

DECLARATION OF CONFORMITY

in accordance with
DIN EN ISO/IEC 17050

Date: 7 December 2023
Email: eda@angst-pfister.com
Issuer: EDA

Declaration subject:

HITEC® FKM 75.16-04 (FKM 75.5/VA75F)

The material described above meets the requirements stipulated in the following guidelines/standards:

Food & Beverage

- FDA CFR 21 - 177.2600 a) – f) *
- EC 1935/2004 (excl. article 15) and EC Regulation 2023/2006 (GMP) *
- BfR XXI Category 4 (Migration test BfR XXI Category 2) *
- D.M. 21/03/1973 (Migration test) *
- Dlgs. 25.01.1992 n.108 Art.2 (ex. DPR 777/82 art 2)- complies with Arsenic content limits *
- GB 4806.11-2016 (Migration test) *

Expiry date if relevant *

Medical / Pharma

- USP Class VI, Chapter <87> (In Vitro) and Chapter <88> (In Vivo) - 121°C *

Oil & Gas

- DVGW EN 549 D1/H3 12.12.2027
- BAM tested for gaseous oxygen: max 40 bar at max 60°C and max 25 bar at >60°C to max 150°C *
- DIN EN 16678 : 2016-02 *

* compliance is declared according to the regulation/directive in force.

The material described above meets the requirements stipulated in the following guidelines/standards:

The following statement is based on the current state of our knowledge and is valid from the declaration revision date until the document is superseded. The declaration is valid until the Regulations and Directives are amended. Due to possible changes in the underlying Regulations and Directives, it is not guaranteed that the status of this document will remain unchanged. It will be renewed in all cases where the declaration is no longer ensured.

We hereby declare that our compound complies with the Regulations and Directives as below:

- **REACH (EC) No 1907/2006** and amendments, Annex XIV, Annex XVII and art 59 (SVHC list as of 14th June 2023)
- **Regulation (EU) 2021/1021** (POP) Commission Delegated amending Annex I to Regulation (EU) 2019/1021. Amended as of 15th March 2021
- **Regulation (EC) N° 1272/2008**, CLP, classification, labelling and packaging of chemical substances. in accordance with Part 3 of Annex VI to Regulation EC N° 1272/2008 ATP15 to CLP Regulation. The material does not contain substance classified as carcinogenic, mutagenic or toxic to reproduction (“CMR”) Cat. 1A/1B in accordance with Part 3 of Annex VI to Regulation EC N° 1272/2008 ATP15 to CLP Regulation.
- **RoHS 2011/65/EU & 2015/863/EU**
- **USA EPA, Toxic Substances Control Act (TSCA)** (decaBDE / PIP 3:1 / 2,4,6-TTBP / HCBP / PCTP) latest status December 2021
- **China RoHS**

Additional chemical substances information

- ADI free (free of Animal Derived Ingredients) resp. TSE/BSE related substances
- Latex-free
- BPA, free of Bisphenol A
- Endocrine Disruptors free
- PAK Cat. 2 (AfPS GS 2019:01)
- PFOA/PFOS free

Validity of this declaration: 12 months from issue date

Angst + Pfister Group Engineering

Zurich, 7 December 2023

(Place and date of issuance)


Valerie Thurnau, PhD

Approval and Regulatory Affairs

Manager

(Name and signature or equivalent authentication of authorized persons)


Matthias Czerny

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