Research Institute for Fragrance Materials, Inc.

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ECHA
European Chemicals Agency

RE: Public Consultation Phase on the CLH for p-t-Butyl-α-Methylhydrocinnamic Aldehyde (BMHCA) (CAS No. 80-54-6)

Dear Sir or Madam,

The Research Institute for Fragrance Materials is a nonprofit research institute formed in 1966. Its purpose is to gather and analyze scientific data, engage in testing and evaluation, distribute information, cooperate with official agencies and to encourage uniform safety standards related to the use of fragrance ingredients.

BMHCA is a fragrance ingredient used in cosmetics, fine fragrances, shampoos, toilet soaps and other toiletries as well as in non-cosmetic products such as household cleaners and detergents. It is a colorless to pale yellow liquid with a powerful, floral-fresh odor. It has no use as flavoring ingredient and therefore has no potential for ingestion. It has not been reported to occur in nature.

After review of the studies and the background data available on the fragrance ingredient, BMHCA, it is the reviewers' opinion that BMHCA has a propensity towards producing adverse male reproductive effects in rats and dogs. These effects do not appear to be ubiquitous in all animals, and have not been demonstrated in all the reported studies in rats and dogs. It should be noted that the reproductive studies in rats and dogs has low relevance to human health because the toxic metabolite is seen at significantly lower levels in humans than in rats and the toxic effects show a clear threshold effect and human exposure is well below this threshold. No testicular effects were observed in rhesus monkeys following administration at one dose level for five days.

The data support that no reproductive effects would be expected via the dermal route of exposure.

The use of BMHCA is already restricted by IFRA based on its dermal sensitization potential. The allowed maximum values are much lower than the no effect levels derived from the animal studies.

An overall NOAEL for BMHCA based on the subchronic and chronic dose studies conducted in animals has been established. Based on the conservative calculated dermal systemic exposure levels to this fragrance ingredient from use of consumer products, the current safety assessment indicates at least a greater than 100-fold safety factor between the reported consumer use levels of BMHCA and the most conservative overall safe level observed in these studies. **As such, RIFM is of the opinion that the data support the safe use of BMHCA under the present declared levels of use and dermal exposure as resulting from the IFRA restriction already in place.**