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□□□□: ETFE □□

Product name: ETFE film

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

□□:2023 □ 8 □ 10 □

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ETFE

ETFE 係指 ETFE 聚合物經擠出或吹膜製成之薄膜，其化學成分與 ETFE 樹脂相同，CAS NO. 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

ETFE

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

ETFE 係指 ETFE 聚合物

ETFE

ETFE, CAS NO.:65324-12-1 係指 ETFE 聚合物，應被歸類為 PFAS 中之“低關注聚合物”。

Above-mentioned fluoropolymers should be classified as “polymers of low concern”, get exclusion of the substances mentioned from the PFAS ban.

ETFE

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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.

ETFE

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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.

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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.

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

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