Release of a plasticizer. tri-2-ethylhexyl trimellitate from polyvinylchloride tubings

ESCP EDINBURGH Mai 2007

Sophie trevis[1]. Valérie Sautou-Miranda[2]. Sandrine Bagel-Boithias[1]. David Balayssac[1]. Jean Chopineau[2]

(1) Department of Pharmacy. G. Montpied Hospital. Clermont-Ferrand. France

(2) Laboratory of Clinical Pharmacy and Biotechnics. UFR Pharmacy. Clermont-Ferrand. France

INTRODUCTION

Di-(2-ethylhexyl)phthlate (DEHP) is the most common plasticizer used to increase the flexibility of PVC medical devices as tubings for infusions. Because DEHP is not chemically bound to PVC it can leach from a PVC-containing medical-device into infused solutions and expose the patient to risk of toxicity: DEHP is a suspected human endocrine disruptor and a possibly reproductive toxicant. Pharmaceutical laboratories investigate alternatives to the DEHP as tri-(2-ethylhexyl)trimellitate (TEHTM) to give flexibility to PVC medical devices. The aim of our study is to assess the release of the TEHTM from PVC tubings in solutions in contact with these tubings

PVC tubings containing TEHTM

PVC tubings are filled with polysorbate 80 (mg/ml)

MATERIALS ET METHODS

TEHTM concentrations in the solutions were determined by liquid chromatography after liquid /liquid extraction

Influence of the following parameters on TEHTM release has been tested

RESULTS

Influence of polysorbate concentration on TEHTM release					
Polysorbate concentration (mg/ml)	0.05 (n=6)	0.4 (n=6)	0.8 (n=6)	1.6 (n=6)	2 (n=6)
TEHTM concentration (µg/ml)	0.047	0.053	0.035	0.083	0.040

Influence of temperature and time of contact on TEHTM release (Polysorbate concentration: 2mg/ml)						
Time of contact	1 hour		5 hours		20 hours	
Temperature of contact	4℃ (n=9)	20℃ (n=9)	4℃ (n=9)	20℃ (n=9)	4℃ (n=9)	20°C (n=9)
TEHTM concentration (µg/ml)	0.137	0.03	0.07	0.065	0.01	0.053

A release of TEHTM was highlighted in all the solutions but this quantity was very weak even negligible.The release was not proportional to the concentration of polysorbate in solutions (p=0.35). The concentration of TEHTM leached did not vary significantly with the temperature(p=0.2) and the time of contact (p=0.25). .

CONCLUSION

TEHTM seems to be an interesting alternative plasticizer to DEHP in PVC tubings because its release is very limited. However very little information is available on its biological effects and some studies including toxicity. disposition and metabolism are required.