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Product□
PTFE,CAS NO.: 9002-84-0
FEP, CAS NO.: 25067-11-2
ETFE, CAS NO.:65324-12-1
PFA, CAS NO.: 26655-00-5

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

Details:
PTFE,CAS NO.: 9002-84-0
FEP, CAS NO.: 25067-11-2
ETFE, CAS NO.:65324-12-1
PFA, CAS NO.: 26655-00-5
Above-mentioned fluoropolymers should be be classified as “polymers of low concern”,get exclusion of the substances mentioned from the PFAS ban.

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.

PTFE 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. Polytetrafluoroethylene 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 PTFE 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.

Docs

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

Barbara J Henry, Joseph P Carlin, Jon A Hammerschmidt, Robert C Buck, L William Buxton, Heidelore Fiedler, Jennifer Seed, Oscar Hernandez

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