Study Focuses on How Plasticizers in PVC Affect Non-PVC Plastics

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Scores of medical manufacturing professionals have contacted Teknor Apex Company in the few days since we announced the results of a study we conducted on the effects of plasticizer migration on non-PVC device components that come into contact with components made of PVC. One reason for this interest is that some device manufacturers are considering the use of PVC compounds that contain alternatives to the phthalate plasticizers, such as DEHP, that have been widely used in the industry thus far.

For decades, PVC compounds that have been made flexible through use of standard plasticizers such as the phthalates have been materials of choice for many extruded and injection molded medical device applications. Proper design has reduced or eliminated problems caused by plasticizer migration at the interface between PVC and non-PVC components (PVC tubing, for example, and polycarbonate connectors). This migration can cause softening, cracking, or other defects in non-PVC components used in conjunction with them.

PVC by itself is rigid and requires a high addition level of plasticizer—30% is not unusual—for it to be rendered flexible. There are various types of plasticizer, differing in accordance with their underlying chemistry. Similarly, there are various types of non-PVC plastic that may be used in conjunction with a component made of flexible PVC. Whether or not defects may occur as a result of plasticizer migration

depends, in short, not only on the specific plasticizer contained in the PVC but also the specific non-PVC plastics used in conjunction with it.

In our study, we focused on four materials commonly used in conjunction with PVC: ABS, acrylic, polycarbonate (PC), and polystyrene (PS). We tested these materials to determine their responses to ten different types of plasticizer, including DEHP and two other phthalates, plus seven non-phthalate alternative plasticizers.

Plasticizers Ranked by Migration Effects on Plastics in Contact with PVC

ABS	Polycarbonate	Polystyrene	Acrylic
TOTM	Polymeric	Polymeric	Polymeric
DPHP	TOTM	TOTM	TOTM
DOTP	*DPHP*	DOTP	*DPHP*
DEHP	*DINP*	*DINP*	DINCH
DINCH	DINCH	*DPHP*	*DINP*
DINP	DOTP	*DEHP*	DOTP
Polymeric	*DEHP*	DINCH	*DEHP*
DOA	ATBC	DOA	DOA
ATBC	DOA	ATBC	ATBC
Benzoate	Benzoate	Benzoate	Benzoate

The results show that certain plasticizers may cause defects in non-PVC components while others exhibit little or no such effects. Veterans in the industry already know that DEHP, long a standard plasticizer in medical applications, may have adverse effects on non-PVC plastics. Our study confirmed this in the case of three of the four non-PVC materials tested. On the other hand, we also found that certain non-phthalate plasticizers also had adverse effects, while two other alternative formulations proved usable with all four non-PVC plastics in the study. The table accompanying this article provides a summary of the results for all materials tested.

Teknor Apex conducted this study to help manufacturers make informed decisions about prospective alternative PVC formulations, and indeed about the materials used in conjunction with PVC. For example, it may be that one solution to the problem of plasticizer migration is to switch from one of the non-PVC materials to rigid PVC. Any such major change, of course, would entail formulation changes on our part and likely tooling changes on the part of the device manufacturer.

In any case, we are prepared to supply each customer with exactly the right PVC compound, whether it incorporates a standard plasticizer or any of the alternatives now available.

The phthalate plasticizers in the study included DEHP and DINP, neither of which was ideally suited for contact with three of the four non-PVC materials; and DPHP, which was found acceptable for contact with three of them.

The non-phthalate plasticizers and recommendations based on the study include:

- Polymeric: usable for contact with all four non-PVC materials.
- TOTM, a trimellitate: usable for contact with all four non-PVC materials.
- DOTP, a terephthalate considered a non-phthalate because of a different chemical structure from traditional phthalates: suggested for contact only with ABS..
- DINCH: suggested for contact only with ABS.
- DOA, an adipate: not ideally suited for contact with any of the four non-PVC materials.
- Benzoate: not ideally suited for contact with any of the four non-PVC materials.
- ATBC, a citrate: not ideally suited for contact with any of the four non-PVC materials.

We performed our tests at 23°C and 50°C at intervals of 26 days, 52 days, 78 days and 104 days. Detailed results follow for the non-PVC “contact” plastics. It should be noted that even in the case of plasticizers that performed well in contact with a particular plastic, there may nevertheless be extreme conditions (high heat, high humidity or high pressure) that could cause failure.

ABS

ABS was affected the least of the four plastic materials evaluated. Only the ATBC- and the benzoate-plasticized compounds greatly affected the surface of the ABS. The DOA-plasticized compound had a slight surface effect after 78 days of contact at 50°C, and also had a significant effect on the tensile properties of the ABS at 23C.

It is recommended that DOA-, ATBC- and benzoate-plasticized compounds be the last to be selected for applications in which flexible PVC will come in contact with ABS. The other seven plasticizers performed well enough to be considered more acceptable for contact with ABS.

Polycarbonate

While none of the plasticized compounds performed exceptionally well in contact with polycarbonate, the ATBC, DOA and benzoate caused the most significant damage. Plasticizers that performed best (for surface effect and tensile property retention) include the polymeric, TOTM, and DPHP.

Polystyrene

The surface of polystyrene was affected significantly by most of the plasticizers at 50°C and by many of the plasticizers at 23°C. The polymeric performed best when in contact with the polystyrene. TOTM performed relatively well and could be acceptable, but it affected the surface of the polystyrene at all four time intervals at 50°C.

Acrylic

While none of the plasticized compounds performed exceptionally well in contact with acrylic, the ATBC and benzoate caused the most significant damage. Plasticizers that performed best for surface effect include the polymeric, TOTM, and DPHP.

Details on the study, including the brands of non-PVC plastic and certain of the plasticizers used in the tests, are posted at http://www2.teknorapex.com/PVC-Plasticizer-Migration [1]. Further information is also available by emailing vinyl@teknorapex.com [2].

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