

6 Commerce Drive • Danbury, CT 06810 • ph (203) 830-4000 • fax (203) 830-4010

September 26th, 2023

Re: #962 LIMEDIENE

BRI # 962 Limediene contains 0.3% Toluene as an unavoidable production related impurity. The following applies to Toluene in fragrance compounds/mixtures:

The level of Toluene has to be kept as low as practicable and should never exceed 100 ppm in the fragrance compound/mixture or fragrance oil.

A copy of the Toluene IFRA standard is attached to this letter for your convenience.

I hope this statement is satisfactory. If you need additional information, please do not hesitate to contact me.

Kind Regards, Joseph Bania Regulatory Affairs Manager (203) 830-4000 jbania@bedoukian.com



Toluene

CAS-No.:	The scope of this Standard includes, but is not limited to	Molecular formula: Structure:	C ₇ H ₈
Synonyms:	Toluol Methylbenzol Methylbenzene		

History:	Publication date:	2004 (Amendment 38)	Previous	Not
			Publications:	applicable.

Implementation	For new submissions*:	May 6, 2004		
dates:	For existing fragrance compounds*:	May 6, 2005		
	*These dates apply to the supply of fragrance mixtures (formulas) only, not to the finished			
	consumer products in the marketplace.			

RECOMMENDATION:	PROHIBITION / SPECIFICATION

FRAGRANCE INGREDIENT PROHIBITION:	Toluene should not be used as a fragrance
	ingredient.

FRAGRANCE INGREDIENT SPECIFICATION:	The level of Toluene has to be kept as low as practicable and should never exceed 100 ppm						
	in the fragrance compound/mixture or fragrance oil.						

CONTRIBUTIONS FROM OTHER SOURCES:	NONE 1	TO (CONSIDER	(SEE	ALSO	THE
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Toluene

SECTION ON CONTRIBUTIONS FROM OTHER SOURCES IN CHAPTER 1 OF THE GUIDANCE FOR THE USE OF IFRA STANDARDS)

INTRINSIC PROPERTY DRIVING RISK L MANAGEMENT:

LIVER TOXICITY

EXPERT PANEL FOR FRAGRANCE SAFETY RATIONALE / CONCLUSION:

The Expert Panel for Fragrance Safety reviewed all the available data for Toluene and recommends not to use Toluene as or in fragrance ingredients in any finished product application other than described in the above fragrance ingredient specification.

REFERENCES:

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

- The RIFM Safety Assessment on Toluene 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.p df).

- 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).
- Cosmetic Ingredient Review, Journal of the American College of Toxicology JACT 6 (1) 1987.
- IARC (International Agency for Research on Cancer) Monographs Vol 47, p .79 (1989); Vol 71 p. 829 (1999).



Toluene

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.