Consumer Exposure Profile for 2-Butoxyethanol (CAS: 111-76-2)

Additional Product Concentration Limits

Final Report

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1.0 Executive Summary

Environment and Health Canada released the Final Risk Assessment Report on 2-Butoxyethanol (2-BE) in August 2002. The assessment proposed that 2-BE is not toxic for the environment. However, it is considered toxic based on health hazard potential and because of a concern that it may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. On August 9, 2003, the federal Ministers of the Environment and Health published the final decision concerning the assessment of 2-BE in the *Canada Gazette*, Part I and recommended that this substance be added to the **List of Toxic Substances** (Schedule 1) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999). Further, on October 25, 2003, a proposal to add 2-BE and 2-ME to Schedule 1 of CEPA 1999 was published in Canada Gazette, Part I. In the event that 2-BE is added to the List of Toxic Substances (Schedule 1) of CEPA 1999 options for managing this substance will have to be developed and implemented by Environment and Health Canada.

2-BE is a component in many consumer products, resulting in human exposure upon use of these products. The CEPA PSL assessment report identifies an exposure concentration below which adverse human effects are not expected. In this regard, a Tolerable Concentration (TC) of 11 mg/m³ for 2-BE has been established (Environment and Health Canada, 2002: CEPA PSL assessment) based on chronic exposure. Although the potential for dermal absorption of airborne 2-BE was not explicitly accounted for in the determination of the TC this chronic exposure limit is considered sufficiently conservative to account for the fact that airborne or direct exposure by the cutaneous route contributes to overall exposure[1] . The conclusion of the CEPA assessment states that although this exposure limit was based on chronic exposure, the health effects of concern have also been noted in shorter-term studies. Implementation of this TC in risk management requires assessment of which products would be expected to exceed the TC under normal use patterns and whether this TC can be used to develop product-specific limits.

The primary questions that needed to be addressed at this stage therefore were:

- *When consumers use products containing 2-BE what air concentrations of 2-BE are they exposed to during typical contact times?*

- *Can product-specific limits for 2-BE be developed that ensure compliance with the TC?*

To answer these questions a number of approaches were used. Headspace testing and emission chamber studies were undertaken to confirm product 2-BE content and to determine emission factors for a variety of products containing 2-BE that are currently on the market (AirZOne One, March 2004: products chosen from inventory in ToxEcology, 2001 and 2003). In addition, exposure modelling was used to estimate consumer exposure to 2-BE for a variety of product types under realistic product use scenarios exposure. The exposure modelling approach was also used to develop recommended product-specific limits for 2-BE for consumer products.

The above studies developed recommended product concentration limits for 2-BE in the following product types:

- All purpose cleaner (aerosol)
- All Purpose cleaner (non-aerosol)
- Glass cleaner (aerosol)
- Glass cleaner (non-aerosol)
- Auto cleaner
- Paint or Coating (non-aerosol)
- Paint or Coating (aerosol)
- Rug or Carpet Cleaner
- Nail Polish Remover
- Hair Dye
- Waterless Hand Cleaner / Skin Cleanser

Product concentration limits for the above product types have been included in the proposed "2-BE Regulations" (Working Draft of the "2-BE Regulations" dated December 2004). These proposed regulations are currently open for public comment. At this stage, there is a need to develop product concentration limits for a number of additional product types that are not currently included in the draft 2-BE regulations but in which 2-BE can be used. The exposure modelling approach was also used to develop the required product-specific limits for the additional consumer products categories that may contain 2-BE. The following product concentration limits are recommended:

Product Category	Proposed Limit (%)
Floor / Baseboard Strippers	2
Paint Strippers / Paint Thinners	0.5
Inks	None proposed
Pesticide: Disinfectant / Sanitizer cleaners	5
Pesticide: Insecticides, consumer use, aerosol	1.2
Hair dyes	14
Waterless Hand Cleaner / Skin Cleanser	13

[1] For example, conservative elements in the risk assessment include the fact that extrapolation from rodent studies may have overestimated the risk to humans due to the potential for preening/grooming to contribute to overall exposure via ingestion (see page 49 of 2-BE CEPA Assessment 2002 for further details)