

产品名称: **ETFE 膜**

Product name: ETFE film

申报单位: 上海氟塑新材料科技有限公司

**Submitter: Shanghai Fluoplus New Material Science
and Technology Co., LTD.**

日期: **2023 年 8 月 23 日**

Date: August

23,2023

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CAS □□ 65324-1-1

ETFE film is extruded by melt extrusion process which use ETFE as raw material, neither new component will be involved during film extrusion process nor new by-product will be generated, ETFE film has the exactly same chemical component with ETFE which CAS NO. is 65324-12-1

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We apply for the exclusion of the substances mentioned from the PFAS ban.

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ETFE, CAS NO.:65324-12-1 □□□□□□□□□□,□□□ PFAS □
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Above-mentioned fluoropolymers should be
classified as “polymers of low concern”, get
exclusion of the substances mentioned from the
PFAS ban.

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ETFE film has excellent mechanical properties, light
transmission, weather resistance and
biocompatibility, ETFE film is widely used in
construction, photovoltaic, medical and aerospace
fields. In many industries like aerospace field and
construction field, there are currently no suitable
alternatives.

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Above-mentioned fluoropolymers are distinctly different from other polymeric and nonpolymeric PFAS and should be separated from them for hazard assessment or regulatory purposes. Above-mentioned fluoropolymers can be classified as “polymers of low concern”. Grouping fluoropolymers with all classes of PFAS for “read across” or structure-activity relationship assessment is not scientifically appropriate.

ETFE ,
 PLC
 ETFE
 CFDA
 MFDS PMDA ISO 10993
 ETFE ETFE

PFAS 符合 PLC 要求 PFAS 符合
PFAS 要求

ETFE as an example to show that fluoropolymer toxicity data, human clinical data, and physical-chemical characteristics, Above-mentioned fluoropolymers satisfy the widely accepted regulatory assessment criteria to be considered as PLCs. Fluoropolymers are high molecular weight, have narrow molecular weight distribution, and have negligible oligomer content and organic and inorganic leachables. Data show that fluoropolymers have thermal, chemical, photochemical, hydrolytic, and biological stability. ETFE has been extensively tested to comply with US and EU food contact and global medical device regulations (e.g., USFDA, CFDA, Korea MFDS, Japan PMDA), including ISO 10993 biocompatibility testing and preclinical animal testing. Toxicology studies on ETFE demonstrate the absence of acute or subchronic systemic toxicity, irritation,

sensitization, local toxicity on implantation, in vitro and in vivo genotoxicity, hemolysis, complement activation, or thrombogenicity. The data presented demonstrate that the fluoropolymer class of PFAS is well defined, meets PLC criteria, and should be considered as distinctly different from other classes of PFAS. The grouping of all PFAS together is not supported by the scientific data.

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A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers

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