Application Note

FESTO

Information on substances in our products



Information on substances in our products

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The operating instructions for Festo products can be found at our **Support Portal**.

Users of this document (application note) must verify that all functions described here also work correctly in the application. By reading this document and adhering to the specifications contained therein, users are also solely responsible for their own application.

Internet: http://www.festo.com

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1 Introduction

Festo SE & Co. KG complies with national and international laws, guidelines, standards, and regulations which are applicable to our products. We constantly monitor the dynamics of legislation, and the following approach supports us in this:

- Our suppliers undertake to comply with substance bans and declaration obligations.
- An internal team of experts assesses products for risk factors.
- Supplied parts are checked cyclically for compliance with substance bans and declaration obligations.
- In case of conspicuous analysis results, we immediately initiate quality assurance measures.
- Products within the scope of an EU directive are CE marked and have a declaration of conformity.

As there are more and more requirements from all over the world, we would like to give an overview about existing information, declaration, and statements. Of course, we cannot cover all upcoming questions, but this Application Note helps to answer the most frequently asked topics.

If your question is not answer, please feel free to contact your local Technical Support or Contact Centre.

2 **CE marking**

If a product is in the scope of a certain regulation of the CE (e.g. ATEX, RoHS, EMC...) there is a CE mark on it and a declaration of conformity is available.

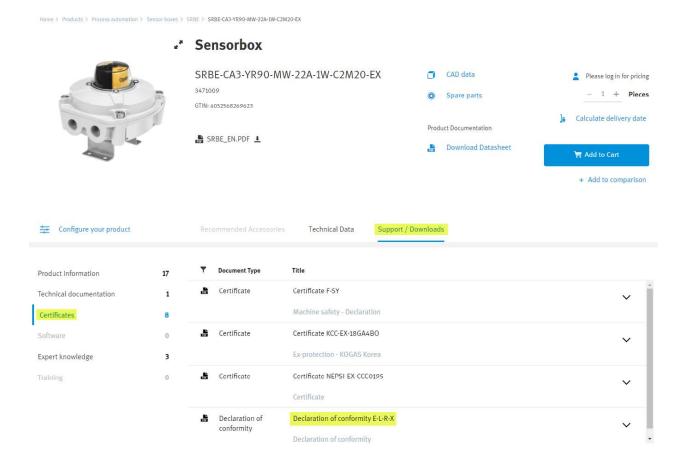
Since a couple of years, there are new Declarations of Conformity (according to CE) available which already describe in the title which directives they contain (e.g. "Declaration of Conformity E-L-R-X").

The European Commission demands (defined in the NLF New Legislative Framework) that all related directives are listed in only one Declaration of Conformity.

The abbreviations in the titles stand for the following directives:

Abbreviation	Definition (EN)	Directive designation (EN)	Directive
E	EMC	EU EMC Directive	2014/30/EU
L	Low voltage	EU Low Voltage Directive	2014/35/EU
M	Machinery directive	EC Machinery directive	2006/42/EC
Pressure	Pressure equipment / Simple pressure vessels	EU Pressure equipment directive / EU Simple pressure vessels directive	2014/68/EU / 2014/29/EU
R	RoHS	EU Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment	2011/65/EU "RoHS 2"
X	ATEX	EU explosion protection directive	2014/34/EU

Here is an example of SRBE:



3 EU directive 2011/65/EU (RoHS)

Festo SE & Co. KG takes into account the expanding scope, the associated CE marking, the expiry dates and the delegated version (EU) 2015/863 when providing information on RoHS 2011/65/EU.

Products which are in direct scope of RoHS do have CE marking and we provide a declaration of conformity in our Support Portal.

Generally you can find information regarding RoHS conformity of certain products in our catalogue pages.

The RoHS-compliant marking includes the application of valid exemptions of Annex III and IV of 2011/65/EU. For Festo products, mainly exemptions 6a, 6b, 6c and 7cI are applied.

RoHS compliance in future:

Festo has already been successively converting its components to RoHS-compliant materials for many years. Our goal is to manufacture all products without using the exemptions in future.

However, this step is not quite so simple, since the technical availability, the economic feasibility and the changing legislation must be taken into account.

The changeover to RoHS compliant materials will therefore accompany us for years.

