**Bitter orange peel oil expressed**

<table>
<thead>
<tr>
<th>CAS N°:</th>
<th>Empirical formula: Structure:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>68916-04-1 72968-50-4</td>
<td>N/A N/A</td>
<td></td>
</tr>
</tbody>
</table>

**Synonyms:**
- Orange Peel Oil, Bitter (*Citrus aurantium* L. subsp amara L.)
- Bitter orange oil (*Citrus aurantium* L. subsp. amara L.)
- Citrus aurantium peel oil
- Curacao peel oil (*Citrus aurantium* L.)
- Daidai peel oil (*Citrus aurantium* L.)

**History:**
- Initial reviews: October 1975, June 1992, July 2002
- Current revision date: 2015
- Implementation date:
  - For new submissions*: Not applicable
  - For existing fragrance compounds*: Not applicable
- Next review date: 2020

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

**RECOMMENDATION:**
- RESTRICTED

**RESTRICTIONS:**

**Limits in the finished product:**

<table>
<thead>
<tr>
<th>Skin contact products:</th>
<th>Rinse-off products:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leave on products:</td>
<td>No Restriction</td>
</tr>
<tr>
<td>1.25%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non skin contact products:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No Restriction</td>
<td></td>
</tr>
</tbody>
</table>

**Including household cleaning products**

**Note box:**
- The Standard is set due to the phototoxic effects of the material. The limit only applies to applications on skin exposed to sunshine, excluding rinse-off products (please refer to Table 4 of the QRA booklet for more detailed information).
- If combinations of phototoxic fragrance ingredients are used, the use levels have to be reduced accordingly. The sum of the concentrations of all phototoxic fragrance ingredients, expressed in % of their recommended maximum level in the consumer product, shall not exceed 100.
- Note: See remark on phototoxic ingredients in the Introduction to the IFRA Standards (Appendix 8 to the IFRA Code of Practice) and the Standard on Citrus oil and other furocoumarins-containing essential oils.

**Fragrance material specifications:**
- N/A

**CONTRIBUTION FROM OTHER SOURCES:**

None to consider (see also the note on the contributions from other sources in the Introduction to the IFRA Standards).
Bitter orange peel oil expressed

CRITICAL EFFECT: PHOTOTOXICITY

RIFM SUMMARIES:

Human Studies: The material was tested for phototoxic potential in human volunteers (Kaidbey and Kligman, 1980). Five μL/cm² of 100% bitter orange oil was applied to 2 cm² under occlusive tape. One cm circular sites were exposed to visible light or 20 J/cm² UVA.

Reactions were read at 24 and 48 hours. All 8 subjects reacted.

Animal studies: The NOEL was based on studies conducted with pooled samples of bitter orange oil in one miniature swine and hairless mice, which showed NOEL of 6.25%.

<table>
<thead>
<tr>
<th>LLNA weighted mean EC3 values (µg/cm²) [no. studies]</th>
<th>Potency Classification Based on Animal Data¹</th>
<th>Human Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NOEL – HRIPT (induction) (µg/cm²)</td>
<td>NOEL – HMT (induction) (µg/cm²)</td>
</tr>
<tr>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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.

¹Data derived from HRIP or HMT.
³WoE NESIL limited to two significant figures.
⁴EC3 value from one LLNA, not the mean.
⁵LOEL from human maximization test, not a human repeated insult patch test.

REXPAN RATIONALE / CONCLUSION:

The RIFM Expert Panel reviewed the critical effect data for orange peel oil, bitter, and recommended that the skin contact level should change to 1.25%, incorporating a 5 fold uncertainty factor.

REFERENCES:


