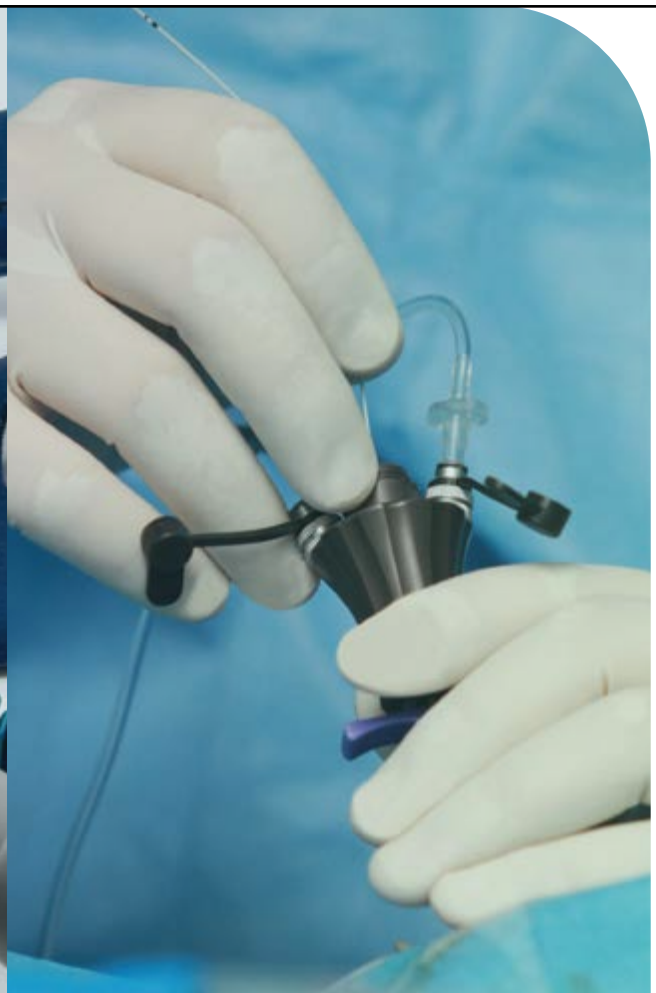


HIGH PERFORMANCE POLYMERS
CHEMICAL & STERILIZATION
RESISTANCE



CHEMICAL RESISTANCE OF ARKEMA'S HIGH PERFORMANCE MEDICAL-GRADE POLYMERS

As healthcare technology continues to advance, the need for high performance medical grade polymers will increase. Arkema, having been a key player in the healthcare market, recognizes the importance of thoroughly understanding the chemical resistance profile of its Medical Grade High Performance Polymers. In order to ensure optimal material selection for its customers, Arkema has conducted a chemical resistance study with the top chemical agents commonly used in hospitals and other healthcare settings along with its Medical Grade High Performance Polymers.

TABLE 1 - LIST OF CHEMICAL AGENTS

MAIN CATEGORY	CHEMICAL COMPOSITION	CAS NUMBERS	COMMERCIAL PRODUCTS (HOSPITAL)
Bleach	Sodium hypochlorite 11-15% diluted at 0.2%	7681-52-9	10% bleach solution
			Clorox Bleach
			Dispatch
			Dispatch™ Hospital cleaner
			Disinfectant with bleach
			Sani-cloth™ Bleach Wipe
			Alcavis Bleach Wipe 1:10
H ₂ O ₂	Hydrogen peroxide (30%) and peracetic acid (38-40%- diluted at 5%)	7722-84-1 and 79-21-0	Accel TB wipes
			Ecolabs oxycide
			Virox
IPA	2-propanol 100%	67-63-0	Isopropyl alcohol (or propan-2-ol or isopropanol)
			70% IPA solution
Phenol	CRESYL (10% hexylene glycol + 1% orthobenzylparachlorophenol + 0.1% O-phenylphenol)	59-50-7 and 90-43-7 and 120-32-1	Wex-cide 128
			Precise
			Sporicidin
			Precise™ Hospital Foam cleaner disinfectant
			Sporicidin™
QAC (Anti-infective agent)	Benzethonium chloride 98% diluted at 0.3%	121-54-0	Sanicloth HB wipe
			Sanicloth Super
			Sanicloth AF3
			Virex TB
Glycol Ether	2-butoxyethanol 99% diluted at 5%	111-76-2	Cavicide
Detergent	Chlorohexidine digluconate 30% diluted at 1%	18472-51-0	Aniospray 29
			Clinell detergent wipe
			Cidex (2.4% glutaraldehyde)
			Cidex OPA
DMSO	Dimethyl sulfoxide 99%	67-68-5	-

Table 2 demonstrates the qualitative performance of chemical resistance based on surface aspect (the appearance of cracks) and coloration. Environmental stress cracking resistance tests (ESCR) were performed using elliptical Bergen jig, which applies a range of strains to a single sample bar and injected plates immersed into the indicated chemical agent at room temperature (23°C) for 24 hours.

