OMUFA: Fragrance Industry Perspective

September 28, 2023

FRAGRANCE CREATORS ASSOCIATION®

Fragrance Creators Association

- Trade association representing majority of fragrance manufacturing in North America
- Diverse membership of 60+ companies
- Full value chain
- Proactively and reactively manage matters related to legislative, regulatory, retailer, consumer, and other stakeholders like NGOs
- Membership also relies upon Research Institute for Fragrance Materials (RIFM)

FRAGRANCE CREATORS
ASSOCIATION®

Role of Fragrance as Excipient in OTC Drugs

- Enhance smell
- Mask malodor
- Palatability/appeal to consumers

Fragrance Creators' Stance on OMUFA

- Value safety and innovation
- Appreciate OMUFA's flexibility
- Support collection of fees for OTC monograph activities
  - Believe in discretion as to where funds are allocated

A More Efficient OMUFA

- Identify industries with a strong safety record
  - Take advantage of existing safety information/expertise
- Use FDA resources where gaps exist

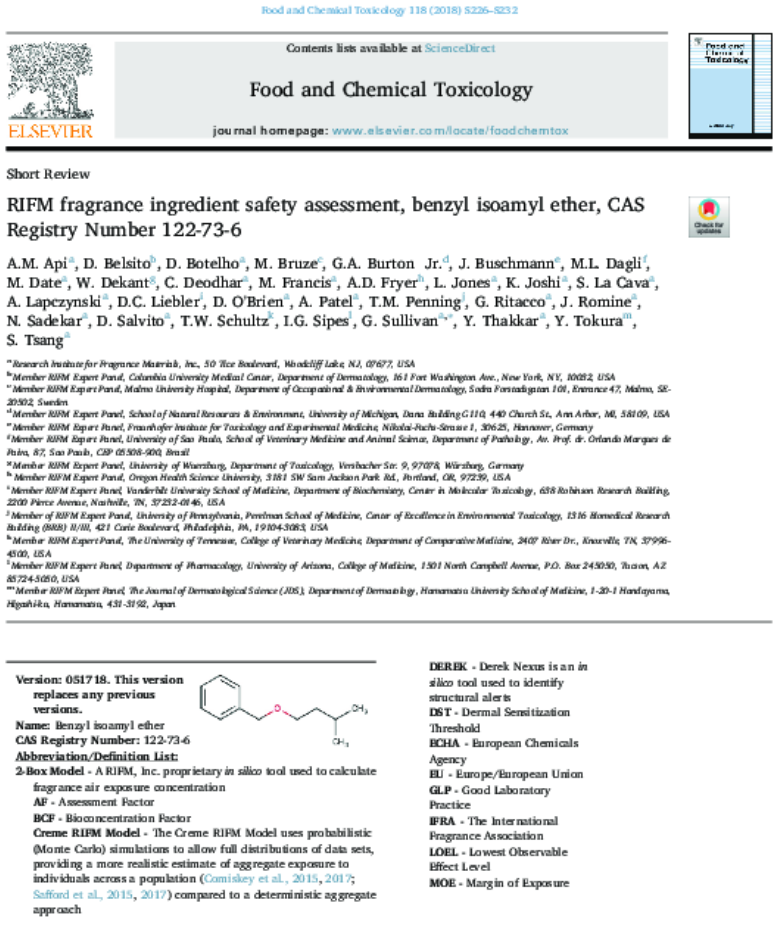
Fragrance Industry: History of Safety

- Established in 1966
- Member-funded non-profit
- Diverse 60+ members
- Staffed by experts in human health and environmental toxicological endpoints

RIFM®
RESEARCH INSTITUTE FOR FRAGRANCE MATERIALS

Fragrance Industry: History of Safety

- Maintain a continuously updated database of safety data
- Generate exposure data using Creme-RIFM Aggregate Exposure Model
- Conduct detailed safety assessments that are peer reviewed and published
- All publications are open-access and available on the Fragrance Material Resource Center
- Research innovative new approach methodologies (NAMs)



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Short Review

RIFM fragrance ingredient safety assessment, benzyl isoamyl ether, CAS Registry Number 122-73-6

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Version: 051718. This version replaces any previous versions.

Name: Benzyl isoamyl ether

CAS Registry Number: 122-73-6

Abbreviation/Definition List:

2-Box Model - A RIFM, Inc. proprietary *in silico* tool used to calculate fragrance air exposure concentration

AF - Assessment Factor

BCF - Bioconcentration Factor

Creme RIFM Model - The Creme RIFM Model uses probabilistic (Monte Carlo) simulations to allow full distributions of data sets, providing a more realistic estimate of aggregate exposure to individuals across a population (Comiskey et al., 2015, 2017; Safford et al., 2015, 2017) compared to a deterministic aggregate approach

DEREK - Derek Nexus is an *in silico* tool used to identify structural alerts

DST - Dermal Sensitization Threshold

ECHA - European Chemicals Agency

EU - Europe/European Union

GLP - Good Laboratory Practice

IFRA - The International Fragrance Association

LOEL - Lowest Observable Effect Level

MOE - Margin of Exposure

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RIFM®
RESEARCH INSTITUTE FOR FRAGRANCE MATERIALS

Fragrance Industry: History of Safety

- Team of experts (academics, physicians) with no affiliations to industry
- Critically review RIFM's safety assessments and research projects
- Determines safety of use for fragrance ingredients through consideration of available information and active generation of additional data

EXPERT PANEL
for FRAGRANCE SAFETY

Fragrance Industry: History of Safety

- Abundance of guidelines for RIFM and manufacturers to properly test
  - Good Laboratory Practice
  - Organization for Economic Cooperation and Development
  - National Toxicology Program

Fragrance Industry: FDA Regulation

- Resource for FDA Office of Cosmetics and Colors in developing the *Modernization of Cosmetics Regulation Act*

Conclusions

- Fragrance industry supports OMUFA
- Program can be most efficient if FDA does not have to duplicate work
- Fragrance Creators and RIFM are expert sources of extensive safety information on fragrances

Thank you!