ethanol 10%	< 1 mg/item

7. NIAS (non-intentionally added substances)

NIAS can be contained in our products as impurities in the raw materials or as reaction by-products. Typical examples of NIAS in our products are:

- degradation products of antioxidants
- aliphatic hydrocarbon compounds (POSH) from the plastic
- acetaldehyde: a by-product of the PET polymerisation

Wipf AG has its products regularly analysed for NIAS in order to ensure that no substances migrate in quantities that, according to the current state of knowledge, could pose a health risk.

8. Bisphenol A (BPA, CAS 80-05-7)

Bisphenol A is not intentionally added to our valve.
This statement is based on our raw materials suppliers' declarations and from the fact that the mentioned substance is not used in our production process. Therefore, we assume that Bisphenol A is not present in our product. The valve was not analysed for Bisphenol A.

9. Directive 94/62/EC

The total amount of lead, cadmium, mercury and chromium (CrVI) does not exceed 100 ppm.

10. REACH/SVHCs

According to Article 3 of Regulation (EC) No. 1907/2006 (REACH), WIPF AG is a manufacturer of articles that do not need to be registered. Our valves do not contain any substances that are deliberately released under normal or reasonably foreseeable conditions of use. Based on the information from our suppliers, we hereby confirm that none of the substances listed

- in the Candidate List of Substances of Very High Concern or in Annex XIV of Regulation (EC) No. 1907/2006 are intentionally used or added in concentration ≥ 0.1%.

- in the Annex XVII of Regulation (EC) No. 1907/2006 are intentionally used or added in concentration above the restrictions reported in this annex.

Please note that our product has not been tested for these substances.

11. Summary

This confirmation applies to the products supplied by Wipf AG. The document is intended for your company only and replaces all previous declarations of conformity for the named product. The information contained must be treated confidentially.
It is up to the user to ensure the suitability of the packaging for the application and the filling good. The document is valid until the next relevant regulatory change with a maximum duration of 3 years from the date of issue.

W i p f AG

Othmar Wohlhauser
CTO

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+++ This PDF has been signed electronically +++