However, we monitor upcoming changes and react fast in order to be able to deliver RoHS compliant products.

3.1 Delegated Directive (EU) 2015/863

The Delegated Directive (EU) 2015/863 is an update of the ANNEX II on the Directive 2011/65/EU. So the Directive (EU) 2015/863 is a part of the EU directive 2011/65/EU.

A RoHS 3 Directive does not exist. Usually the Delegated Directive (EU) 2015/863 is meant.

The phthalates listed in delegated version (EU) 2015/863 are not used at Festo.

3.2 RoHS exemptions

Regarding the use of applicable RoHS exemptions in our products please check the following Excel file or contact your local Technical Support.

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4 China RoHS 2 GB/T 26572

Our components are not subject to the product catalogue of China RoHS (GB/T 26572). We provide information on EU RoHS exemptions we use, these can be used to fill in the table of provisions of SJ/T 11364.

5 Regulation EC (no.) 1907/2006 (REACh)

Festo SE & Co. KG takes the dynamics of the REACh Regulation 1907/2006 (EC) into account. We continuously monitor changes and additions to REACh Annexes XIV, XVII and new candidate substances (SVHCs). We take the up-to-date candidate list into consideration.

Information about SVHCs (Substances of Very High Concern) in our products can be found via the Excel file attached to this Application Note. The file will be updated quarterly.

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As a manufacturer of articles, we ensure the flow of information within the supply chain. Festo has no obligations arising from the registration or notification of substances and preparations.

Here the current Candidate List:

Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)

5.1 SCIP database for articles containing SVHCs

Festo SE & Co. KG makes all relevant SCIP entries.

We fulfil our duty to inform according to Article 33 of the REACh Regulation via the mentioned Excel file: Application Note

ECHA is responsible for the availability and linking of the data provided by Festo in the SCIP database itself. Festo has no influence on this.

Homepage - ECHA (europa.eu)

6 Conflict minerals (US Dodd-Frank Act and Regulation (EU) 2017/821)

While Festo is a privately held corporation and not subject to the Conflict Mineral rules and reporting requirements under the regulation (EU) 2017/821, we understand that our customers may be. As such, we provide this information to assist our customers in complying with their reporting requirements.

Festo supplies roughly 30,000 catalogue products in several hundred thousand variants and develops some 10,000 customer-specific solutions each year. In doing so, Festo works with a great variety of suppliers from many different countries.

In accordance with our position within the supply chain, we follow the recommendations of the OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas, based on which we have implemented risk mitigation measures. Periodically we conduct via CMRT surveys of our suppliers whose products may contain Conflict Minerals to ascertain / update their use of any Conflict Minerals in the materials they supply to us. Based on such supplier statements and an analysis of our product portfolio, we have identified which products may contain Conflict Minerals in our CMRT (Conflict Minerals Reporting Template). Please note that we have not surveyed suppliers or whose materials obviously do not contain any conflict minerals.

However, due to the complexity of supply chains and the remoteness of Festo's procurement of materials from the original smelter (due to the intervention of several production steps and multiple intermediary traders), a clear traceability back to the smelter is not possible. Conflict Minerals, if any, would be in our products in an already processed form. We do not procure directly from non-certified smelters.

For the reasons mentioned above, we refrain from binding declarations or guarantees that our products are 100% free of conflict minerals from high-risk areas.

Experience from interviews with our suppliers shows that the smelters derived from the CMRT (Conflict Minerals Reporting Template) cannot be clearly verified. The background to this is agile, global procurement logistics and multi-sourcing. We therefore refrain from the requirement to contact non-certified smelters.

Our current CMRT can be found attached to this Application Note.

6.1 Cobalt Reporting Template (CRT)

We do not have a CRT as there is no legal obligation for Festo to have one. It only affects a very small number of products anyway (permanent magnets).

7 TSE/BSE/ADI-free

EMEA/410/01 Rev. 3, Note for guidance on minimizing the risk of transmitting animal spongiformencephalopathy agents via human and veterinary medicinal products (Keyword: TSE/BSE/ADI-free)

The raw materials which we use as well as our auxiliary and operating materials used in production are free from materials of animal origin.

This includes the standard lubricants we use, which are sold as device-specific accessories, among other things.

