

The effects of plasticizers on solvent bond strength in flexible PVC tubing

Solvent bonding is a common processing technique used in the medical industry for connecting flexible tubing and rigid parts. The strength of this bond is an extremely important variable to consider when selecting materials for sensitive applications needed in the medical market. These materials should reinforce the strength of the bond between flexible tubing and rigid medical part housings and connectors such as plastic luers. Developing new data around these materials and their effect on solvent bonding is important for medical OEMs as they look for cost-effective non-DEHP options.

A solvent bonding study was conducted to determine whether there are any differences in bond strength associated with the plasticizer choice in flexible PVC tubing, specifically between DEHP and Eastman 168™ SG non-phthalate plasticizer. This study was also used to determine how solvent and plastic

choice affects bond strength between flexible PVC tubing and the plastic luer. The three factors tested were the plasticizer used in making the tubing, the plastic used to make the luers, and the solvent used for bonding. The tensile force required to cause bond failure was monitored over time. Initial bond (two days) strengths were measured along with accelerated aging at 57°C and 50% RH to represent a 1, 1.5, 2, and 3 year shelf life. For this study, tubing with an ID of 0.084" and OD of 0.134" was used.

The table below displays the different bonding scenarios which were studied. The solid circles signify the solvent/plastic combinations leading to tubing failure which is desired as they represent a strong solvent bond. The half circles indicate samples that started out with solvent bond failure and finished the accelerated aging with tubing failure.

Bonding scenarios*

Bonding solvent	Eastman Tritan™ copolyester MX731	Eastar™ copolyester DN003	Medical grade ABS (MABS)	Poly methyl methacrylate (PMMA)	Polycarbonate (PC)	High impact polystyrene (HIPS)
Cyclohexanone (CH)	●	●	○	●	○	◐
Methyl ethyl ketone (MEK)	●	○	●	○	○	◐
Cyclohexanone/ Methyl ethyl ketone (50/50)	●	●	○	●	○	◐
Tetrahydrofuran	●	●	○	●	○	◐

*Data in the table is representative of tests using PVC tubing made with DEHP and PVC tubing made with Eastman 168™ SG non-phthalate plasticizer.

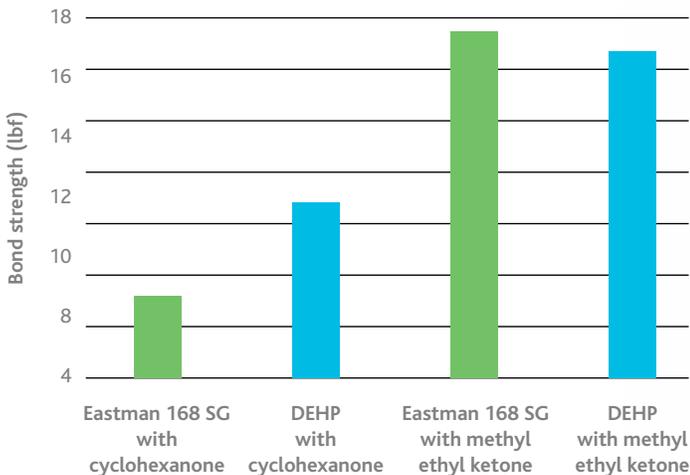
- = Tubing failure
- ◐ = Mixed mode failure
- = Solvent bond failure

This study concluded that there is little difference in bond strength between tubing made with Eastman 168 SG and DEHP when bonding to copolyesters, PMMA, PC, and HIPS. The bond strength chart on the back page shows good bond strength was achieved when bonding PVC tubing made with Eastman 168 SG and DEHP to MABS using MEK as the solvent. The choice of solvent and plastic have the biggest influence on bond strength. Eastman 168 SG allows you to switch from traditional phthalate plasticizers while maintaining good bonding performance in your medical devices.



The data for the following bond strength chart shows that Eastman 168 SG had similar bond strength than DEHP when using MEK to bond to MABS. For this study, represented data is from tubing with 3 years accelerated aging at 57°C and 50% humidity when bonded with CH and MEK.

Bond strength of PVC tubing bonded to MABS



For more information, visit www.Eastman.com/medical.

EASTMAN

The results of insight™

Eastman Chemical Company Corporate Headquarters

P.O. Box 431
Kingsport, TN 37662-5280 U.S.A.

U.S.A. and Canada, 800-EASTMAN (800-327-8626)
Other Locations, +(1) 423-229-2000

www.eastman.com/locations

Safety Data Sheets providing safety precautions that should be observed when handling and storing Eastman products are available online or by request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman product in a given end-use environment is dependent on various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

© 2016 Eastman Chemical Company. Eastman brands referenced herein are trademarks of Eastman Chemical Company or one of its subsidiaries. The ® used on Eastman brands denotes registered trademark status in the U.S.; marks may also be registered internationally. Non-Eastman brands referenced herein are trademarks of their respective owners.