

Company: REMBE Safety+Control GmbH (REMBE®)

Sector: process safety, explosion protection

ECHA application for exemption for rupture discs containing PTFE, FEP or PFA:

PFAS	CAS-Nr.
PTFE	9002-84-0
FEP	25067-11-2
PFA	26655-00-5/ 31784-04-0

Process safety and explosion protection

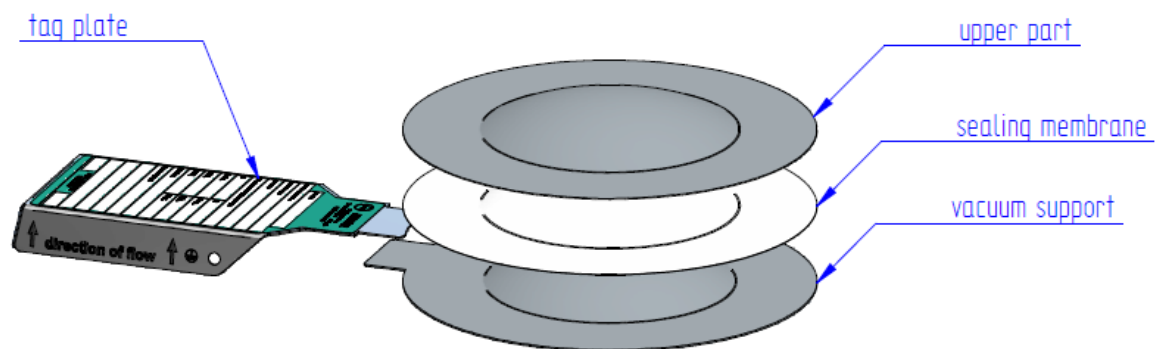
The Annex XV restriction report version 2 does not cover relevant nor essential uses of fluoropolymers in the critical sector of process and explosion protection, which is an indispensable foundation for the safe operation of production plants and industrial processes in various industrial sectors. Rupture discs are one of the essential products required to ensure the safety in these industries.

Definition of rupture discs

Rupture discs are safety devices with defined predetermined breaking points that react to corresponding pressure and are used in a wide variety of applications to relieve pressure. They serve to protect against overpressure or vacuum within a process and to protect people, the environment and machinery. Originally a very simple engineering solution, rupture discs have undergone enormous development in recent years due to growing requirements such as alternating pressures or higher process temperatures and the increasing technologization of processes. The biggest advantage over electronic, pneumatic, or spring-loaded safety systems is the fail-safe nature of rupture discs - making them the most economical and important safety device in industrial operations. The highest possible level of fail-safety is important to prevent unnecessary plant shutdowns. However, how fail-safe a rupture disc is depends to a large extent on the processing and the material used. Rupture discs must often meet requirements which can only be achieved by utilizing PTFE, PFA and FEP as the material for the pressure sealing membrane within. The use of rupture discs is mandatory due to standards (e.g. 2014/34/EU (ATEX) and DGRL (PED) 2014/68/EU).

Design of rupture discs

Rupture discs for pressure relief are round or square, consist of one or more layers. Many rupture discs are equipped with breaking points which are created for example, by means of lasers. These can be simple cuts or even special geometries. This part of the rupture discs is known as the rupture element. Different applications require different types of rupture discs. They are made of metals only or contain parts made of PFAS, (PTFE, FEP, PFA), from one or more layers, and they can be domed or flat. Domed rupture discs either have the dome towards the process (reverse acting rupture disc), or away from the process (forward acting rupture discs). Within these different varieties, there is a broad range of possible combinations.



Schematic of a rupture disc, showing the position of the sealing membrane. Tag plate, upper part and vacuum support are typically made from stainless steel.

The picture above shows a typical – three layered – rupture disc, where the middle layer is responsible to seal both sides of the rupture disc. It is also an important part to control the rupture discs properties towards the bursting pressure. In addition, this part is exposed to the process medium and must resist chemical and temperature effects. PFAS materials like PTFE, FEP and PFA are the only currently known materials, which can achieve this low bursting pressure and offer chemical stability and temperature resistance.

Other materials like stainless steels to higher quality materials such as Inconel, Hastelloy, or Tantalum cannot offer these low bursting pressure, as thin enough material is not available on the market. Furthermore, the handling of these very thin metal foils is very difficult, as they get damaged very easily and have a very high potential to cause injuries during handling within production. Experience on long term use of these materials is also not available in addition to information about aging and long-term stability and ultimately save operation of industrial processes.

Function of PTFE, FEP, PFA in the sector and specific to REMBE®.