Plastic granulates used as raw material for our hoses are also free from materials of animal origin. The processes used to manufacture plastic products also virtually eliminate the risk of contamination with BSE/TSE through exposure to high heat.

8 PFAS

This statement is constantly adapted and updated to the current restriction procedure.

- a) The PFAS restriction proposal in the EU
 - → We are currently dealing with an ongoing restriction procedure under the REACh regulation
 - → There are currently no legal bans or regulations on the ~ 10,000 PFAS substances defined in the restriction proposal
 - → There is currently no obligation to declare the above-mentioned PFAS
- b) PFAS-containing products at Festo
 - → Festo products containing PFAS are identified
 - → Approximately 20% of our entire product portfolio contains PFAS, of which 60% are fluoropolymers and 40% are found in PFTE and PTFE lubricants

Generally, here are the individual materials in which PFAS substances are certainly used at Festo:

Plastics: PTFE, PFA, PVDF, ETFE, PCTFE Elastomers: FKM/FPM, FFKM/FFPM, FVMQ

Greases: PFPE greases

- c) Range of applications for products containing PFAS
 - → High temperature applications >150°C
 - → Applications where chemical and thermal resistance is required
 - → Safety-relevant applications where abrasion resistance, protection against leakage, sliding and dryrunning properties and low wear are required
 - → Applications in the process industry, renewable energies, medical technology, food and packaging, special machinery, electronics industry, etc.
- d) Alternatives to PFAS in our products
 - → In applications where the special material properties can be dispensed with, e.g. NBR or silicone can be used
 - → Festo is testing other/new materials as a replacement for PFAS in corresponding applications
- e) Delivery reliability
 - → As the raw material situation is very dynamic, Festo has secured several sources for the long term.
- f) Activities
 - → Festo participates in public consultation through several bodies and exchanges with other affected industrial companies
 - → We permanently monitor the overall situation surrounding the PFAS restriction project
 - → We currently see no need for further action
 - → The existing bans on PFOA, PFOS, PFHxS and other perfluorinated carboxylic acids in both the REACh and POP regulations are not covered by the currently running restriction proposal. Our products are regularly checked for this and applicable bans are complied with.

8.1 Regulation (EU) 2019/1021 on persistent organic pollutants (POPs)

The persistent organic pollutants regulated by the Stockholm Convention and the EU POP Regulation are neither used nor applied in Festo's products or production processes. The ban on the release of persistent organic pollutants is necessary because:

- They remain in the environment for a long time
- They accumulate through the food chain
- They can be transported over long distances in the environment
- They may harm human health and the environment

8.2 (EU) 2020/784 perfluorooctanoic acid (PFOA) in the POP Regulation

Since 8 April 2020, perfluorooctanoic acid (PFOA) and its salts and PFOA precursors have been included in the POP Regulation via the delegated version (EU) 2020/784. The production, placing on the market and use of PFOA itself, in mixtures or in articles is therefore prohibited under Article 4 of the EU POP Regulation. In addition, the production and use of PFOA has been banned since 4th July 2020 via Annex XVII of the REACh Regulation.

Festo products are free of PFOA. Traces cannot be excluded as PFOA is ubiquitously present in the environment.

9 Plasticizers in tubes, seals and cables

Festo products do not contain any plasticizers from the phthalates substance group regulated under REACh (EC) 2006/1907 as SVHC and the delegated version of RoHS (EU) 2015/863 (see RoHS explanation). The plasticizers used are currently not on any prohibition or declaration list.

10 Latex

We do not intentionally use latex or natural rubber in our products. It is not a component of the ingredients used in the materials, but we cannot rule out the possibility of traces of it.

11 US TSCA (Toxic Substance Control Act)

Competent authority: EPA - Environmental Protection Agency

The US EPA regulation "Persistent, Bioaccumulative and Toxic (PBT) Chemicals under TSCA Section 6" refers to persistent chemicals similar to the EU POP Regulation (2019/1021). The regulated substances are not identical.

Five new substances included in TSCA, in force since 09 March 2021.

Product Scope: Substances, Mixtures, Products and Articles

Substance restrictions concern: Manufacturing, Processing, Distribution

EPA plans to issue a proposal for new rulemaking on all five PBT chemicals. The current provisions of the final risk management rules remain in effect while EPA is working on this new rulemaking effort:

The presence must be communicated along the supply chain, similar to REACh.

