



Endorsed at the TM IV 2012 and amended after TMIII 2013 to take into account changed default human factors values

Ispra, 12/11/2012

HEEG OPINION

Biocidal products: model for dipping of hands/forearms in a diluted solution

INTRODUCTION

There are exposure scenarios where an individual dips the hands (or hands and forearms) into a diluted solution which necessitates the regulator to assess the person's exposure to that liquid, such as pulling weed out of a biocide-treated garden pond. The following proposes a means by which this exposure can be assessed.

PROPOSAL

The ConsExpo 4.1 Consumer Exposure and Uptake Models and related Cleaning products Fact Sheet (RIVM report 320104003/2006, page 35) has previously described a means to assess the exposure for dipping of hands and forearms into aqueous liquids. The approach assumes that upon contact with the liquid, the skin will be covered by a layer of the liquid from which all substance is available for skin contact and absorption. The approach uses an estimated thickness of the liquid layer on the skin to be 0.01 cm. This value originates from the *European Communities (2003) Technical guidance documents on Risk Assessment in support of Commission directive 93/67/EEC on risk assessment for new notified substances*.

The approach is currently under consideration by RIVM and is in due course to be changed, since the assumed layer thickness has no scientific basis nor does it necessarily reflect the worst case conditions of the exposure. Preferably, the exposure is to be assessed using diffusion coefficients and exposure durations. However, such information is rarely available, moreover at this moment there are no accepted or proposed methods available. For these reasons, the currently available approach described in the Cleaning Products Fact Sheet is suggested by the HEEG to be used.

EXPOSURE OF BOTH HANDS

Where hands only are exposed, the default total surface area of both hands of an adult (palms and backs) is 820 cm². Therefore, for an adult the total amount of liquid retained on the palms and back of both hands of an adult following the dipping of the hands in a liquid can be calculated as:

$$\begin{aligned} V &= A_{\text{palms+backs}} \times \text{liquid film} \\ &= 820 \text{ cm}^2 \times 0.01 \text{ cm} \\ &= 8.2 \text{ cm}^3 \\ &= \mathbf{8.2 \text{ ml}} \end{aligned}$$

Where:

$$A_{\text{palms+backs}} = \text{area of palms and backs of both hands (cm}^2\text{)} = 820 \text{ cm}^2$$

$$\text{liquid film} = \text{thickness of liquid film on skin (cm)} = 0.01 \text{ cm}$$

[Reference: HEEG Opinion – Default human factor values for use in exposure assessments for biocidal products – endorsed at TMII 2013]

EXPOSURE OF BOTH HANDS AND BOTH FOREARMS

Where both hands and both forearms are exposed, the default total surface area of both hands of an adult (palms and backs) is 890 cm² (mean value) and for both forearms is 1109.2 cm² (mean value). Therefore, for an adult the total amount of liquid retained on the palms and back of both hands and both forearms can be calculated as:

$$\begin{aligned} V &= (A_{\text{palms+backs}} + A_{\text{forearms}}) \times \text{liquid film} \\ &= (820 \text{ cm}^2 + 1128.8 \text{ cm}^2) \times 0.01 \text{ cm} \\ &= 19.49 \text{ cm}^3 \\ &= \mathbf{19.5 \text{ ml}} \end{aligned}$$

Where:

$$A_{\text{palms+backs}} = \text{area of palms and backs of both hands (cm}^2\text{)} = 820 \text{ cm}^2$$

$A_{\text{forearms}} = \text{area of both forearms (cm}^2\text{)} = 1128.8 \text{ cm}^2$ [Forearm area based on US-EPA Exposure Factors Handbook, volume 1, August 1997 data. *This default parameter is in the HEEG Opinion on Default human factor values for use in exposure assessments for biocidal products which was endorsed at TMII 2013]*

$$\text{liquid film} = \text{thickness of liquid film on skin (cm)} = 0.01 \text{ cm}$$

For assessment purposes, it is proposed the general default value for the total amount of liquid retained on the adult's two hands (backs and palms) following immersion in a liquid be 8.2 ml and for immersion of both hands and both forearms be 19.5 ml.

This model is meant to be used for diluted solutions and similar viscosity to water [1 centipoise; or alternatively, having a similar density of 1 kg/litre=1000 mg/cm³ (estimate density of pure water)]. However, it is acknowledged that density, viscosity, temperature and surface tension can influence the amount of liquid remaining in contact with the skin and that the RMS will need to consider this when using the proposed default values.