

SHPP's Inputs to the Public Consultation Comments to Annex XV PFAS Restriction Proposal

Question number 6: Missing uses: PTFE Used as Internally Lubricated Thermoplastic Compounds for Medical Devices

Executive Summary

SABIC's Specialties business (SHPP) produces a range of highly differentiated products, including high-performance thermoplastics, compounds, and additives that meet complex thermal, mechanical, optical, and electrical property requirements.

PTFE internally lubricated engineering thermoplastic (ETP) compounds are widely utilized in medical devices, some of which are lifesaving and include drug delivery auto-injectors for diabetes and emergency anaphylaxis response, surgical tools for laparoscopic surgeries, and robotic surgical equipment. These compounds offer differentiated properties, such as low friction and high wear resistance, resulting in reliable and repeatable operation of these devices. In general, these compounds are more expensive than non-internally lubricated compounds and are only used when other materials fail to meet application requirements.

The Society of Environmental Toxicology and Chemistry publishes an Environmental Toxicology and Chemistry and Integrated Environmental Assessment on fluoropolymers. In this report, they state that emissions during the use phase of final articles are negligible, because PTFE is bound within the polymer. The emissions in the waste stage depend on the pre-treatment method. Data shows that fluoropolymers are stable and not expected to transform to dispersive nonpolymeric PFAS.

Evaluating the possible alternatives shows that no known alternatives provide the same performance functions and the same/better safety and socio-environmental benefits. Finding an alternative to PTFE in internally lubricated ETP compounds is challenging and would require at least 5-7 years of research and invention. Additionally, numerous tiers, OEMs and moulders across the globe would need to re-design and re-test their tooling, components and systems, which could take 7-10 years for medical devices customers to fully replace. Therefore, it could take at least 12-17 years to develop a new material solution with the same performance and environmental benefits as PTFE, and to replace it in existing applications.

Therefore, SHPP requests a 12-year derogation for PTFE used in internally lubricated engineering thermoplastic (ETP) compounds for medical devices.

Substance Information:

Substance Name: Poly(1,1,2,2-tetrafluoroethylene)

Synonyms/Abbreviations: PTFE

Molecular formula: $(C_2F_4)_n$

EC/List no.: 618-337-2

CAS number: 9002-84-0

Type: Solid

Application: PTFE used in internally lubricated engineering thermoplastic (ETP) compounds for medical devices.