

Safrole, Isosafrole and Dihydrosafrole

CAS-No.:	94-59-7 120-58-1 94-58-6 The scope of this Standard includes, but is not limited to the CAS number(s) indicated above; any other CAS number(s) used to identify these fragrance ingredients should be considered in scope as well.
Synonyms:	94-59-7: 1,3-Benzodioxole, 5-(2-propenyl)- 3,4-Methylene dioxyallylbenzene 4-Allyl-1,2-methylene dioxybenzene 5-Allyl-1,3-benzodioxole Safrol 120-58-1: 1,2-Methylenedioxy-4-propenylbenzene 1,3-Benzodioxole, 5-(1-propenyl)- 5-Prop-1-en-1-yl-1,3-benzodioxole Iso-safrole 94-58-6: 1,3-Benzodioxole, 5-propyl- 3,4-Methylenedioxypropylbenzene 5-Propyl-1,3-benzodioxole

History:	Publication date:	1987 (Amendment 17)	Previous Publications:	1976
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Implementation dates:	For new creation*:	Not applicable.
	For existing creation*:	Not applicable.
	*These dates apply to the supply of fragrance mixtures (formulas) only, not to the finished consumer products in the marketplace.	

RECOMMENDATION:

PROHIBITION / RESTRICTION

FRAGRANCE INGREDIENT PROHIBITION:

Safrole, Isosafrole and/or Dihydrosafrole as such should not be used as fragrance ingredients.

The natural extracts containing Safrole, Isosafrole and/or Dihydrosafrole should not be used as substitutes for these ingredients.

MAXIMUM ACCEPTABLE CONCENTRATIONS IN THE FINISHED PRODUCT (%):

Safrole, Isosafrole and Dihydrosafrole

Category 1	See notebox	Category 7A	See notebox
Category 2	See notebox	Category 7B	See notebox
Category 3	See notebox	Category 8	See notebox
Category 4	See notebox	Category 9	See notebox
Category 5A	See notebox	Category 10A	See notebox
Category 5B	See notebox	Category 10B	See notebox
Category 5C	See notebox	Category 11A	See notebox
Category 5D	See notebox	Category 11B	See notebox
Category 6	See notebox	Category 12	See notebox

Fragrance ingredient restriction - Note box

On the basis of established maximum concentration levels of this substance in commercially available natural sources (like essential oils, extracts and absolutes), exposure to this substance from the use of these oils and extracts is regarded acceptable as long as the total concentration of Safrole, Isosafrole and Dihydrosafrole in the finished consumer product does not exceed 0.01%.

FLAVOR REQUIREMENTS:

Due to the possible ingestion of small amounts of fragrance ingredients from their use in products in Categories 1 and 6, materials must not only comply with IFRA Standards but must also be recognized as safe as a flavoring ingredient as defined by the IOFI Code of Practice (www.iofi.org). For more details see chapter 1 of the Guidance for the use of IFRA Standards.

CONTRIBUTIONS FROM OTHER SOURCES:

SEE ANNEX ON CONTRIBUTIONS FROM OTHER SOURCES

INTRINSIC PROPERTY DRIVING RISK CARCINOGENICITY MANAGEMENT:

EXPERT PANEL FOR FRAGRANCE SAFETY RATIONALE / CONCLUSION:

The Expert Panel for Fragrance Safety reviewed all the available data for Safrole, Isosafrole and Dihydrosafrole and recommends not to use Safrole, Isosafrole and Dihydrosafrole as or in fragrance ingredients in any finished product application.

However, the presence of Safrole, Isosafrole and Dihydrosafrole in natural extracts used as ingredients in finished consumer products is tolerated only according to the upper concentration level mentioned in the Notebox if the natural extracts are not being used to provide an alternative, indirect source of the banned substance.

Safrole, Isosafrole and Dihydrosafrole**REFERENCES:**

The IFRA Standard on Safrole, Isosafrole and Dihydrosafrole is based on at least one of the following publications:

- The RIFM Safety Assessment on Safrole, Isosafrole and Dihydrosafrole is available at the RIFM Safety Assessment Sheet Database: <http://fragrancematerialsafetyresource.elsevier.com/>.
- Api A.M., Belsito D., Bruze M., Cadby P., Calow P., Dagli M. L., Dekant W., Dent M., Ellis G., Fryer A. D., Fukayama M., Griem P., Hickey C., Kromidas L., Lalko J., Liebler D.C., Miyachi Y., Politano V.T., Renskers K., Ritacco G., Salvito D., Schultz T.W., Sipes I. G., Smith B., Vitale D., Wilcox D.K. (2015). Criteria for the Research Institute for Fragrance Materials, Inc. (RIFM) safety evaluation process for fragrance ingredients. *Food Chem Toxicol.* 2015 Aug;82 Suppl:S1-S19 (doi: 10.1016/j.fct.2014.11.014) (http://fragrancematerialsafetyresource.elsevier.com/sites/default/files/Criteria_Document_Final.pdf).
- IDEA project (International Dialogue for the Evaluation of Allergens) Final Report on the QRA2: Skin Sensitisation Quantitative Risk Assessment for Fragrance Ingredients, September 30, 2016 (<http://www.ideaproject.info/uploads/Modules/Documents/qra2-dossier-final--september-2016.pdf>).
- Salvito D.T., Senna R. J., Federle T.W. (2002). A framework for prioritizing fragrance materials for aquatic risk assessment. *Environ Toxicol Chem.* 2002;21:1301-1308 (<https://www.ncbi.nlm.nih.gov/pubmed/12069318>).
- Conclusions of the Scientific Committee on Cosmetology of the EEC on Safrole and on the similarity of the biological activity of these substances (Scientific Committee of Cosmetology of the EEC, opinion reached on September 2, 1980; Communication to the EEC Commission ENV/521/79 and IARC Monograph Vol. 10, 1976, 231-244).

Additional information on the application of IFRA Standards is available in the Guidance for the use of IFRA Standards, publicly available at www.ifrafragrance.org.