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November 2nd, 2023

# *Re:* #801-SUS NOOTKATONE (CRYSTALS 98+%)

Nootkatone has an IFRA standard associated with it. Nootkatone should only be used as a fragrance ingredient if at least 98% pure, with a melting point of at least 32°C.

A copy of the 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 vtra

# Nootkatone

CAS-No.:	4674-50-4 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:	5,6-Dimethyl-8-isopropenylbicyclo(4.4.0)dec-1-en-3-one 4a,5-Dimethyl-1,2,3,4,4a,5,6,7-octahydro-7-keto-3-isopropenylnaphthalene 4betaH,5alpha-Eremorphila-1(10),11-dien-2-one (4R-(4alpha,4a alpha,6beta))-4,4a,5,6,7,8-Hexahydro-4,4a-dimethyl-6-(1- methylvinyl)naphthalen-2(3H)-one 4,4a,5,6,7,8-Hexahydro-6-isopropenyl-4,4a-dimethyl-2(3H)-naphthalenone 2(3H)-Naphthalenone, 4,4a,5,6,7,8-hexahydro-4,4a-dimethyl-6-(1-methylethenyl)-, (4R,4aS,6R)-

History:	Publication date:	2006 (Amendment 40)	Previous Publications:	1980	
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	For new creation*:	December 11, 2006
dates:	For existing creation*:	December 11, 2007
	*These dates apply to the supply of fragrance mixtu	res (formulas) only, not to the
	finished consumer products in the marketplace.	

RECOMMENDATION:	SPECIFICATION
FRAGRANCE INGREDIENT SPECIFICATION:	Nootkatone used as a fragrance ingredient should be at least 98% pure, with a melting point of at least 32°C. Lower purity grades may not be used as a fragrance ingredient.
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)

Nootkatone is found in natural extracts, but its natural contributions are not relevant for the fragrance ingredient specification mentioned above.

### Nootkatone

#### INTRINSIC PROPERTY DRIVING RISK MANAGEMENT:

DERMAL SENSITIZATION

DERMAL SENSITIZATIC

## EXPERT PANEL FOR FRAGRANCE SAFETY RATIONALE / CONCLUSION:

The Expert Panel for Fragrance Safety reviewed all the available data for Nootkatone. Based on their expert judgement, they recommend to use the fragrance ingredient according to its specification mentioned above.

### **REFERENCES:**

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

• The RIFM Safety Assessment on Nootkatone 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.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).

• Research Institute for Fragrance Materials, Inc., 1971. Sensitization and irritation study of nootkatone. Unpublished report from Givaudan, May 24, Report number 41820.

• Research Institute for Fragrance Materials, Inc., 1977. Report on human maximization studies. RIFM report number 1702, June 6c.

• Research Institute for Fragrance Materials, Inc., 1978. Report on human maximization studies. RIFM report number 1698, January 13a.

• Research Institute for Fragrance Materials, Inc., 1979. Report on human maximization studies. RIFM report number 1775, September 11.

• Research Institute for Fragrance Materials, Inc., 2005. Repeated insult patch test with nootkatone. Unpublished report from Bedoukian Research, Inc., May 11. Report number 46155.

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.