

Melissa oil (genuine *Melissa officinalis* L.)

CAS-No.:	8014-71-9 84082-61-1 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 this fragrance ingredient should be considered in scope as well.	Molecular formula:	Not applicable.
Synonyms:	Balm oil (<i>Melissa officinalis</i> L.) Lemon balm oil Melissa officinalis leaf oil Melissa oil (<i>Melissa officinalis</i> L.) Oil of balm		

History:	Publication date:	2020 (Amendment 49)	Previous Publications:	2008 2009
-----------------	--------------------------	---------------------	-------------------------------	--------------

Implementation dates:	For new submissions*:		February 10, 2021
	For existing fragrance compounds*:		February 10, 2022
	*These dates apply to the supply of fragrance mixtures (formulas) only, not to the finished consumer products in the marketplace.		

RECOMMENDATION:	RESTRICTION
------------------------	--------------------

RESTRICTION LIMITS IN THE FINISHED PRODUCT (%):			
Category 1	0.11 %	Category 7A	1.2 %
Category 2	0.032 %	Category 7B	1.2 %
Category 3	0.65 %	Category 8	0.063 %
Category 4	0.60 %	Category 9	1.2 %
Category 5A	0.15 %	Category 10A	4.2 %

Melissa oil (genuine *Melissa officinalis* L.)

Category 5B	0.15 %	Category 10B	4.2 %
Category 5C	0.15 %	Category 11A	2.3 %
Category 5D	0.15 %	Category 11B	2.3 %
Category 6	0.35 %	Category 12	No Restriction

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: NONE TO CONSIDER (SEE ALSO THE SECTION ON CONTRIBUTIONS FROM OTHER SOURCES IN CHAPTER 1 OF THE GUIDANCE FOR THE USE OF IFRA STANDARDS)

INTRINSIC PROPERTY DRIVING RISK MANAGEMENT: DERMAL SENSITIZATION

RIFM SUMMARIES:

Recommended concentration levels are based on a comprehensive safety assessment, considering various endpoints. Depending on the outcome of the safety assessment, it might be one or more endpoint(s) that will drive the derivation of the concentration levels. If more than one endpoint is of relevance, the recommended concentration levels for each product category is derived from comparing maximum permitted level per endpoint consideration (dermal sensitization and/or systemic toxicity). Such recommended concentration levels correspond to the lowest level obtained per category.

Melissa oil (genuine *Melissa officinalis* L.)

Additional information is available in the RIFM safety assessment for Melissa oil (genuine *Melissa officinalis* L.), which can be downloaded from the RIFM Safety Assessment Sheet Database: <http://fragrancematerialsafetyresource.elsevier.com/>.

EXPERT PANEL FOR FRAGRANCE SAFETY RATIONALE / CONCLUSION:

The Expert Panel for Fragrance Safety reviewed all the available data for Melissa oil (genuine *Melissa officinalis* L.) and recommends the limits for the 12 different product categories, which are the acceptable use levels of Melissa oil (genuine *Melissa officinalis* L.) in the various product categories.

REFERENCES:

The IFRA Standard on Melissa oil (genuine *Melissa officinalis* L.) is based on at least one of the following publications:

- The RIFM Safety Assessment on Melissa oil (genuine *Melissa officinalis* L.) if 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 (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>).

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.