# MELISSA OIL
# (genuine Melissa officinalis L.)

**CAS Nº:** 8014-71-9
84082-61-1

**Empirical formula:** N/A

**Synonyms:** Balm oil (Melissa officinalis L.)
Lemon balm oil
Melissa officinalis leaf oil
Melissa oil (Melissa officinalis L.)
Oil of balm

**History:** Initial reviews: July 2008 (43th Amendment)

Current revision date: 2009

**Implementation date**: for new submissions*: August 7, 2009

for existing fragrance compounds*: August 7, 2011

**Next review date**: 2014

* 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:**
For a description of the categories, refer to the QRA Information Booklet.

| | | | |
|---|---|---|---|
| Category 1 - See Note box (1) | 0.04 % | Category 7 | 0.11 % |
| Category 2 | 0.05 % | Category 8 | 1.40 % |
| Category 3 | 0.21 % | Category 9 | 5.00 % |
| Category 4 | 0.63 % | Category 10 | 2.50 % |
| Category 5 | 0.33 % | Category 11 | See Note box (2) |
| Category 6 - See Note box (1) | 1.01 % | | |

**Note box**:

(1) IFRA would recommend that any material used to impart perfume or flavour in products intended for human ingestion should consist of ingredients that are in compliance with appropriate regulations for foods and food flavourings in the countries of planned distribution and, where these are lacking, with the recommendations laid down in the Code of Practice of IOFI (International Organisation of the Flavor Industry - www.iofiorg.org)

(2) 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.

**Fragrance material specification:** N/A

**Contribution from other sources:** N/A

# MELISSA OIL
# (genuine Melissa officinalis L.)

**Critical effect**: **Sensitization**

**RIFM Summaries**:

| LLNA weighted mean EC3 values ($\mu g/cm^2$) [no. studies] | Potency Classification Based on Animal Data[2] | Human Data | | | WoE NESIL[3] ($\mu g/cm^2$) |
|---|---|---|---|---|---|
| | | NOEL – HRIPT (induction) ($\mu g/cm^2$) | NOEL – HMT (induction) ($\mu g/cm^2$) | LOEL[1] (induction) ($\mu g/cm^2$) | |
| 4500 [1][5] | Weak | 1470[4] | NA | NA | 1400 |

All data in this Table are available from RIFM and are listed in the RIFM Database.
NOEL = No observed effect level; HRIPT = Human Repeat Insult Patch Test; HMT = Human Maximization Test; LOEL = lowest observed effect level; NA = Not Available.

[1]Data derived from HRIPT or HMT.
[2]Based on animal data using classification defined in ECETOC, Technical Report No. 87, 2003.
[3]WoE NESIL limited to two significant figures.
[4]MT-NOEL = Maximum Tested No Effect Level. No sensitization was observed in human predictive studies. Doses reported reflect the highest concentration tested, not necessarily the highest achievable NOEL..
[5]EC3 value from one LLNA, not the mean.

**REXPAN Rationale / Conclusion:**

The RIFM Expert Panel reviewed the critical effect data for Melissa oil and, based on the weight of evidence, established the No Expected Sensitization Induction Level (NESIL) as 1400 $\mu g/cm^2$. They recommend the limits for the 11 different product categories, which are the acceptable use levels of Melissa oil in the various product categories. These were derived from the application of the exposure-based quantitative risk assessment approach for fragrance ingredients, which is detailed in the QRA Expert Group Technical Dossier of June 22, 2006.

**References:**

RIFM (Research Institute for Fragrance Materials, Inc.), 2001. Human repeated insult patch test. Unpublished study from Robertet, 21 February. Report number 36641. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2008a. Local Lymph Node Assay. Unpublished study from Robertet. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2008b. Human repeated insult patch test. Unpublished study from Robertet. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2009 Repeated insult patch test on melissa oil in humans. Unpublished summary report from Robertet, June 2009 (RIFM, Woodcliff Lake, NJ, USA).