HOSPITAL CLEANER RESISTANT ALLOYS

RTP 2000 HC Series for Medical Devices

- Excellent resistance to hospital cleaners even when under molded in stresses
- Available in UL94 V-0 flame retardant and EMI Shielding versions
- Colorable, and provide good UV resistance

KEY BENEFITS

- Resists damage and degredation due to harsh chemical disinfectants and cleaners
- Global availability
- Same shrinkage as PC/ABS
- Drop-in replacement for PC, PC/ABS and other amorphous polymers
- Colorable
- Improved UV resistance
- UL94 V-0 @1.5mm/ 5VA @ 3.0mm in all colors

The Risk of Hospital Acquired Infections (HAIs)

According to the US Center for Disease Control HAI Prevalence Survey, there were 722,000 hospital acquired infections reported in 2011 and approximately 75,000 people died during their hospitalization. Similar numbers are being reported by hospitals in Europe and Asia. Eliminating these infections has become top priority in hospitals around the globe. One major weapon in the arsenal against HAIs is improving cleaning and disinfection procedures used to kill bacteria, viruses and other microbial organisms on hospital equipment and surfaces where they can grow. These improved procedures have lead to the increased use of hospital cleaners and disinfectants, both in terms of frequency and amounts.

Hospital Cleaners and Disinfectants

Cleaners and disinfectants used to sanitize medical devices often include one or more of six basic chemistries: alcohols, peroxides, aldehydes, quaternary compounds, alkyl amines and chlorine releasing compounds. These solutions can be sprayed on the surface, delivered via a wipe or cloth, or applied by other methods. One item they have in common is that they release molded in stresses within plastic parts and cause weakness, cracking and catastrophic failure, in some cases, after only a few cleaning cycles.

RTP Company Technical Plastic Solutions

Prompted by OEMs and injection molding companies who reported that their plastic housings were breaking in record numbers and that the issues were traced back to the use of harsh chemical disinfectants, RTP Company began searching for solutions. The goal was to identify resins with physical properties similar to PC alloys, but that also demonstrated a vastly improved resistance to commonly used hospital cleaners.

Many commercially available resins were screened, but none provided the desired performance. RTP Company then created new alloys using unique combinations of resins and additives, and tested them for strength and functional performance when exposed to hospital cleaners. The result is a new polyester alloy known as the RTP 2000 HC series, which is designed with superior resistance to damage and degradation caused by hospital cleaners (HC). The series includes a Flame Retardant and a non-Flame Retardant version, and can be further enhanced with properties such as UV resistance, EMI shielding, and colorability.

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Test Method

A test procedure was established using existing thermoplastic housing materials to simulate the failures occurring in the field. Many different procedures were screened, ranging from full chemical immersion to periodic exposure. After a review of the data was conducted, it was determined that the combination of placing the test specimen under strain and simulating the chemical exposure and drying phases produced the results most indicative of the failure experienced in the field. This procedure was established as the method used to accurately predict and measure performance of material composition with respect to chemical exposure.

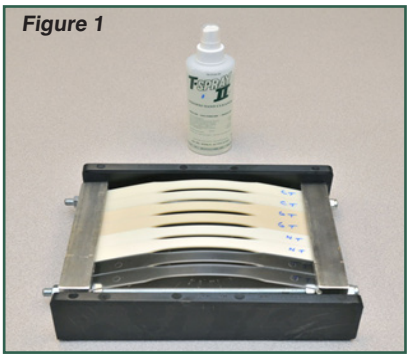


Figure 1

Figure 2

The test procedure consisted of molded ASTM D638 Type 1 tensile bars, which were placed in a specially designed fixture to ensure the samples were strained to 1.0% (Figure 1). A gauze patch was applied to the center of the specimen and saturated every 24 hours with a specific chemical agent (Figure 2). This allowed the material to air dry and oxidize as would be seen in a typical field exposure. The testing was performed on each composition in triplicate to confirm consistency.

The selected duration of the test was 96 hours, which proved to be ample time to produce the same failure seen with standard industry housing materials such as PC/ABS, which showed complete failure of the material in test. Those materials that survived the exposure were then tested in accordance with ASTM D638. The tensile strength and tensile elongation were then benchmarked and analyzed for property retention.

The chemical cleaners selected for exposure were intended to cover a wide sampling of those common in the healthcare industry. The chart in Figure 3 shows a list of the chemical disinfectant cleaners chosen for testing, and the active ingredients in each cleaner.

