Elcam Stopcocks

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Plasticizer-Induced Stress Cracking of Polycarbonate Stopcock Body

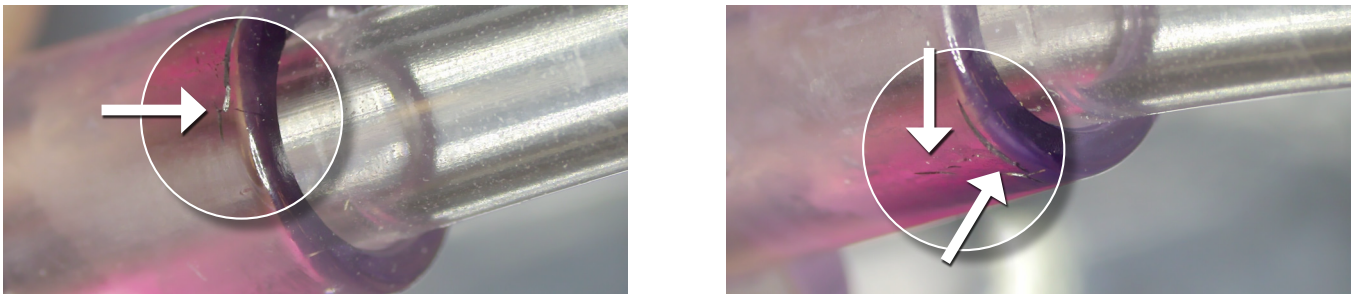
Environmental stress cracking is a failure of the polymer material due to surface initiated micro cracks or fractures. These are caused by the combined presence of stress and environmental effects. Essentially any conventional plastic manufacturing operation, from injection molding and extrusion to blow molding and thermoforming, induce residual stresses within the polymer material.

For many years PVC tubing compounders were using conventional phthalate plasticizers. In recent years, there has been an increased awareness of a phenomenon called "plasticizer-induced stress cracking".

Flexible PVC medical tubing contains plasticizer, the component added to PVC to impart flexibility to the inherently rigid PVC polymer. If this plasticized PVC compound is in direct contact with another polymer surface, the plasticizer can migrate and interact with the surface of that polymer and can often result in marring and/or cracking of that surface. This interaction between the plasticizer in the plasticized PVC compound and the surface of a second plastic part can lead to compromised physical properties and in some cases, catastrophic failure of the second plastic part in contact with the flexible PVC.

There is a growing body of evidence indicating that plasticizer migration is often a time and temperature dependent occurrence. A typical sterilization procedure for a medical tubing would call for exposure of the assembled part by ethylene oxide gas at about 50°-60°C for 12 hours. In addition, the problem may be exacerbated by lengthy shipping and storage at sub optimal conditions.

There appears to be a direct correlation between a plasticizer's viscosity and its ability to induce stress cracking in polycarbonate. Plasticizers with lower viscosities such as DOA (Dioctyl Adipate) and ATBC (Acetyl Tributyl Citrate) were found to more readily induce stress cracking in rigid PVC and PC than plasticizers with higher viscosities such as TOTM (Trioctyl Trimellitate) and ESO (Epoxidized Soybean Oil). It appears that viscosity is not the only determinant. Chemical type, level of use, polarity and severity of the environment all contribute to crack development in stressed PC.



Pic.1: Examples of cracks forming in bonding areas

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Elcam's products are frequently undergoing tube bonding assemblies by a means of solvent bonding. Stopcocks can be particularly challenging to bond, because of additional stress in the region of handle-body interface. The HDPE handle exerts a stress on the PC body of a stopcock, and if a plasticizer is migrating from the PVC tubing to this area, it may cause gradual crack development.

Elcam has conducted an experiment to test the hypothesis and previous findings of the role of plasticizer in the development of stress cracks in Polycarbonate products documented in the relevant literature.

This experiment examined whether the type of plasticizers affect the crack formation level (after accelerated aging) by testing and comparing two groups of products bonded with the following PVC tubes types:

1. Products bonded to PVC tube – containing ATBC plasticizer.
2. Products bonded to PVC tube – containing TOTM plasticizer.

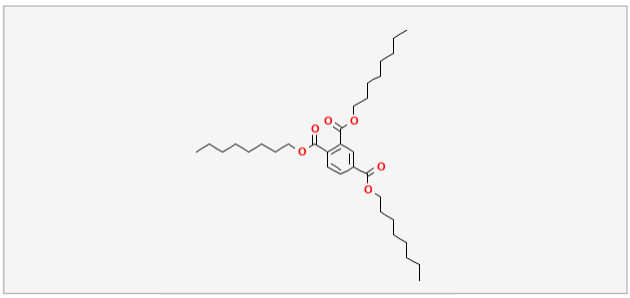
Main Objective of the study

Examine whether the type of plasticizer affects the cracking phenomenon.