These five substances are hardly produced or used in the EU anymore.

DecaBDE (Decabromodiphenyl ether, CAS 1163-19-5)

- SVHC-substance
- listed in REACH Annex XVII
- listed in the POP- Regulation Annex I, Part A and Annex IV
- Restriction in RoHS
- ⇒ This substance is not used in products from Festo

HCBD (Hexachlorobutadiene, (CAS 87-68-3)

- listed in the POP- Regulation Annex I
- listed in the Stockholm Convention, Annex II
- ⇒ This substance is not used in products from Festo

PIP (3:1) (*Phenol, isopropylated, phosphate (3:1), (CAS 68937-41-7)*

- The substance is on the CoRAP list. This is the precursor to an SVHC listing (REACh candidate list)
- March 2022 the EPA published eCFR::40 CFR §751.407 PIP (3:1)
- General: Using PIP (3:1) for processing and distributing in commerce, including PIP (3:1) articles is prohibited since March, 2021
- After October 31, 2024 prohibited from all processing and distributing and for use Exceptions:
- After January 6, 2025, prohibited from all processing and distributing and the use in adhesives and sealants or use such products
- An exception applies for PIP (3:1) in the processing of lubricants and greases
- No threshold defined, which is equivalent to a complete ban.
- Downstream notification
- May be present in lubricants, greases and flame-retardant plastic parts. High risk in PVC, PU foams and epoxy resins.
- This substance is not intentionally added to Festo products, but we cannot rule out the possibility of traces of it.

2,4,6-TTBT (2,4,6-Tris(tert-butyl)phenol, CAS 732-26-3)

- The substance is on the CoRAP list. This is the precursor to an SVHC listing (REACh candidate list)
- Restriction/prohibition applies only to substances/mixtures and not to articles.
- Restriction/prohibition > 0,3% w/w
- ⇒ This substance is not intentionally added to Festo products, but we cannot rule out the possibility of traces of it.

PCTP (Pentachlorothiophenol, CAS 133-49-3)

- . The substance is on the CoRAP list. This is the precursor to an SVHC listing (REACh candidate list)
- Restriction/prohibition applies to all articles.
- Restriction/prohibition > 1% w/w
- ⇒ This substance is not intentionally added to Festo products, but we cannot rule out the possibility of traces of it.

11.1 TSCA Section 8(a)(7) – PFAS Reporting and Recordkeeping requirements for certain per- and polyfluoroalkyl substances

40 CFR Part 705

This part specifies reporting and recordkeeping procedures for manufacturers and importers of per- and polyfluoroalkyl substances (hereafter referred to as PFAS) under section 8(a)(7) of the Toxic Substances Control Act (TSCA).

Festo is identifying all products containing PFAS by the start of the reporting phase. Festo will then fulfill its reporting obligation from November 2024 - May 2025.

12 IHM – Hongkong Convention

Resolution MEPC.269(68)

EU SRR – regulation (EU) Nr. 1257/2013

Guidelines of 2015 for the compilation of the inventory of hazardous materials

Purpose: These guidelines provide recommendations for the preparation of the Inventory of Hazardous Materials (IHM), for compliance with the Hong Kong International Convention for the Safe and Environmentally Sound Recycling of Ships, 2009.

An IMO IHM is similar to an EU SRR IHM, but the IMO IHM reportable substances list is slightly shorter.

The substances listed in Table A are not deliberately used in Festo products. Some of the substances are ubiquitous, so we cannot rule out traces of them.

For the substances listed in Table B, MEPC has made reference to the RoHS Directive 2011/65/EU, Annex II and set the limit values accordingly. Our information on RoHS applies here.

From 3.3.2 of MEPC. 269(68) the following information can also be found: Although electrical and electronic equipment must be listed in the inventory, the amount of hazardous materials that may be contained in printed circuit boards (PCBs) of the equipment need not be listed in the inventory.

Festo products therefore comply with the requirements of MEPC. 269(68) and the SRR (EU) Nr. 1257/2013.

