Processed Product for Medical Device

Application Number: Medical devices (Annex E.2.9.)
Application Name: For medical device

Materials used in this product is PFA (CAS NO:26655-00-5).

· This product is to be used under the following conditions.

Subject to use: to be used as materials for flow meters in dialysis machines, and packings, pumps, etc., in the sterilization and cleaning processes of dialysate supply equipment.

Chemical solution to use: Sodium hypochlorite, acetic acid

Usage environment: room temperature to 90°C

Use conditions: not to be affected by chemicals in the use environment, and no elution.

For example, sodium hypochlorite used as a dialysate solution or disinfectant used in hemodialysis machines is corrosive, hence it is necessary to have chemical resistance and corrosion resistance. These properties need to be ensured especially for medical applications, and no alternative product is considered to be available at this time.

In addition, if the use of the material is restricted by PFAS regulations, parts necessary for hemodialysis machines will not be available, affecting approximately 350,000 people*1) in need of hemodialysis and risking their lives.

The global dialysis market is expected to reach US$174,446.7 million*2) by 2030 due to the increasing number of elderly people, diabetes and hypertension, and if the machines cannot be manufactured, it has a significant impact on the market size.

In light of the above, it is essential that PFA be used in applications for medical devices, and we request a regulatory exemption of this material from the subject of PFAS regulations.

References

*1) Number of patients in Japan at the end of 2021: (cited from "Current Status of Chronic Dialysis Therapy in Japan" by the Japan Society for Dialysis Therapy)
*2) Cited from a report published by Panorama Data Insights on Feb. 24, 2022. [https://prtimes.jp/main/html/rd/p/000000088.000091008.html]

Table 2 Chemical Resistance and Solvent Resistance of Various Plastics and Rubbers*

Chemicals and solvents (concentration: %) \ Material	Polyethylene	Polypropylene	Poly(4-methylpentene)	Polyvinyl chloride		Polymethyl methacrylate	Polystyrene	Polyvinylidene chloride	4-fluoroethylene	Silicon rubber	Fluororubber
				Soft	Hard						
Hydrochloric acid (10)	◎	◎	◎	○	◎	○		◎	◎	○	◎
(38)	◎	◎	◎	△	◎	○		◎	◎	×	◎
Nitric acid (30)	○	○	○	△	○	×	×	○	◎		◎
Sulfuric acid (10)	◎	◎	◎	◎	◎	◎	◎	◎	◎		◎
(98)	△	△	△	×	△	×	×	×	◎	×	◎
Formic acid (90)	◎	◎	◎	×	○	×		○	◎	○	△
Acetic acid (10)	◎	◎	◎	○	◎	○		○	◎	○	○
(100)	△	△	◎	×	△	×		×	◎	○	○
Aqueous ammonia	◎	◎	◎	○	◎	○		◎	◎	◎	◎
Sodium hydroxide (10)	◎	◎	◎	○	◎	○	◎	◎	◎	×	○
Ethanolamine	○	○	○	×	×				◎	○	×
Ethylenediamine	○	○	○	×	×	×			◎	◎	×
Pyridine				×	×	×			◎		×
Methanol	○	○	○	×	○	×		△	◎	○	○
Ethanol	○	○	○	×	○	×		○	◎	○	◎
Isopropanol	◎	◎	◎	×	○	×		○	◎	◎	◎
Ethylene glycol	◎	◎	◎	×	△				◎	◎	◎
Diethyl ether	×	△	×△	×	△			×	○	×	×
Diisopropyl ether	○	○	○	×	△	×			◎		×
Dioxane				×	×					△	×
Formaldehyde (40)	○	◎	◎	○	○	○		○	◎		◎
Acetone	△	△	△	×	×	×	×	×	◎	○△	×
Methyl ethyl ketone	△×	△	△	×	×	×	×	×	◎	△	×
Ethyl acetate	△	△	△	×	×	△		×	◎	△	×
Butyl acetate	△	△	△	×	×	×	×	×	◎	×	×
Hexane	×	△	×△	×	○	△			◎	×	◎
Isooctane	△			×	×	△			◎	×	◎
Benzene	△	△	△	×	×	△	×	×	◎	△	○
Toluene	△	△	△	×	×	△		×	○	×	○
Methylene chloride	×	△	×△	×	×	×	×	×	◎	×	○
Chloroform	×	×	×	×	×	×	×	×	○	×	○
Carbon tetrachloride	×	△	×△	×	×	×	×	×	◎○	×	◎
Chlorine gas	△	△	△	△	○	○	◎	○	○		◎
Ammonia gas	◎			△	○			×	◎	◎	×
Ozone	△			○	○	△		◎	◎	◎	◎
Potassium permanganate (5)	◎	◎	◎	○	◎			◎	◎		
Sodium hypochlorite (5)	◎	◎	◎	○	◎	○		◎	◎	◎	◎

Resistance to inorganic chemicals was determined by focusing on changes in the appearance of the sample, the degree of liquid contamination and changes in physical properties. ◎= Superior: no or little influence, ○= Good: some influence, but can withstand use under certain conditions, △= Acceptable: should not be used as much as possible, × = Unacceptable: not suitable for use due to severe influence.
Resistance to organic oils and solvents was classified according to the following by immersing the sample at room temperature for 48 hours and measuring the weight change rate. Weight change rate = ◎: 10% or less, ○ : 11 to 30%, △ : 31 to 100%, × : 101% or more
*Excerpted from references 1) and 2).
Table shows results obtained at room temperature. Resistance decreases at high temperatures and may be usable at room temperature but not usable at high temperatures.

Reference

*3) Masahiro Natsume, National Institute of Science and Technology Agency, Nagoya University, Faculty of Agriculture, "Chemical and Solvent Resistance of Plastic Laboratory Equipment"