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Institute for Health and Consumer Protection
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HEEG Opinion 13

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HEEG opinion on

Assessment of Inhalation Exposure of Volatilised Biocide Active Substance

This document was prepared by DE and UK in cooperation with HEEG.

INTRODUCTION

Some Dossiers have dismissed potential risks from inhaling vapours of an active substance volatilised from treated surfaces by informing that "due to the a.s.'s low vapour pressure risks from inhaling the vapour are negligible" [*]. Such assessments wrongly ignore the toxicology of the active substance's vapour. Even though an active substance might have a low vapour pressure, the vapour – even at low concentrations in the air – can still be inhaled. Therefore, the exposure to inhaled vapour needs to be estimated and then compared to an appropriate toxicological endpoint.

Please note: the following does not apply to inhalation of mists, aerosols, fumes etc., but is intended for long-term exposure to volatilised residues (e.g. volatilization of vapour from a surface following application of a biocide). This proposal can also be used to determine the worst-case inhalation long-term exposure to biocides (such as liquids/impregnated mats) which are heated to give off vapour.

* [1] informs that as a general rule a substance should be considered volatile only if it has a vapour pressure >10 mPa at 20°C. This is also proposed in [2].

PROPOSAL

As a Tier-1 screening tool whether inhalation exposure can be neglected or should be included into the risk assessment, the following screening test which is based on the toddler representing the worst case is proposed.

Let *mw* and *vp* denote the molecular weight (in g/mol) and the vapour pressure (in Pa). For toddler (based on an inhalation rate of 8 m^3/24 hr and bw of 10 kg) and using an *AEL* in mg a.s./kg bw/d, if

$$0.328 \cdot \frac{mw \cdot vp}{AEL_{long-term}} \leq 1$$

then risk from inhalation exposure for the toddler is negligible, otherwise inhalation exposure should be included in the risk assessment. If the inhalation risk for the toddler is negligible then the inhalation risk for the infant, child and for the adult can also be considered to be negligible.

In case an *AEC* (mg a.s./m^3) is given (e.g. in the case of local effects), the following screening test is used instead; if

$$0.410 \cdot \frac{mw \cdot vp}{AEC_{long-term}} \leq 1$$

then risk from inhalation exposure for the infant, toddler, child and adult is negligible, otherwise inhalation exposure should be included in the risk assessment.

JUSTIFICATION

The above suggested criterion can be derived by considering the saturated vapour concentration for 24 hours per day, as well as by a worst-case ConsExpo scenario. It comprises a full risk assessment of the inhalation exposure. The fact that exposure by other routes may be present at the same time is totally ignored. This simplification is considered acceptable since the saturated vapour concentration (SVC) approach is very rough and very conservative, as well as the assumption of a daily exposure of 24 hours.

SATURATED VAPOUR CONCENTRATION

As Tier 1 assessment, it can be assumed a person is exposed to the saturated vapour concentration of the active substance for 24 hours a day. This is the worst-case scenario as it is not possible for the air to hold more than the saturated vapour concentration of the active substance at a given ambient temperature and it is not possible for a person to be exposed more than 24 hours per day. Table 1 summarises parameter values to be used for the computations.

Table 1 Parameter values

parameter	**symbol**	**value**	**justification**	
gas constant	*R*	8.31451 J mol^{-1} K^{-1}	[3] physical constant	
temperature	*T*	293 K	assumed room temperature = 20°C	
toddler inhalation rate	*ir*	8 m^3/24 h	[4]	The toddler will represent a worst case – see also the remarks section below. [This inhalation rate and bodyweight are in the current HEEG Opinion On Default Human Factors].
toddler body weight	*bw*	10 kg	[4]	

(a) The SVC of an active substance is calculated as follows:

$$SVC = \frac{mw[\text{g/mol}] \cdot vp[\text{Pa}]}{R[\text{J mol}^{-1}\ \text{K}^{-1}] \cdot T[\text{K}]} = 0.41 \cdot mw \cdot vp \quad [\text{mg/m}^3]$$

