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September 13th, 2023

BRI # 279-SUS Hydrofleur® has an IFRA standard associated with it.

There are restriction limits for 6-Hydroxy-2,6-dimethylheptanal in finished products.

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

Additionally, US EPA has published the following Significant New Use Rule (SNUR) for this material 40CFR721.11568:

The significant new use includes processing the chemical substance to a concentration of greater than or equal to 1.0% in the final end use formulation and any predictable or purposeful release of the new chemical substance, or any waste stream from manufacturing or processing containing the new chemical substance, that results in surface water concentrations exceeding 14 ppb. In summary, the following restrictions in the United States are expected to be as follows:

- Final end use formulations should be limited to less than 1%
- No releases to surface water exceeding 14 ppb.

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

Kind regards,
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6-Hydroxy-2,6-dimethylheptanal

CAS-No.:	62439-42-3 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:	6-Hydroxy-2,6-dimethylheptanal Heptanal, 6-hydroxy-2,6-dimethyl-

History:	Publication date:	2023 (Amendment 51)	Previous Publications:	Not applicable
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Implementation dates:	For new creation*:	March 30, 2024
	For existing creation*:	October 30, 2025
	*These dates apply to the supply of fragrance mixtures (formulas) only, not to the finished consumer products in the marketplace.	

RECOMMENDATION:	RESTRICTION
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MAXIMUM ACCEPTABLE CONCENTRATIONS IN THE FINISHED PRODUCT (%):			
Category 1	0.22 %	Category 7A	1.8 %
Category 2	0.066 %	Category 7B	1.8 %
Category 3	1.3 %	Category 8	0.11 %
Category 4	1.2 %	Category 9	2.4 %
Category 5A	0.32 %	Category 10A	0.91 %
Category 5B	0.32 %	Category 10B	8.7 %
Category 5C	0.32 %	Category 11A	0.11 %
Category 5D	0.11 %	Category 11B	0.11 %
Category 6	0.73 %	Category 12	No restriction

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
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6-Hydroxy-2,6-dimethylheptanal

	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.
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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)
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INTRINSIC PROPERTY DRIVING RISK MANAGEMENT:	DERMAL SENSITIZATION AND SYSTEMIC TOXICITY
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RIFM SUMMARIES:

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 6-Hydroxy-2,6-dimethylheptanal, 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 all the available data for 6-Hydroxy-2,6-dimethylheptanal and recommends the concentrations for the 12 different product categories, which are the maximum acceptable concentrations of 6-Hydroxy-2,6-dimethylheptanal in the various product categories.

REFERENCES:

The IFRA Standard on 6-Hydroxy-2,6-dimethylheptanal is based on at least one of the following publications:

- The RIFM Safety Assessment on 6-Hydroxy-2,6-dimethylheptanal if available at the RIFM Fragrance Material Safety Assessment Center: <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 (http://fragrancematerialsafetyresource.elsevier.com/sites/default/files/Criteria_Document_Final.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

6-Hydroxy-2,6-dimethylheptanal

(<https://www.ncbi.nlm.nih.gov/pubmed/12069318>).

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.