

EUGENOL

CAS N°: 97-53-0

Empirical formula: C₁₀H₁₂O₂
HO-C₆H₃(OCH₃)-CH₂-CH=CH₂

Synonyms: 4-Allylcatechol-2-methyl ether ; 1-Allyl-4-hydroxy-3-methoxybenzene ; 4-Allyl-2-methoxyphenol ; Caryophyllic acid ; 2-Hydroxy-5-allylanisole ; 1-Hydroxy-2-methoxy-4-allylbenzene ; 4-Hydroxy-3-methoxy-1-allylbenzene ; 1-Hydroxy-2-methoxy-4-propenylbenzene ; 2-Methoxy-4-allylphenol ; 2-Methoxy-4-(2-propenyl)phenol ; Phenol, 2-methoxy-4-(2-propenyl)- ; Eugenol ; Allylguaiacol ; 4-Allylguaiacol

History: Initial reviews: January 2004

Current revision date: Remains January 2004**

Implementation date: for new submissions*: June 11, 2006**

for existing fragrance compounds*: June 11, 2007**

Next review date: 2009

* This date applies to the supply of fragrance compounds (formulas) only, not to the finished products in the marketplace

STANDARD: RESTRICTED

RESTRICTIONS:

Limits in the finished product:

Skin contact products:

Leave-on products: 0.5%

Rinse-off products: 0.5%

including household cleaning products

Non skin contact products:

Due to negligible skin contact, the concentration of the fragrance ingredient should not exceed the usual concentration of the fragrance compound in the finished product***

Note box: Names of essential oils containing eugenol, or other sources of eugenol, which should also be considered in the application of the Standard, are provided in the Annex 1. Maximum percentage of the reference material is included for use when no analytical data is available.

This Standard replaces the one issued as part of the 38th Amendment.

** The compliance time is only linked to changes resulting from taking into account the new rules for non-skin contact products (see also IL 731).

***These are the restrictions as for category 11 in the new QRA risk assessment concept (see IL 745). Category 11 includes all non-skin contact or incidental skin contact products.

Due to negligible skin contact the concentration of a fragrance ingredient should not exceed the usual concentration of the fragrance compound in the finished product.

For example, hypothetically if the usual concentration of a fragrance compound in the final product, for example a candle, is at 5%, then any individual fragrance ingredient (in this case eugenol) must not exceed 5% in the candle.

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Fragrance Material Specification: Not applicable

Contribution from other sources: see Annex 1

Critical effect: **Sensitization**

RIFM summaries:

A number of Human Repeated Insult Patch Tests were conducted on eugenol. When a solution of 5% (or 5,905 ug/cm²) in a 3:1 ethanol (EtOH):diethyl phthalate (DEP) vehicle was tested, an excessive amount of irritation reactions were observed and it was not possible to determine if any of the reactions were due to sensitization (RIFM, 1999a). A 2% (or 2362 ug/cm²) solution of eugenol in the same vehicle resulted in 0/114 reactions (RIFM, 1999b). Eugenol was tested at 5% in a 3:1 DEP:EtOH vehicle and no reactions were in 108 subjects (RIFM, 2001).

Predictive animal studies show that it is a sensitizer but there are few studies that show its potential for sensitization at lower levels. Local Lymph Node Assay EC3 values range from 5.3 - 15.1% (1325 - 3775 ug/cm²) depending on the vehicle (Lalko et al., 2004). Therefore the skin sensitization potency for eugenol was determined to be a weak to moderate sensitizer.

Numerous reactions to eugenol at a variety of doses have been reported in clinical tests.

The weight of evidence supports a NOEL in the region of 5% (or 5,905 ug/cm²) or a use level of 0.5% on the skin.

Rexpan Rationale / Conclusion:

After reviewing the critical effect data, the Panel concluded that there were sufficient data to support this Standard.

References:

Lalko J., Isola D. and Api A.M. (2004). Ethanol and Diethyl Phthalate: Vehicle Effects in the Murine Local Lymph Node Assay (LLNA). Submitted to the International Journal of Toxicology.

Research Institute for Fragrance Materials, Inc. (1999a). Repeated insult patch test of eugenol in human subjects. RIFM report number 35078, November 16.

Research Institute for Fragrance Materials, Inc. (1999b). Repeated insult patch test of eugenol in human subjects. RIFM report number 35079, November 16.

Research Institute for Fragrance Materials, Inc. (2001). Repeated insult patch test of eugenol in human subjects. RIFM report number 39081, May 15.