(b) The inhalation exposure of an infant, toddler, child and adult over a total of 24 hours can then be calculated as follows:

$$Exposure = SVC[\text{mg/m}^3] \cdot \frac{ir[\text{m}^3/24\,\text{h}]}{bw[\text{kg}]} = 0.410 \cdot \frac{mw \cdot vp \cdot ir}{bw} \quad [\text{mg/kg bw/24 h}]$$

(c) Comparing exposure to *AEL* and substituting the values for the toddler (which represents the worst case) from Table 1 gives

$$\frac{Exposure}{AEL} = \frac{0.410 \cdot mw[\text{g/mol}] \cdot vp[\text{Pa}] \cdot ir[\text{m}^3/24\,\text{h}]}{AEL[mg/kg] \cdot bw[\text{kg}]} = 0.328 \cdot \frac{mw \cdot vp}{AEL}$$

(d) Comparing exposure to *AEC* and substituting the values from Table 1 gives

$$\frac{SVC}{AEC} = \frac{0.410 \cdot mw[\text{g/mol}] \cdot vp[\text{Pa}]}{AEC[mg/m^3]} = 0.410 \cdot \frac{mw \cdot vp}{AEC}$$

REMARKS

- In case the vapour pressure is given for 25°C instead of 20°C, the same formula can be applied. (Strictly, the 0.41 coefficient changes to 0.40 while 0.328 is unchanged.)
- The test does take into account that an infant and others (e.g. the elderly which are bed bound) can be exposed for 24 hours in a day. Professionals are included as well.
- The assessment using the SVC approach gives a very worst-case inhalation exposure as, at a given ambient temperature, air cannot hold more than the saturated vapour concentration of a substance.
- If the proposed screening test results in a value > 1, this means "with this simple test, a risk from inhalation exposure cannot be excluded." It does not mean: "there is a risk from inhalation exposure." So risk from inhalation exposure has to be assessed in detail.
- It remains to justify the choice of the "toddler" data as worst case. In equation (c), all values except *ir* and *bw* are independent of the considered person. Therefore, *Expo/AEL* will be greatest when *ir/bw* is greatest. As can be seen from Table 2, this is the case for the toddler. This means that the greatest exposure will always be to the toddler, regardless of the a.s.
- As an alternative approach, ConsExpo's evaporation model can be used to identify a "generic worst-case inhalation exposure" over all possible scenarios. In the extreme case of pure substance and using the usually very conservative Langmuir estimate for the mass transfer rate, the evaporation model gives the same result as the SVC approach thus supporting the proposed criterion for the exposure to be negligible. However, it is not clear whether or not this approach is independent as in extreme cases the Langmuir method may reduce to the SVC approach.

Table 2 Parameter values

Parameter	**Infant** **irrespective of gender *(based on female 6 to <12 months old)***	**Toddler** **irrespective of gender *(based on female 1 to <2 years old)***	**Child** **irrespective of gender *(based on female 6 to <11 years old)***	**Adult** **irrespective of gender *(based on female 30 to <40 years old)***
long-term inhalation rate ***ir*** [m^3/24 h]	5.4 [4]	8.0 [4]	12.0 [4]	16.0 [4]
body weight ***bw*** [kg]	8 [4]	10	23.9 [4]	60 [4]
ir/bw [m^3/kg / 24 h]	**0.68**	**0.80**	**0.50**	**0.27**

REFERENCES

[1] Curry, P.B., Iyengar, S., Maloney, P.A. and Maroni, M., (1995). 'Methods of Pesticide Exposure Assessment'. Plenum Press, New York. ISBN 0-306-45130-1

[2] Manual of Technical Agreements of the Biocides Technical Meeting (MOTA), version 6, 2013

[3] Atkins Physical Chemistry, 5th Edition

[4] 'Default Human Factor Values For Use In Exposure Assessments For Biocidal Products'. Manual of Technical Agreements (MOTA) version 6 (2013)