Amendment 49

IFRA STANDARD

Styrax

CAS-No.: 8046-19-3
          8024-01-9
          94891-27-7
          94891-28-8
          101227-15-0

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.

Synonyms:

Prohibition of the crude material:
Styrax crude gums

Restriction and Specification of the distillates:
Styrax resin
Styrax oil
Styrax oil, rectified
Styrax oil, pyrogenated, distilled

History:

<table>
<thead>
<tr>
<th>Publication date:</th>
<th>2020 (Amendment 49)</th>
<th>Previous Publications:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1977</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2013</td>
</tr>
</tbody>
</table>

Implementation dates:

For new creation*: February 10, 2021
For existing creation*: February 10, 2022

*These dates apply to the supply of fragrance mixtures (formulas) only, not to the finished consumer products in the marketplace.

RECOMMENDATION:

PROHIBITION / RESTRICTION / SPECIFICATION

FRAGRANCE INGREDIENT PROHIBITION:

Crude gums of Liquidambar styraficula L. var. macrophylla or Liquidambar orientalis Mill. should not be used as fragrance ingredients for any finished product application.

MAXIMUM ACCEPTABLE CONCENTRATIONS IN THE FINISHED PRODUCT (%):

<table>
<thead>
<tr>
<th>Category</th>
<th>Acceptable Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1</td>
<td>0.12 %</td>
</tr>
<tr>
<td>Category 2</td>
<td>0.034 %</td>
</tr>
<tr>
<td>Category 3</td>
<td>0.69 %</td>
</tr>
<tr>
<td>Category 7A</td>
<td>1.3 %</td>
</tr>
<tr>
<td>Category 7B</td>
<td>1.3 %</td>
</tr>
<tr>
<td>Category 8</td>
<td>0.068 %</td>
</tr>
</tbody>
</table>
Styrax

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>0.64 %</td>
<td>9</td>
<td>1.3 %</td>
</tr>
<tr>
<td>5A</td>
<td>0.16 %</td>
<td>10A</td>
<td>4.5 %</td>
</tr>
<tr>
<td>5B</td>
<td>0.16 %</td>
<td>10B</td>
<td>4.5 %</td>
</tr>
<tr>
<td>5C</td>
<td>0.16 %</td>
<td>11A</td>
<td>2.5 %</td>
</tr>
<tr>
<td>5D</td>
<td>0.16 %</td>
<td>11B</td>
<td>2.5 %</td>
</tr>
<tr>
<td>6</td>
<td>0.38 %</td>
<td>12</td>
<td>No Restriction</td>
</tr>
</tbody>
</table>

**Fragrance ingredient restriction - Note box**

Only extracts or distillates (resinoids, absolutes and oils), prepared from exudations of Liquidambar styraciflua L. var. macrophylla or Liquidambar orientalis Mill., can be used.

**FRAGRANCE INGREDIENT SPECIFICATION:**

Styrax oil can be obtained from solvent extraction or pyrolysis. Styrax oil obtained through pyrolysis shall be rectified according to Good Manufacturing Practices (GMP) and the content of Polycyclic Aromatic Hydrocarbons (PAH) resulting from their use shall respect the following requirement: Benzo[ghi]perylene and 1,2-Benzanthracene are to be used as markers for PAH. If used alone or in combination with rectified Cade oil, rectified Birch tar oils or rectified Opoponax oil, the total concentration of both of the markers should not exceed 1 ppb in the final product.

**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 BEYOND TRACES (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:**
**Styrax**

Maximum acceptable concentrations 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 maximum acceptable concentrations for each product category are derived from comparing maximum permitted level per endpoint consideration (e.g. dermal sensitization and/or systemic toxicity). Such maximum acceptable concentrations correspond to the lowest level obtained per category.

Additional information is available in the RIFM safety assessment for Styrax, which can be downloaded from the RIFM Fragrance Material Safety Assessment Center: http://fragrancematerialsafetyresource.elsevier.com/.

**EXPERT PANEL FOR FRAGRANCE SAFETY RATIONALE / CONCLUSION:**

The Expert Panel for Fragrance Safety reviewed data available for Styrax distillates and recommends the limits for the 12 different product categories, which are the acceptable use levels of Styrax distillates in the various product categories.

In addition, they recommend to use Styrax distillates according to its specification above mentioned.

The Expert Panel for Fragrance Safety further recommends not to use Styrax crude in any finished product application.

**REFERENCES:**

The IFRA Standard on Styrax is based on at least one of the following publications:

- The RIFM Safety Assessment on Styrax if available at the RIFM Fragrance Material Safety Assessment Center: http://fragrancematerialsafetyresource.elsevier.com


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.