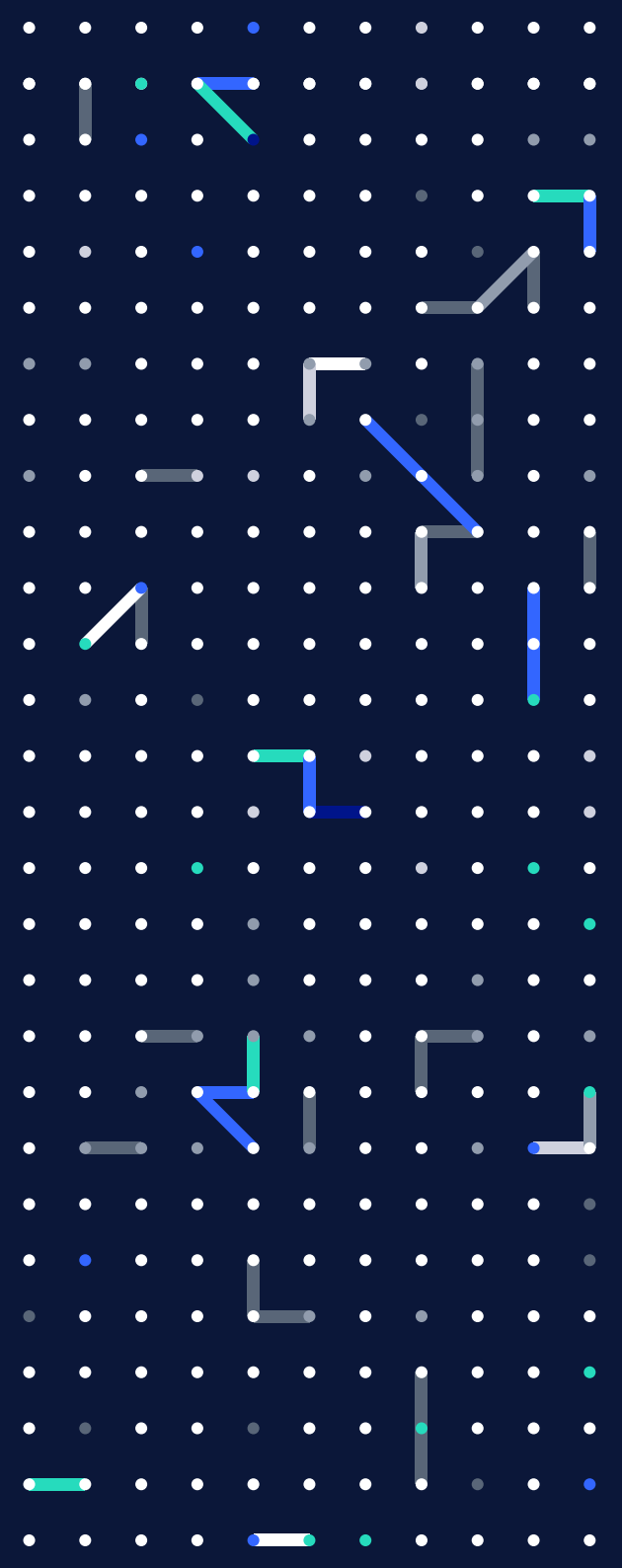**Creme Global**

Creme Global
Personal Care
Expertise and Solutions

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Our Expertise

Creme Global has over 15 years of experience in the personal care and cosmetics domain. Our in-house expert team of data scientists specialising in cosmetics and personal care products have used predictive modelling, data analytics and cloud computing to help our clients understand the impact of products on consumer health.
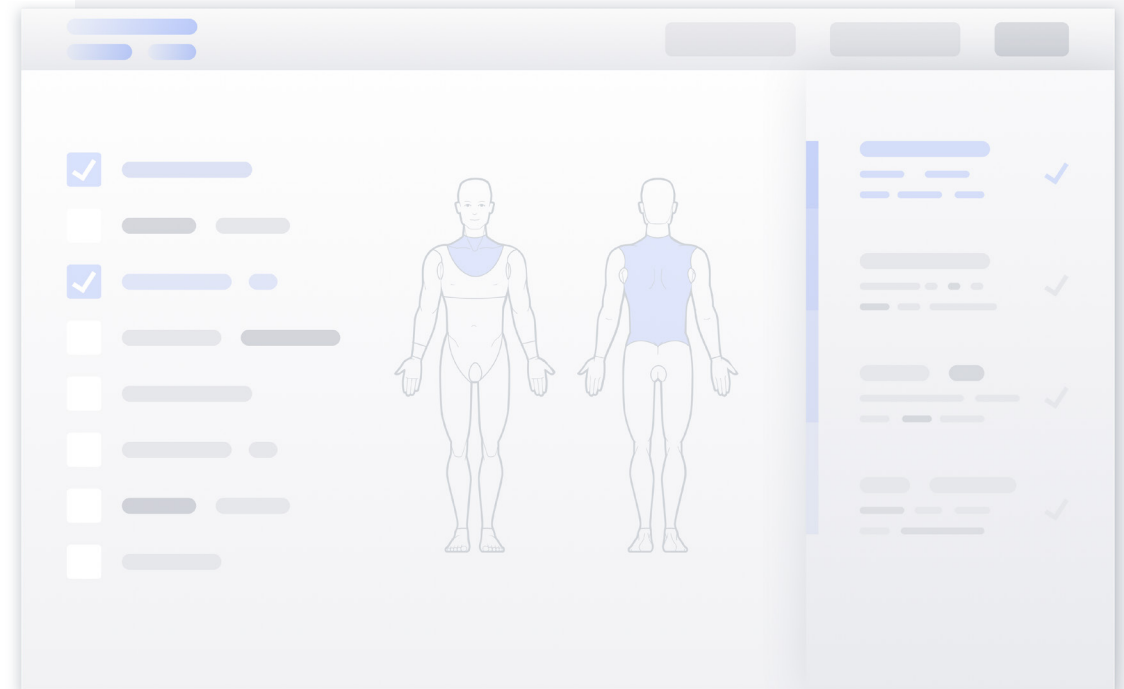
We help our customers understand and predict stability and shelf-life of cosmetics, save time and money on challenge studies and determine consumer exposure to any chemicals or ingredients using probabilistic models based on real consumer habits and practices data from around the globe.

Our Model

Creme RIFM/Care has the data to assess exposure for consumers across Europe and the USA. The benefits of using this model include:

- Avoiding over-estimation of exposure
- Providing a solid scientific basis for IFRA limits for systemic effects
- More accurate and realistic evaluation of ingredient exposure
- Reduction in the need for clinical toxicity testing and studies
- Satisfying the European Commission's request for information on aggregate exposure when assessing dermal sensitisation
- Satisfying the USA Toxic Substances Control Act (TSCA) Reform legislation that specifically asks for aggregate exposure of a chemical ingredient
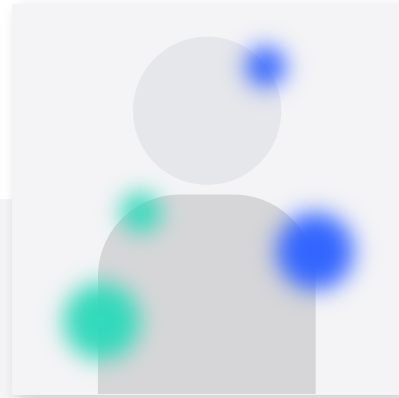- Providing a unified approach to Chemical Safety Assessments under REACH

Benefits for the industry

Predict Stability and Shelf-life

Apply predictive microbiology to understand and predict stability and shelf-life of cosmetics. Save time and money on challenge studies.
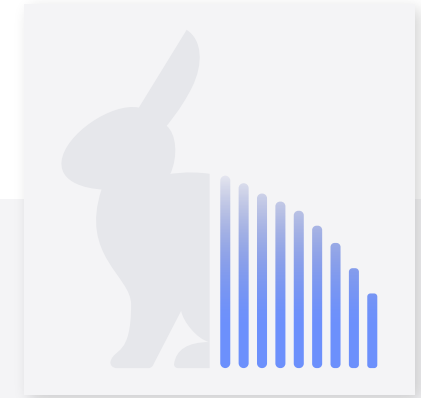
Determine Consumer Exposure