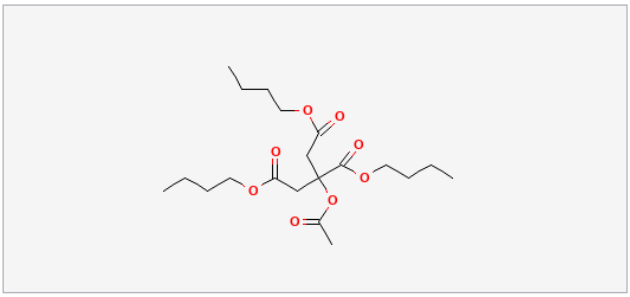
Guiding considerations

- Based on results of the preliminary experiments carried out in Elcam and Literature review of professional articles1,2 , it can be inferred that the ATBC plasticizer might cause polycarbonate cracking at a much greater rate than the TOTM plasticizer. Therefore, 2 different tube types, one with ATBC and one with TOTM, were selected for this experiment.
- The plasticizers are groups of materials (liquids and solids) mixed with the main PVC material, for flexibility improvement. The plasticizers tend to be released from the main material under the influence of time and temperature, and when these plasticizers- come into contact with polycarbonate under stress, they can cause cracking.
- Stress cracking is more prevalent in low molecular weight polycarbonates;
- Compared to ATBC, TOTM is branched and has 3 functional groups versus 4, which makes it less prone to migration and less chemically active.

TOTM



ATBC



Pic.2: Chemical structure of TOTM and ATBC plasticizers

- In preliminary experiments, it was found that groups of stopcocks bonded with a tube that contains (ATBC) plasticizer could be 100% cracked after 72 hours of accelerated aging at 52 °C.

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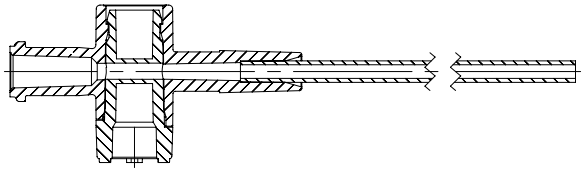
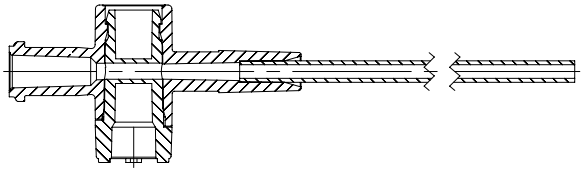
Test Products

Concentrated table of product groups:

Tube Plasticizer Type	Graphic Representation	Stopcock Body material MAKROLON 1805 (supplied by Covestro)
TOTM plasticizer PVC TUBE 2.8x1.8mm [0.110x0.070] DEHP FREE		
ATBC plasticizer PVC TUBE 2.8x1.8mm [0.110x0.070] DEHP FREE		

Test protocol

Purpose: Examine the effect of tubing plasticizer migration on development of cracking in PC stopcocks.

Method of Examination: visual inspection under 8X magnification.

Sample Size: 100 units.

Acceptance Criteria: product without cracks after 72 hours of accelerated aging at a temperature of 52 °C.

Methods

Each group comprised of 100 products.

Bonding - Each product was bonded with an automatic machine as follows:

The PVC tubing (7.9" in length/20 cm) was smeared with solvent formulation (50% Cyclohexanone 50% (MEK) by an automatic solvent dispenser to an appropriate depth to ensure full coverage of the bond area.

Tubing was automatically inserted into a mated unit and held together for several seconds to allow the initial setting of the bond to occur.

Aging: To induce accelerated aging, tubing assemblies were placed in an oven at 52° C for 72 hours.

Inspection: After the accelerated aging, both groups were inspected visually to determine the number of cracks in each different tube.

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Test Results

Product Description	Cracked Products
Products with TOTM tube	0 from 100
Products with ATBC tube	74 from 100

Summary and Conclusions

- In products bonded to PVC tubing containing the TOTM plasticizer, no cracks were detected. While under the same conditions, products bonded to tubing containing the ATBC plasticizer, cracks were detected: 74 of 100 products were showing cracking after 3 days of accelerated aging under 52°C.
- The results of this experiment have proven our hypothesis of the relationship between plasticizer type and the cracking phenomenon.

Acronyms and abbreviations

PC	Polycarbonate
PVC	Polyvinyl chloride
MEK	Methyl ethyl ketone
ATBC	Acetyl tributyl citrate
TOTM	Tris (2-Ethylhexyl) Trimellitate
°C	Celsius degrees

1. Plasticizer-Induced Stress Cracking of Rigid PVC and Polycarbonate, **Paul Kroushl: Technical Service Associate, Teknor Apex Company**
2. Teknor Apex to introduce new PVC compounds at MD&M West, **Medical Plastics News, 28 January 2019**