Table 3 demonstrates the solvent absorption of all the medical grades based on standard ASTM D543. Sample injected plates (1 mm thickness) were immersed in the designated solvent. The samples were maintained at room temperature (23°C) until the swelling reached a complete saturation of the material (approximately 1,300 hours). The weight absorption was measured regularly by removing the sample from the solvent, wiping it and weighing.

STERILIZATION COMPATIBILITY OF ARKEMA'S HIGH PERFORMANCE MEDICAL-GRADE POLYMERS

AUTOCLAVE

Common technique to kill microorganisms on a medical device using moist heat.

Autoclaving is a fast and inexpensive technique used to sterilize re-usable instruments and devices.

Two different programs were performed to study the impact of steam sterilization on the range of medical grades with temperature ranging from 121°C up to 134°C.

Test Conditions

- Program 1: 121°C (250°F) for 30min at 1 bar (total cycle: 69 min)
- Program 2: 134°C (273°F) for 12min at 2 bars (total cycle: 53 min)

GAMMA RADIATION

Gamma irradiation process uses Cobalt 60 radiation to penetrate and kill microorganisms on a variety of disposable healthcare devices in a specially designed cell. Gamma radiation is generated by the decay of the radioisotope Cobalt 60, with the resultant high energy photons being an effective sterilant. The unit of absorbed dose is kiloGray, expressed as kGy.

Test Conditions

- Dosage exposure: 25 kGy and 50 kGy

ETHYLENE OXIDE

ETO Sterilization is a low-temperature process (typically between 37°C and 63°C) that uses Ethylene Oxide gas to reduce the level of infectious agents. ETO is a gas that acts as a strong alkylating agent.

ETO Sterilization is mainly used for products that cannot withstand the heat of typical autoclave sterilization.

Gas concentration, temperature, humidity and exposure time must be precisely controlled to ensure proper sterilization.

Test Conditions

- Concentration: 600 mg/L of 100 % EtO
- Temperature: 40 °C (104 °F)
- Exposure time: 241 minutes
- Relative humidity: 51 %



RILSAMID® MED POLYAMIDE 12	Steam (121°C, 30 min, 1 Bar)				Steam (134°, 12 min, 2 Bar)			
	1 cycle	3 cycles	5 cycles	25 cycles	1 cycle	3 cycles	5 cycles	25 cycles
AESNO MED	++	++	+	+	++	++	+	+
AMNO MED	++	++	++	+	++	++	0	0
RILSAN® MED POLYAMIDE 11								
BMNO MED	++	++	+	+	++	++	+	0
BESNO MED	++	++	+	+	++	++	+	+
BESVOA MED	++	++	++	++	++	++	++	++
8020	+	+	+	+	+	+	+	+
RILSAN® CLEAR MED TRANSPARENT POLYAMIDES								
G850 Rnew MED	+	+	+	+	+	+	+	+
G170 MED	++	++	++	+	+	+	+	+
PEBAX® MED ELASTOMERS								
MV1074 SA01 MED	++	+	+	0	++	+	+	0
2533 SA01 MED	+	+	+	+	0	0	0	0
3533 SA01 MED	+	+	+	+	+	0	0	0
4033 SA01 MED	+	+	+	+	+	+	+	+
4533 SA01 MED	++	++	++	+	+	+	+	+
5533 SA01 MED	++	++	++	+	+	+	+	+
6333 SA01 MED	++	++	++	+	+	+	+	+
7033 SA01 MED	++	++	++	+	+	+	+	+
7233 SA01 MED	++	++	++	+	+	+	+	+
7433 SA01 MED	++	++	++	+	+	+	+	+

RILSAMID® MED POLYAMIDE 12	GAMMA STERILIZATION		ETHYLENE OXIDE
	25 KGY	50 KGY	
AESNO MED	+	+	++
AMNO MED	+	+	++
RILSAN® MED POLYAMIDE 11			
BMNO MED	+	+	++
BESNO MED	+	+	++
BESVOA MED	+	+	++
8020	++	++	++
RILSAN® CLEAR MED TRANSPARENT POLYAMIDES			
G850 Rnew MED ⁽¹⁾	+	+	++
G170 MED ⁽¹⁾	+	+	++
PEBAX® MED ELASTOMERS			
MV1074 SA01 MED	++	++	+
2533 SA01 MED	+	+	+
3533 SA01 MED	+	+	++
4033 SA01 MED	+	+	++
4533 SA01 MED	+	+	++
5533 SA01 MED	+	+	++
6333 SA01 MED	+	+	++
7033 SA01 MED	+	+	++
7233 SA01 MED	+	+	++
7433 SA01 MED	+	+	++

(1) A temporary purple coloration change could occur after gamma sterilization exposure

QUALITATIVE KEY FOR STERILIZATION RESISTANCE

- ++ Suitable - No change
 - +
 - 0
- Suitable - Change in color but no change in mechanical performance
- Not suitable



Arkema Inc.

900 1st Ave,
King of Prussia, PA
19406, USA
+1 610-205-7000

Headquarters: Arkema France

420 rue d'Estienne d'Orves
92705 Colombes Cedex
France
T +33 (0)1 49 00 80 80

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