The following PFAS material properties are indispensable for the use as sealing membrane and as of our knowledge and experience unique to PFAS like PTFE, PFA and FEP, as they come in direct contact with the customer process medium, which require:

- Chemical Inertness
 - Sealing membrane is in direct contact with the customers process medium.
 - Food or pharma processes in addition require frequent cleaning (high temperature, alkaline and acid agents)
- Thermal Stability (180°C permanent exposure)
 - Within the customer process resulting in a wider range of applications
 - Production of the sealing membrane (thermoforming process)
 - Keeps flexibility also in low temperature conditions.
- Long-Lasting Chemical Stability – Aging
 - Material aging will result in premature failure of the rupture disc, resulting is a health, environmental hazard, and destruction of production facilities.

- **low tensile strength** combined with high elongation **and low permeability** of the sealing membrane material.
- Non-Stick Surfaces
 - preventing adhesion of bacteria and or dirt.
 - Clean environment in food or pharma applications
 - Required by regulations.
 - Only certified and approved PFAS materials allowed.
- Insensitivity against bending and breaking.
 - Also, in low temperatures
 - Easier handling in production
 - Reduction of failure

Most importantly for us, PFAS can be sourced in various material thicknesses down to 0.025mm. This allows us to use PFAS-based sealing membranes - in addition to the unique properties mentioned above - in rupture discs that have a very low burst pressure < 1 bar. No other material enables such a low burst pressure, which is required for the safe operation of numerous industrial processes.

PFAS materials are used as sealing membranes to have a leak-tight rupture discs to prevent emissions to the environment of the process medium. Norms and customer specifications require the use of PTFE, FEP or PFA in certain application due to food regulations and/or requirements towards cleaning between process changes or batches.

Affected products from company REMBE®

PTFE, FEP and PFA are used throughout the different product lines of rupture discs offered by REMBE.

In mean 14% of the yearly production requires PFAS to function (see table in confidential upload for details).

Four product groups are mainly affected by a potential PFAS restriction. 50 – 84% of the yearly production contains PTFE, FEP or PFA as sealing membrane (see table in confidential upload for details).

Due to the unique properties of the PFAS used within the rupture discs they are usually utilized within very specialized applications requested by our customers. Being able to offer these products is not only important to contribute a significant % to the annual turnover, furthermore they enable REMBE® to get access to specialized markets and applications.

Consumption of PTFE, FEP or PFA in REMBE® products

~1600 kg is the average annual amount of PFAS purchased by REMBE. **Only ~10% - ~160 kg - of this amount ends up in the products supplied to our customers.** ~90% of the purchased PFAS materials are collected sorted in production and returned to our supplier for recycling (see confidential documents for more details).

The recycling rate is so high because of offcuts, the material properties (quality control of the raw material), the manufacturing process (thermoforming process), and the legal requirements (destructive tests for each batch).

Application of products from REMBE®

REMBE® products and especially the rupture discs are used in a wide range of industries and applications. The most important sectors and sub uses are listed below. See confidential documents for more details on customers and their applications.

Relevant sectors for the usage of PTFE, PFA and FEP within rupture discs

- Process safety
- Explosion protection
- Plant safety
- Operational safety
- Occupational Safety and Health

Sub uses:

- Food industry (incl. sectors such as the production of baby food)
- Feed industry
- Agricultural sector
- Dust collection
- Spray dryer
- Conveyor Industry
- Pharmaceutical industry
- Energy sector Energy production and storage (coal, gas, hydrogen, biomass)
- Gas engines on ships
- Wood processing industry
- Bulk materials industry
- Mining and surface mining
- Aerospace
- Automotive industry
- Battery production
- ATEX Equipment

Processing of PTFE, PFA and FEP within REMBE®

Products containing PTFE, PFA and FEP are processed at our production facility in Brilon, Germany. PTFE, PFA and FEP are purchased from suppliers and usually delivered in form of film on rolls. The raw material is cut to fit the specific dimensions of the rupture disc. Each cut is undergoing quality control, especially focussing on holes and leakage potential in the texture of the film.

Possible substitute materials that have been used in the past.

We only substitute PTFE by other PFAS materials – PFA or FEP. The selection of PFAS used, is partially controlled by customer requirements and availability of source materials. We are not aware of any comparable material, which could replace PFAS in our product – even on a long-term scale.

Possible alternatives for PTFE, PFA and FEP

Multiple past and present attempt were made within REMBE® R&D to find a suitable replacement for PFAS based sealing membranes.

So far, **no alternatives have been found**, and none are in sight.

