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Comments re Proposed Risk Management Approach for 1,3-Butadiene, 2-Methyl (Isoprene) Chemical Abstracts Service Registry Number (CAS RN): 78-79-5 Canada Gazette Vol. 143, no 5 – January 31, 2009

We would agree with the conclusion that based on information available, isoprene meets one or more of the criteria set out in section 64 of the Canadian Environmental Protection Act, 1999.

The screening risk assessment notes that the principal route of exposure for the general population will likely be through inhalation of ambient and indoor air, and that off-gassing of isoprene from consumer products manufactured from polyisoprene may also contribute to the levels of the substance in indoor air.

The manufacture of more than 10,000 000 kg, import of 1,000 000 - 10 000 000 kg and its various consumer uses is of significant concern.

The health risk assessment found effects from isoprene, – methyl, on the thymus – an indication of possible immunotoxicity, and isoprene and its analogue 1-3 Butadiene to reproductive organs (ovaries), at lower concentrations compared to higher concentrations – indicating that this substance may be an endocrine-disruptor at lower levels of exposure. The main concern is for carcinogenicity, and it is considered that there is a possibility of harm at any level of exposure. Isoprene is considered a reproductive toxicant in California.

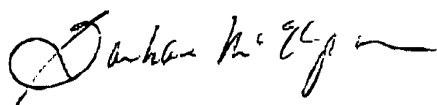
The Risk Management Approach

Consumer products are not targeted in the Risk Management Approach. The substance profile for the Challenge noted that this substance is used in fragrance/perfume, soap and cleaning products, and as a deodourizer/flavouring agent but makes it clear that “risk management actions will not include those activities controlled under the Pest Control Products Act or the Food and Drugs Act”.

Perhaps because of this limitation, only polyisoprene rubber products are mentioned in section 9.3 of the SRA regarding consumer products, and since the source of exposure from rubber products is expected to be low, it is stated that no action will be taken on consumer products for this reason. Disregarding those products that would be of greatest concern for transdermal or oral routes of exposure via consumer use should not be an option for any reason. However as we have stated in other submissions, if actions cannot be taken on consumer products because they fall under other statutes then this **should be publicly stated in the SRA.**

In addition this is another chemical substance that is considered an “indirect food additive” in the United States, and in Europe where a maximum residual concentration is regulated, and migration limits are regulated below the limit of detection. We would **recommend that a similar control limit be applied to restrict its use in and on foods.**

We agree that isoprene should be added to the Cosmetic Ingredient Hotlist to prohibit it from being deliberately used in cosmetics sold on the Canadian market.



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