Determine consumer exposure to any chemicals or ingredients using probabilistic models based on real consumer habits and practices data from around the globe.
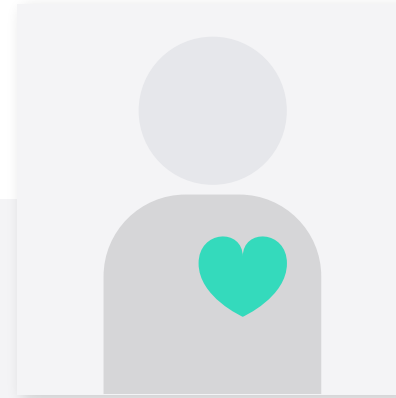
Consumer Health

Use refined risk assessment models to understand the impact of consumer products on consumer health; no more worst-case assumptions.

Replace Animal Testing

Predict the safety of new product formulations and reduce and replace the need for human and animal testing.

Calculating Exposure

The model calculates both dermal exposure (impact on the skin) and overall systemic exposure (impact on the whole body).

Equation 1

Equation 1 shows the formula for calculation of a subject's dermal exposure, at a particular application site, to a fragrance from a particular product on a particular day.

Daily Dermal Exposure (DDE)

$$\text{Aggregate Exposure} = \frac{\text{Frequency} \times \text{Amount} \times \text{Retention} \times \text{Concentration}}{\text{Surface Area}}$$

Equation 2

Equation 2 shows the formula for calculation of a subject's systemic exposure, at a particular application site, to a fragrance from a particular product on a particular day.
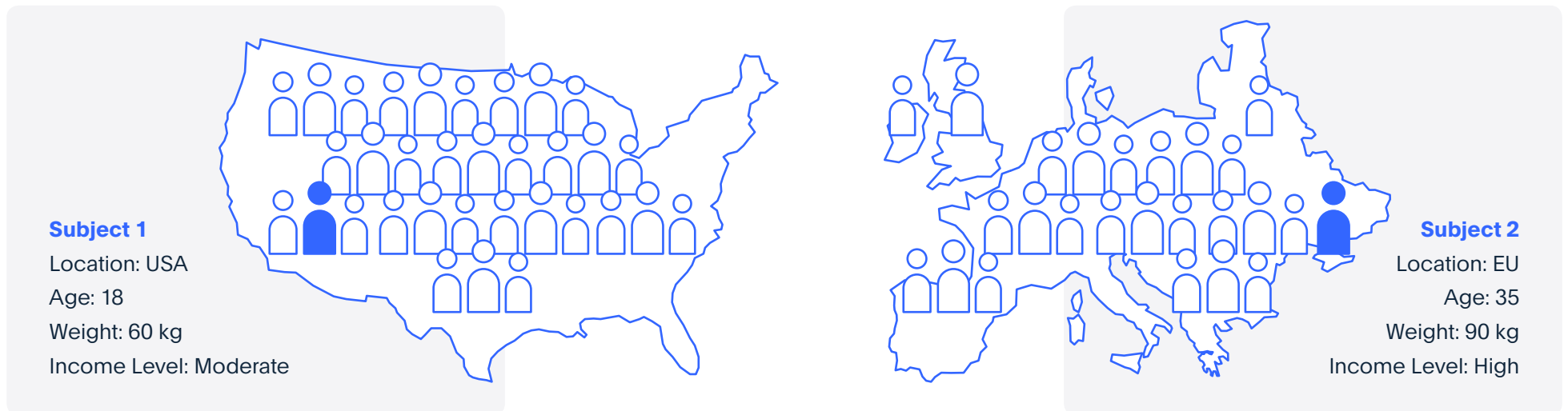
Daily Systemic Exposure (DSE)

$$\text{Aggregate Exposure} = \frac{\text{Frequency} \times \text{Amount} \times \text{Retention} \times \text{Concentration} \times \text{Penetration}}{\text{Body Weight}}$$

Data Sources

✓	**Frequency Data**	Frequency data is extracted from the Kantar Online Consumption Diaries

