Exposure Assessment Framework for Materials Selection in Consumer Products

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ABSTRACT

The use of exposure and risk assessment methodologies is crucial in materials selection for consumer products, particularly those involving long-term dermal contact. The tiered exposure and risk assessment described in this article is applicable not only to materials selection for automobile interiors, but can be extended to the materials selection for various types of consumer products.

Keywords: plasticizer, chemical analysis, phthalate, exposure assessment

1 INTRODUCTION

The use of exposure and risk assessment methodologies is crucial in materials selection for consumer products, particularly those involving long-term dermal contact. While biocompatibility test procedures designed for medical devices, such as those described in ISO 10993-12:2012 [1], can be used to evaluate chemicals that may leach out of products during use, these test methods may not provide accurate assessment based on real world, consumer-use scenarios. In this study, we describe a tiered risk assessment framework that is used to improve materials selection for consumer products, and apply this framework for components in automobile interiors [2].

2 RISK ASSESSMENT FRAMEWORK

The risk assessment framework involves three parts: i) identification and semi-quantification of chemical(s) of interest present in the product, ii) quantitative evaluation of the different pathways where consumers are potentially exposed to the chemical(s) of interest from standard use of the product, and iii) determination of the potential human health risk from these exposures.

2.1 Chemical Identification

For the first part of the framework, potential exposure to chemicals present in vehicle seats upholstered with artificial leather were assessed using the modified NIOSH 9100 [3] and ASTM D6661 [4] wipe sampling methods. Diundecyl phthalate was the predominant organic compound identified by gas chromatography/mass spectroscopy in the wipe samples from the vehicle seats. The physicochemical properties and the use of diundecyl phthalate in automobile interiors and consumer products were evaluated with respect to potential human exposures. The toxicological studies and regulatory guidelines for diundecyl phthalate were reviewed for comparison with the intake or contact dose.

2.2 Exposure Assessment

In the second part of the framework, an exposure assessment of diundecyl phthalate via oral, dermal, and inhalation routes resulting from contact with automobile seats was conducted. To quantitate the possible daily dose of diundecyl phthalate via the oral, dermal, and inhalation routes, exposure assessments were conducted using the available sampling data. The values were used to calculate the potential quantity ingested due to hand-to-mouth contact, potential inhalation exposures, and the potential dermal dose from material-to-skin contact.

2.3 Dose Comparison

For the third part of the framework, the estimated doses were compared with derived reference doses based on animal toxicological studies and also with the derived no-effect levels (DNELs) listed by the European Chemicals Agency (ECHA) (Figure 1). The estimated daily intake (contact or absorbed dose) of diundecyl phthalate from automobile seats were far lower than the no-observed-adverse-effect-levels (NOAELs) reported in and derived from animal studies, and were significantly below the reported DNELs for the general population.

3 ILLUSTRATION

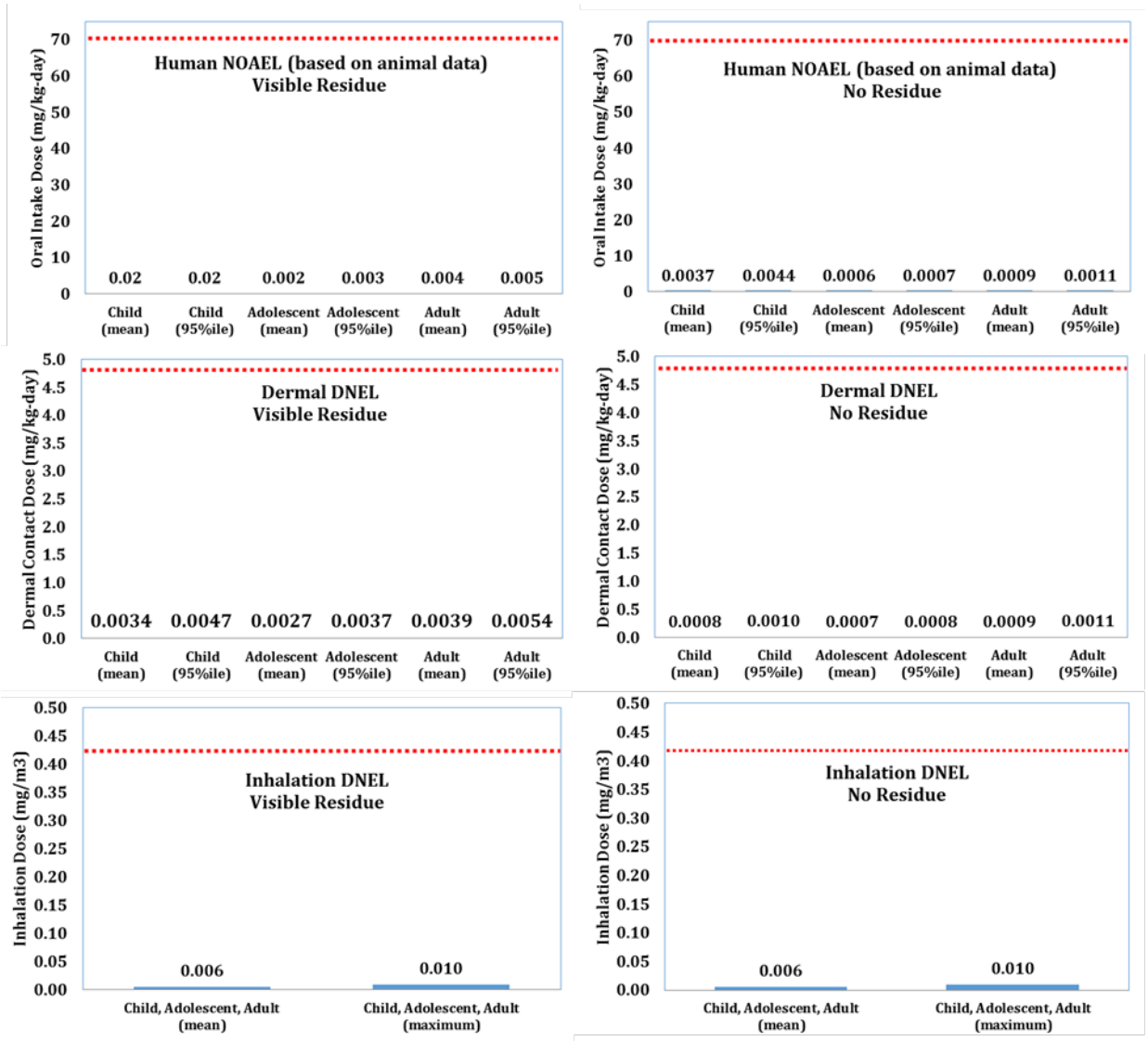

Figure 1: Estimated daily doses for diundecyl phthalate from automobile seats (with and without visible residue) were compared with derived reference doses based on animal toxicological studies and also with the derived no-effect levels (DNELs) listed by the European Chemicals Agency (ECHA).

4 REFERENCES

[1] ISO 10993-12:2012 – Biological Evaluation of Medical Devices -- Part 12: Sample Preparation and Reference Materials.

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