

# **RIFM AGGREGATE EXPOSURE MODEL: BACKGROUND FOR DEVELOPING A NEW MODEL**

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# RIFM Aggregate Exposure Task Force Members



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# Older RIFM Method: Dermal Systemic Exposure



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Type of Cosmetic Product	Frequency of Use (times/week)	Amount of Product Used (g)	Exposure Factor (g/cm <sup>2</sup> )	Exposure (mg/cm <sup>2</sup> /day)	Fragrance Ingredient/mixture	Fragrance Ingredient mg/day	Fragrance Ingredient mg/kg/day
anti-perspirant	1.00	0.010	1.000	0.010	1.00	0.050	0.0008
bath products	1.00	0.020	1.000	0.020	0.050	0.001	0.0000
body lotion	8.00	0.71	1.000	0.004	0.050	0.227	0.0038
eau de toilette	0.75	1.00	1.000	0.080	1.00	0.600	0.0100
face cream	0.80	2.00	1.000	0.003	0.050	0.001	0.0000
fragrance cream	5.00	0.29	1.000	0.040	0.050	0.002	0.0000
hair spray	5.00	2.00	0.010	0.005	0.050	0.002	0.0000
shampoo	8.00	1.00	0.010	0.005	1.00	0.004	0.0001
shower gel	1.00	0.012	1.000	0.012	1.00	0.006	0.0001
toilet soap	1.00	0.015	1.000	0.015	1.00	0.007	0.0001
<b>Total</b>							<b>0.0255</b>

**Only 10 Product Types Dermal Exposure Only Does NOT Use New Measured Exposure Data**

**97.5%ile Use of Fragrance Ingredient in Hydroalcoholic Products**

**Cumulative Deterministic Exposure**

# Aggregate Exposure TF

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- Should the current fragrance industry approach to assessing consumer exposure to fragrance ingredients be modified?
  - Yes it should be modified to include the new measured exposure data from all the sources used in the QRA Dermal Sensitization Method
- If it should be modified, should the approach be limited to dermal exposure of consumer products?
  - No, the total systemic exposure should be included from all consumer product types
- Should dermal aggregate exposure be considered?
  - Yes a model should be developed to include dermal aggregate exposure

# Exposure Assessment

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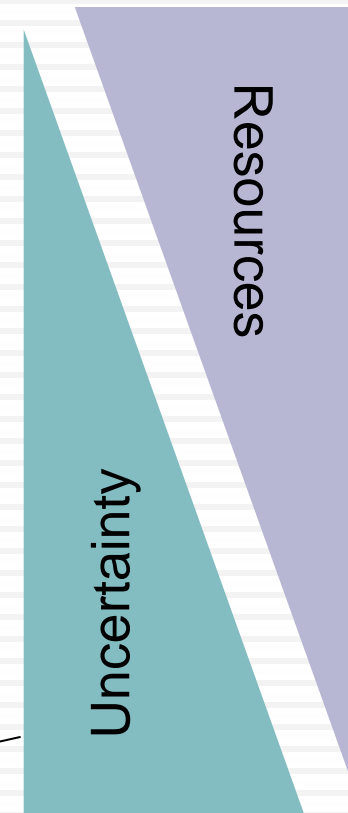
Tier 5: Direct Measurement

Tier 4: Probabilistic Models

Tier 3: Distributional Models

Tier 2: Deterministic Models

Tier 1: Conservative Calculations



Note: Uncertainty in terms of over-estimation

# RIFM Aggregate Exposure Model

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- To develop a standard approach that can be used widely for industry where total systemic exposure includes:
  - Estimate for entire population (preferably World Wide but initially for Europe and North America)
  - From all exposure pathways – dermal, oral and inhalation
  - From all key products in which fragrance ingredients are used
- The data will also be made available in a software model which can be used to perform assessments in the future

# RIFM Aggregate Exposure Model – Products Included



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## Phase I

- Body Lotion (prestige vs. mass market)
- Deodorant/antiperspirants
- Face cream/Moisturizers
- Shampoo/Conditioners
- Hair Styling Products (excluding hair spray)
- Hand Cream
- Hydroalcoholics
- Lipstick
- Liquid/Makeup Foundation
- Mouthwash
- Shower Gel
- Toothpaste

## Phase II

- Bar Soap
- Liquid Hand Soap
- Body Spray
- Inhalation
  - Air Fresheners
  - Candles
  - Hair Spray, Perfume, Deodorant Spray

**These products cover  
the major exposure  
contribution to  
fragrance ingredients**

# Why is Aggregate Exposure Important?



- Avoid over-estimation – current method is overly conservative and unrealistic
- Basis for IFRA limits for systemic effects – if adverse systemic effects are observed, an accurate exposure assessment is necessary
- Dermal aggregate exposure needed for incorporation in the QRA Dermal Sensitization methodology



# Creme Approach

- Use probabilistic and deterministic factors
- Incorporate co-use and non-use of product data, will build a consumer model of a large number of subjects incorporating real co use and non use factors into the behavior
- Will incorporate extent of use data

# Dermal Sensitization Aggregate Exposure



- Part of a larger project to evaluate aggregate exposure to cosmetic products
- Calculate total exposure per surface area from all products on that area
- This exposure per surface area can then be used to assess dermal sensitization

# MORE INFORMATION

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SEARCH

What People are Saying

RIFM's short film "What People Are Saying" on public opinion about the fragrance industry and fragrance safety.

view video

**News & Events**

5/24/11 - RIFM Relaunches Web Site

3/29/11 - RIFM Respiratory Science Poster Wins First Place Blue Ribbon at SCF's 80th Anniversary Annual Meeting Poster Presentation

2/23/11 - RIFM Presents Fragrance Science At Society of Toxicology 50th Anniversary Annual Meeting

FR160 - IF YOU MISSED RIFM'S MAY 2010 NEWS, YOU CAN STILL VIEW THE PRESENTATIONS

industry news  
news and events

**New Publications**

Design and Feasibility of an International Study Assessing the Prevalence of Contact Allergy to Fragrances in the General Population: The European Dermato-Epidemiology Network Fragrance Study

The first article from the SCF sponsored epidemiology study on the true prevalence of fragrance allergy.

more info >

more publications >

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