

The Research Institute for Fragrance Materials (RFIM) and its Safety Assessment Process

The Research Institute for Fragrance Materials (RIFM; <u>rifm.org</u>) is an independent non-profit scientific research institute. Established in 1966, RIFM generates, analyzes, evaluates, and distributes data to provide a scientific basis for the safe use of fragrances. In addition, and as part of this process, RIFM engages in testing and evaluation, cooperates with official agencies, and encourages uniform safety standards related to fragrance ingredients. RIFM makes all of its published, peerreviewed work—including its fragrance ingredient safety assessments—available for free via the Fragrance Materials Safety Resource Center (fragrancematerialsafetyresource.elsevier.com).

The Expert Panel for Fragrance Safety (<u>https://fragrancesafetypanel.org/</u>), an independent international group of scientists, provides scientific authority and objectivity to RIFM's work. They have guided, overseen, and ultimately must approve all of RIFM's scientific projects and results before submission for peer-reviewed publication.

RIFM has compiled the most comprehensive, worldwide source of toxicology data, literature, and general information on fragrance and flavor raw materials: The RIFM Database. RIFM's fragrance ingredient safety assessment program draws from this comprehensive database of over 78,000 references and more than 145,000 human health and environmental studies.

RIFM's Safety Assessment process

RIFM has a team of 16 scientists specializing in various areas of human health and environmental sciences. They come from biology, chemistry, engineering, and toxicology programs across the globe.

Using up-to-date, cutting-edge science, the RIFM evaluates six endpoints of human health plus environmental impact in its comprehensive safety assessments. Following the protocol of the peer-reviewed <u>RIFM Criteria Document</u> and <u>NCS</u> <u>Criteria Document</u>, RIFM considers the following endpoints to ensure the safe use of fragrance ingredients:

- **Genotoxicity** (the potential to alter or damage the genetic material in the body's cells)
- **Repeated dose toxicity** (the potential to cause systemic adverse effects due to prolonged usage and exposure)
- **Reproductive toxicity** (the potential to cause adverse effects on pre-and post-natal development in infants and children or on the sexual function in adults
- **Skin sensitization** (the potential of an ingredient to cause a rare allergic reaction on the skin)
- **Photoirritation/Photoallergenicity** (the potential to cause a lightinduced skin reaction or allergic reaction
- Local Respiratory toxicity (the potential to cause adverse effects in the organs of the respiratory system)
- **Environmental toxicity** (the potential environmental impact).

RIFM's scientists work together to evaluate data and consumer exposure to determine conditions of safe use. RIFM assesses the safety of fragrance ingredients by the most current, internationally accepted guidelines—and has done so since its founding. The safety assessment process starts with RIFM scientists evaluating the existing data and ensuring that every conclusion in every <u>RIFM safety assessment</u> is grounded in internationally recognized guidelines. For example, RIFM considers tests on fragrance materials that follow <u>Good Laboratory Practices (GLP)</u> and comply with the <u>OECD (Organisation for Economic Co-operation and Development)</u> <u>Test Guidelines for Chemicals</u>, internationally accepted specifications for testing chemicals. In addition, any tests necessary to fill data gaps are conducted by independent external labs, not RIFM.

To further enhance its understanding of these endpoints, RIFM is active in collaborative projects with scientists worldwide to develop new and reliable ways to assess the safety of fragrance ingredients. These New Approach Methodologies (NAMs) are being developed as animal-alternative testing strategies. (RIFM does not perform animal testing for its human health endpoints.)

Oversight and peer review

Since 1967, the <u>Expert Panel for Fragrance Safety</u> has guided, overseen, and ultimately must approve all of RIFM's safety assessments before submission for peer-reviewed publication. The Expert Panel elects its members, who serve on a rotating basis and comprises internationally known academic scientists, including dermatologists, pathologists, toxicologists, and environmental scientists. It meets three times a year to review, evaluate, and assess the safety of fragrance materials. The Expert Panel meeting Agendas and Minutes are <u>available on their</u> <u>website</u>.

RIFM's safety evaluations and research papers are submitted for peer-reviewed publication, ensuring another layer of scientific objectivity. RIFM makes all of its published, peer-reviewed work—including its fragrance ingredient safety assessments—available for free via the Fragrance Materials Safety Resource Center (fragrancematerialsafetyresource.elsevier.com). As of June 2023, safety assessments covering 1,543 fragrance ingredients have been peer-reviewed, published, and available for free download on the Fragrance Materials Safety Resource Center, with another 200 currently being peer-reviewed.

Finally, RIFM collaborates with others to ensure that its work is <u>reproducible</u>. For example, RIFM collaborated with the government of India's Institute of Toxicology Research (IITR) to have IITR scientists follow its <u>Safety Assessment Criteria</u> <u>Document</u> on four ingredients and see if their conclusions would match RIFM's. Their results, published in their <u>Annual Report for 2019-2020</u>, were identical to RIFM's for these four ingredients, confirming RIFM's science-based safety assessment process.