13 Halogen-free (chlorine, fluorine, bromine)

- The circuit boards we use may contain halogens
- PVC cables and sealing elements contain chlorine and therefore halogen
- Products made of PTFE, PFA or FKM contain fluorine and therefore halogen
- All other Festo products are halogen-free

Food: difference between FDA, extended material information (F-MATI) and the declaration of conformity according to Regulation (EC) No 1935/2004, (EU) No 10/2011, (EC) No. 2023/2006?

FDA:

We don't provide FDA certificates.

In its "Codes of Federal Regulations", the FDA publishes a list of materials and chemicals at regular intervals which are approved for contact with foods. The mentioned FDA listings always refer to individual materials and not complete products, which usually consist of a variety of different components and/or materials. Since we sell products and not materials, we cannot issue an FDA certificate or anything of the like.

Extended material information (F-MATI):

The extended material information is basically an additional information to the datasheet.

Products with extended material information are typically not intended for direct contact with foods. The extended material information only indicates which materials are listed by which authorities (e.g. BfR, FDA, (EU) No 10/2011 Annex I). Under certain circumstances, some of the utilized materials are not even listed at all. Extended material information is intended to help the customer conduct a risk assessment in order to determine whether and to what extent the respective product can be used in a specific application.

An application in which food is continuously in contact with the product (e.g. food as the medium), is by no means covered by this and has neither been tested nor approved. In each individual case, an evaluation is required to determine whether and to what extent the product can be used. Continuous contact is thus excluded! The assessment/evaluation is the responsibility of the customer.

Declaration of conformity:

Regulation (EC) No 1935/2004, (EU) No 10/2011, (EC) No. 2023/2006

This regulation goes far beyond the extended material information. According to the mentioned regulations (e.g. (EU) No 10/2011) it includes migration tests with so-called food simulants (e.g. water, acetic acid of a given concentration etc.), which come into contact with the product for a specified duration at a specified temperature. Even taste tests are conducted to determine whether the material or product influences the taste of the food.

Also, the good manufacturing practice (GMP) according to (EC) No. 2023/2006 is taken into consideration and must be substantiated with various verifications.

It is also necessary to ensure the traceability of food contact materials in accordance with Regulation (EC) No 1935/2004.

If a product has a declaration of conformity according to these regulations, it can be used in the applications tested and described in the declaration of conformity.

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15 California Proposition 65 (CP 65)

- California Proposition 65 is a consumer protection law and applies exclusively in the State of California.
- Festo's products are industrial and not consumer products and are therefore outside the scope of the CP65.
- The law lists over 1020 substances that are carcinogenic and/or toxic to reproduction.
- Festo products are "infrequently handled products" and are therefore not dangerous.
- The limit values mentioned are exposure limits. No exposure of hazardous substances, thus occupational safety is guaranteed

None of Festo's products contain hazardous substances which could escape during proper use and endanger people.

16 IMDS database

In general, if we receive inquiries regarding IMDS entries we assume that we are talking about the "usage of products in passenger cars".

Unfortunately it is not possible for us to create an IMDS entry for any of our standard catalogue products. This product range has never been tested or is approved by us for use in an automobile.

An IMDS entry also requires a clear reference of component and supplier and the material used. For catalogue products and their individual parts, we cannot guarantee this unambiguousness, as these are subject to change. Also, the existing quality processes for our catalogue products do not meet the requirements of the automotive industry for components used inside passenger cars.

17 Asbestos

Asbestos is regulated e.g. in the REACh regulation (Annex XVII). This means the production and use is nearly totally forbidden in the EU.

For all our products we confirm that they do not contain any Asbestos fibers.

18 Services from Festo

We offer a so called "Extended Material Analysis" for material-specific customer inquiries that go beyond a legal declaration or information obligation as well as a Full Material Declaration (FMD), against payment. Requirements such as these must therefore be the subject of a contract or will be invoiced accordingly as a service.

For further details on this service, please contact your local Technical Support or Contact Center at Festo.

19 Generals

Many substances are ubiquitous and can contaminate products both via the raw material and production processes.

Festo SE & Co. KG can therefore not exclude the possibility that traces of the above-mentioned substance groups are present in our products.

20 Others

Additional technical information e.g. regarding possible operating medium can be found in the following document:

Techinfo_en.pdf (festo.com)