SAFETY, HYGIENE, HEALTH EFFECTS

Fluoropolymer resins like Halar® ECTFE are known for their high chemical stability and low reactivity. Where toxicological studies have been conducted on fluoropolymers, no findings of significance for human health hazard assessment have been reported. None of the fluoropolymers is known to be a skin irritant or sensitizer in humans.

Following massive exposure to fluoropolymer resin dust by inhalation, increases in urinary fluoride were produced; however, no toxic effects were observed. Some Halar® resins are formulated with additives such as fillers, pigments, stabilizers, etc, to provide favourable processing, or other characteristics. These additives may present other hazards in the use of the resins.

The Safety Data Sheet, available for each of the commercial grades, should be consulted for specific health information and to follow all the necessary safety instructions.

For further details, please consult the brochure “Guide for the Safe Handling of Fluoropolymers Resins”

Toxicity of decomposition products

The main Halar grades must be processed at temperatures between 260°C and 280°C. Under these conditions, there is no risk of decomposition of the ECTFE polymer (except in the presence of contaminants)

In general, it is important to ensure good ventilation in the workplaces. In order to avoid decomposition, it is imperative that the material not be heated to a temperature above 350°C. The main fluorinated product emitted during combustion is hydrofluoric acid (HF) which is dangerous if inhaled or if it comes into contact with the skin or the mucous membranes.

As an indication with respect to HF, the ACGIHTLV-Ceiling value (the concentration that should not to be exceed during any part of the working exposure) is 2 ppm (1.7 mg/cm^3), the indicative occupational exposure limit values established by Directive 2000/39/EC is 3 ppm (2.5 mg/m^3) for short-term (15-minutes) exposure period and the IDLH (Immediately Dangerous to Life or Health Concentrations) value set by NIOSH is 30 ppm.

In the event of fire, it is preferable to extinguish it with sand or extinguishing powder; use of water may lead to the formation of acid solutions.

Approvals

Food Contact

The fluorinated monomers used in the Halar copolymers (ethylene, chlorotrifluoroethylene) and terpolymers (ethylene, chlorotrifluoroethylene, perfluoropropylvinylether) meet the requirements of European Commission Directive 2002/72/EC and its amendments, relating to plastics materials and articles intended to come into contact with foodstuffs.

Halar® ECTFE grades comply with the specifications of the United States Food and Drug Administration (FDA) 21CFR 178.1380.

Several grades of Halar® are recognized under each of these standards. Information on current listings for specific grades is available from your Solvay Solexis representative.

International Water Contact Standards

Listings expire periodically and depending on market demand they may or may not be recertified. Contact your Solvay Solexis representative for the latest listing.

National Sanitation Foundation

NSF International is a no-profit, non-governmental organization that develops standards for public health and safety. It also provides lists of materials that conform to their standards.

NSF Standard 61 – Drinking Water System Components – Health Effects

The table below lists the Halar® ECTFE polymers certified to meet NSF Standard 61 at 85°C (185°F)

Table 16: Halar® ECTFE in compliance with NSF Standard 61

Grade
Halar® 300LC - Halar® 350LC - Halar® 500LC Halar® 901 - Halar® 902

Medical Applications

Biological tests ca rried out on Halar® ECTFE according to USP chapter 88 “Biological reactivity tests, in vivo” have demonstrated its compliance with the requirements of USP Plastic Class VI.

Although USP Class VI testing is widely used and accepted in the medical products industry, it does not fully meet any category of ISO 10993-1 testing guidelines for medical device approval.

Each specific type of medical product must be submitted to appropriate regulatory authorities for approval. Manufacturers of such articles or devices should carefully research medical literature, test and determine whether the fluoropolymer is suitable for the intended use. They must obtain all necessary regulatory agency approvals for the medical product including any raw material components.

Solvay Solexis does not allow or support the use of any of its products in any permanent implant applications. If you have any questions regarding the company’s implant policy, please contact your Solvay Solexis representative