For rupture discs with higher bursting pressures, we usually use metal-based stainless steel membranes. A 10µm thin film provides burst pressures in the range of 4 bar. PFAS of similar thickness are well below 1 bar.

Apart from the large discrepancy in the resulting burst pressure, metal foils below 10µm are not available on the market and are difficult to handle in production and pose a risk of injury due to their very thin and therefore sharp edges. These foils are very easily damaged (bends and breaks) during handling in production, transport, and assembly. The smallest bends, dents or notches lead to premature failure after installation at the customer's site due to mechanical failure and fatigue spreading from these weakened areas in the material.

Recently, PEEK (CAS-Nummer: 29658-26-2) has been investigated by our R&D department as an alternative material, with practical tests revealing many insurmountable disadvantages. The material is less flexible and can be easily depressed and bent, which leads to quality problems in manufacturing. Deep drawing is only possible at about 160-200 °C (PFAS at room temperature). Comparing PEEK and PTFE, FEP, PFA at same material thickness (25 µm) the resulting bursting pressure is about 3 times higher and well above 1 bar. Therefore, the required low burst pressures cannot be achieved with PEEK. Long-term chemical resistance, oxidation resistance and UV resistance are not given. Rupture discs are often in contact with free atmosphere on their side facing away from the process.

Time required for possible alternatives

With no alternatives in sight, no clear answer can be given.

Based on our experience with the initial implementation of PFAS in our products we can estimate the following - in case a material very similar in its properties to the currently use PFAS would become available. A set of different materials to cover the property range of PFAS would drastically extend these estimates.

REMBE® would require:

- Validation of alternative materials: 3+ years
- Securing suppliers for the new material in the right quality, amounts and dimensions: 2+ years
- Laboratory testing: Evaluating the alternative after it is identified to get a clear constrain on the properties compared to current PFAS solutions: 2+ years
- Field tests (selected customers and regulatory authorities): 5+ years
- Implementation of the new material into the production process - changing processes, creating new tools and machines, train personal: 2+ years

In addition, the regulatory framework must be adapted to the new material. Many of our products require type approvals, which can take multiple years to get finalized even after production in is sorted and working.

Recycling/reuse

Offcuts remnants of PTFE, FEP, PFA are collected separately within the production process and are recycled/reused by our supplier. The PFAS containing sealing membrane within the rupture discs delivered to our customers can be separated from the product and recycled. As shown above, the amount of PFAS delivered to our customers per year is relatively small. In addition, rupture discs do not have an expiration date and stay within a production facility

for a very long time, often for the plant lifetime. Replacements are only required in case of failure or in some cases due to preventive maintenance by the customer.

Socio-economic consequences due to the elimination of PTFE, PFA, FEP

Rupture discs are utilized in a vast variety of chemical, pharmaceutical or food production processes. The use of rupture discs is mandatory due to European guidelines (e.g. 2014/34/EU (ATEX), DGRL (PED) 2014/68/EU) and indispensable for the safe operation of these processes. In summary, all processes with pressures above 0,5bar must be safeguarded.

Due to the wide variety of uses of rupture discs, it is impossible to provide a complete overview of all affected processes, products, and companies.
See attached confidential customer list with their area of operation.

An unlimited PFAS regulation would lead to potential permanently shutdown of effected processes (<1bar) as they can no longer be protected within regulatory requirements. In addition, processes outside the regulatory controlled area must be protected to ensure safe occupational, health and environmental requirements, e.g. to prevent uncontrolled and undefined emissions or explosions.

The permanent or long-term shutdown of processes will have unforeseeable consequences throughout the industry and along the value chain, affecting industrial production capacities and the availability of food and medical products. This will not only affect the European market, but also weaken the position within the international community and markets. Industry will migrate to areas where there are no PFAS regulations to continue manufacturing certain products. Overall, this is a great opportunity for international companies to take market share and technology away from the EU. We will lose market share and must buy back products from international markets, which now can be produced inside EU borders.

Socio-economic consequences for REMBE®

PFAS-related products account for 14% of annual rupture disc production and up to 84% within specific product groups. The low bursting pressure applications are mostly tailor-made solutions for very specific customer requirements, which give REMBE® a unique selling point in the EU and international markets. This access to international customers would be lost, with an additional negative impact on this customer base and sales of other products. It will also strengthen the market share of international companies operating in the same market segment. This will increase the negative impact on REMBE®, reducing market share and market access, affect sales and profits, and will ultimately lead to employee layoffs.

We herewith apply for an exemption of PTFE, FEP and PFA from the intended PFAS restriction.