✓	**Amounts Used or Consumed**	Amounts Used or consumed data is sourced from the following studies

Europe: COLIPA (Hall et al., 2007; 2011), Ficheux et al., 2016
USA: CTFA (Loretz et al., 2005; 2006; 2008)
Hydroalcoholics: Tozer et al., 2004

✓	**Fragrance/Chemical Concentration**	Fragrance/Chemical Concentration are known values for fragrance and personal care companies and are used as the model input

✓	**Retention Factors**	Retention Factors are extracted from the literature or sourced from RIFM

✓	**Height and Weight Data**	Height and Weight Data are extracted from the following databases

Europe: France - INCA2, Poland - Kilmek-Piotrowska et al., 2015, Others - NHANES data scaled based on EU country average weights and heights
**USA:** 2009-2014 NHANES Survey

Population Exposure Modelling

Using detailed information about the subjects, such as geographical, demographic or behavioral data, we can assess the risks related to the chemical exposure in sub-populations of interest. For example, we can focus on a particular age group, or compare the risks across different income bands or genotypes.

Subject 1
Location: USA
Age: 18
Weight: 60 kg
Income Level: Moderate

Subject 2
Location: EU
Age: 35
Weight: 90 kg
Income Level: High

Individual Exposure

For every subject in the survey, a record of individual personal care use habits and the amount s used is given. To each of those "application events", a model assigns a substance concentration. The concentration can either be a single point estimate or can be randomly sampled from a distribution of possible concentrations, taken from the concentration data. It can also be weighted or have a likelihood of being present.
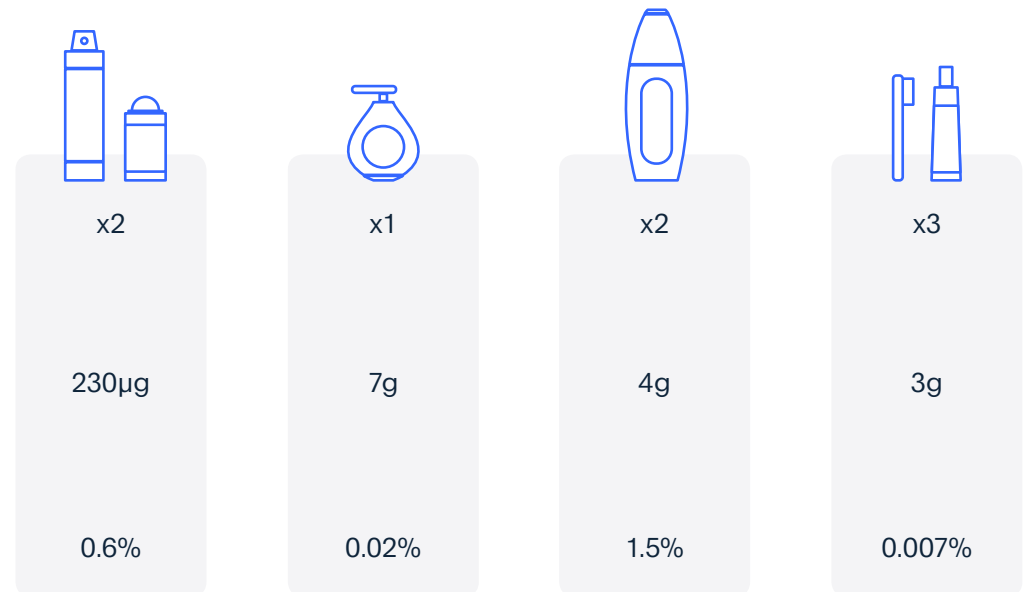
DAY

1
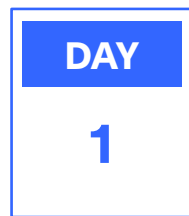
Diary Day 1

|			
Consumption Frequency	x2	x1	x2	x3
Amount Applied	230µg	7g	4g	3g
Substance Concentration	0.6%	0.02%	1.5%	0.007%

Published Methodology

RIFM published a series of papers on the methodology from 2015-2017 in, Regulatory Toxicology and Pharmacology, a peer-reviewed scientific journal.