Figure 3: Cleaners and their active ingredients	
Birex®	P-Tertiary Amylphenol 5-10%, #2 Phenylphenol 5-10%, Phosphoric Acid 15%, Isapropanol 7.5%, Dodecylbenzene Suflonic Acid <5
CaviCide 1®	Isopropanol 15%, Ethanol 7.5%, Ethylene Glycol Monobutyl Ether (2-Butoxyethanol) 1-5%, Didecyldimethyl Ammonium Chloride 0.76%
Cidex Plus®	Glutaraldehyde 3.4%
Incides N®	Propan-2-ol 25-35%, n-Propanol 25-35%
Incidin Plus®	Glucoprotamin 25-25%, 2-(2-Butylethoxy) Ethanol (Butyldiglcyol) 10-20%, 2-Phenoxyethanol 10-20%, Fatty Alcohol Ethoxylate 1-5%
Incidin Pro®	2-Phenoxyethanol 10-20%, N-(3-Aminopropyl)-N-Dodecylpropane-1,3-Diamine 5-10%, Benzalkonium Chloride 5-10%, Ethanolamine 1-2.5%, d-Glucopyranose, Oligomeric, Decyl Octyl Glycosides 1-2.5%, Alkylpolyglycosides 1-2.5%
Sani-Cloth Active®	Quaternary compounds
Sani-Cloth Bleach®	Trisodium Phosphate Dodecahydrate 1-2.5%, Sodium Hypochlorite < 1%
Sani-Cloth Plus®	Isopropanol 10-20%, Ethanol, 2-Butoxy- 1-4%, Benzyl-C12-18-Alkyldimethyl Ammonium Chloride < 0.125%, Quaternary Ammonium Compounds, C12-18-Alkyl [(Ethylphenyl) Methyl] Dimethyl, Chloride < 0.125%
Super Sani-Cloth®	Isopropanol 30-60%, Benzyl-C12-18-Alkyldimethyl Ammonium Chloride 0.1-1%, Quaternary Ammonium Compounds, C12-18-Alkyl [(Ethylphenyl) Methyl] Dimethyl, Chloride 0.1-1%
T-Spray II™	Octyl Decyl Dimethyl Ammonium Chloride 3.255%, Dioctyl Dimethyl Ammonium Chloride 1.628%, Didecyl Dimethyl Ammonium Chloride 1.628%, Alkyl Dimethyl Ammonium Chloride 4.339%

Test Results

To find the best possible combination of chemical resistance and physical property performance, numerous compositions and alloys were screened. One proprietary polyester alloy, now known as the RTP 2000 HC series, provided not only superior chemical resistance, but also all the required properties important for medical housing function, such as impact resistance, dimensional stability, flame retardancy, and colorability (see Figure 4).

Figure 4: Property Comparison

PROPERTY	RTP 2000 HC A	RTP 2000 HC FR A	PC/ABS	PC/ABS FR
Healthcare Chemical Damage Resistance	Excellent	Excellent	Poor	Poor
Izod, Notched (J/m)	800	640	640	590
Tensile Strength (MPa)	47	43	55	55
Tensile Elongation (%)	>100	>50	>50	>10
Flexural Modulus (MPa)	1585	1650	2275	2600
HDT @ 264 psi (°C)	93	93	110	96
Mold Shrinkage (%)	0.6	0.6	0.6	0.6
UL 94	HB	V-0/5VA	HB	V-0/5VA

For purposes of providing pass/fail criteria, rules were set for analysis of performance after chemical exposure. As a general rule of thumb, materials with an elongation of >10% were required to be considered a ductile material, which is critical to housing function. For tensile strength, a 75% retention of properties was also set as an acceptable level after chemical exposure. With these criteria in mind, Figure 5 provides an overview comparing the performance of the RTP 2000 HC series versus an industry standard PC/ABS composition.

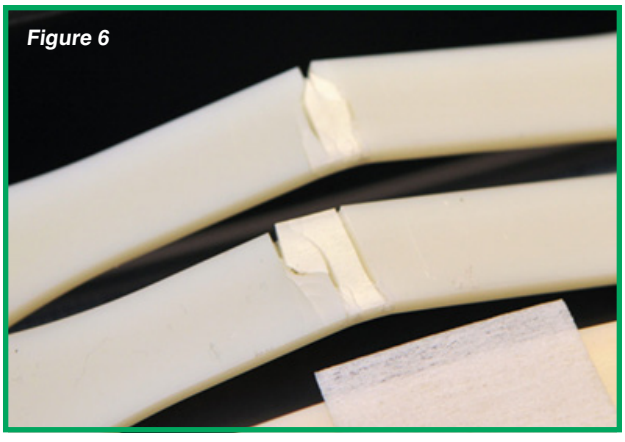
Figure 5: Pass/Fail, ASTM D638 Tensile Strength/Elongation

Cleaner	RTP 2000 HC Series	Standard PC/ABS
Birex®	✓	✓
CaviCide 1®	✓	X
Cidex Plus®	✓	X
Incides N®	✓	X
Incidin Plus®	✓	X
Incidin Pro®	✓	X
Sani-Cloth Active®	✓	X
Sani-Cloth Bleach®	✓	✓
Sani-Cloth Plus®	✓	X
Super Sani-Cloth®	✓	X
T-Spray II™	✓	X

Test Summary

With the exception of Birex® and Sani-Cloth Bleach® exposure, results showed that the RTP 2000 HC series had much better chemical resistance as compared to standard PC/ABS. Complete failure was recorded for standard PC/ABS when exposed to Cidex Plus® and CaviCide 1® (Figure 6).

Testing was performed on standard and flame retardant compositions with very similar results for both the RTP 2000 HC and PC/ABS products.



* Raw testing data is available upon request.

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Applications

There is a wide range of applications that could benefit from the RTP 2000 HC series, including any medical device or structure with a plastic housing that is exposed to routine cleaning and disinfection with hospital cleaners. Key application areas include enteral feeding pumps, x-ray and ultrasound machines, MRI equipment, beds, IVD testing equipment, dialysis machines, EKG devices, mobile devices and other patient contact applications.

Conclusion

The RTP 2000 HC series are resistant to cracking and degradation when disinfected with hospital cleaners. As a result, they can improve product performance and life span, providing OEMs and injection molding companies a new realm of possibilities in the design of hospital equipment with plastic housing requiring frequent sterilization.

The RTP 2000 HC series are now available globally in Flame Retardant (RTP 2000 HC A FR) or non-Flame Retardant (RTP 2000 HC A) versions, and the compounds are colorable. The series is also available in sheet format, with thicknesses ranging from .02 - .25", through Engineered Sheet Products (ESP), a division of RTP Company.

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