The papers are available on the RIFM website at: www.rifm.org in the Human Health Science section, on the Creme RIFM Aggregate Exposure Model for Fragrance Ingredients page: www.rifm.org/rifm-science-human-health-content.php?id=40&science=human#.WuHnFi7wa70 and in the Publications section. These papers can also be found on the Fragrance Material Safety Assessment Resource Center, published by Elsevier: www.fragrancematerialsafetyresource.elsevier.com

Case Studies and Project Overviews
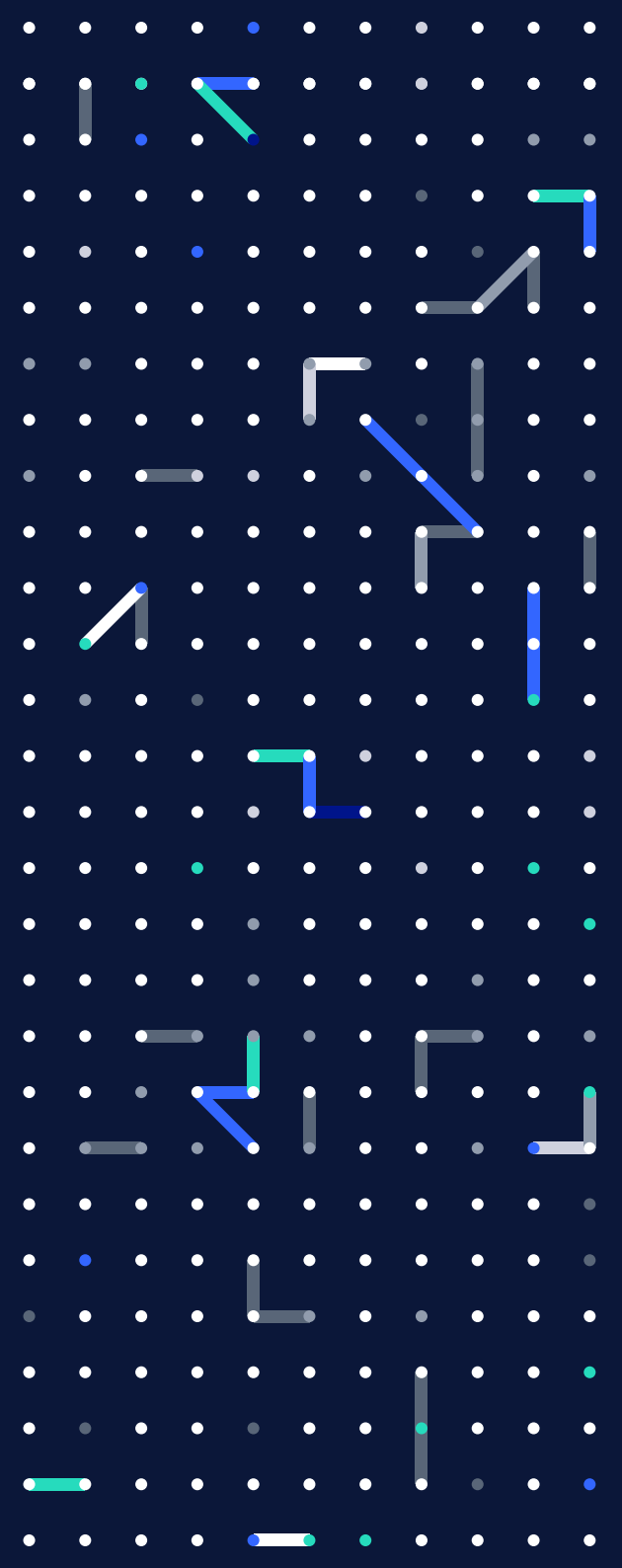
RIFM

The Research Institute for Fragrance Materials and Creme Global partnered to develop an aggregate exposure model for fragrance materials. The Creme RIFM Aggregate Exposure Model has made a substantial impact on both the improvement of consumer safety and the reduction of animal testing.

We developed a consumer exposure model built on large volumes of market survey and scientific data from a wide variety of sources. The model estimates aggregate exposure to fragrances in consumer products, i.e. the total exposure coming from all different sources.

RIFM
Case Study

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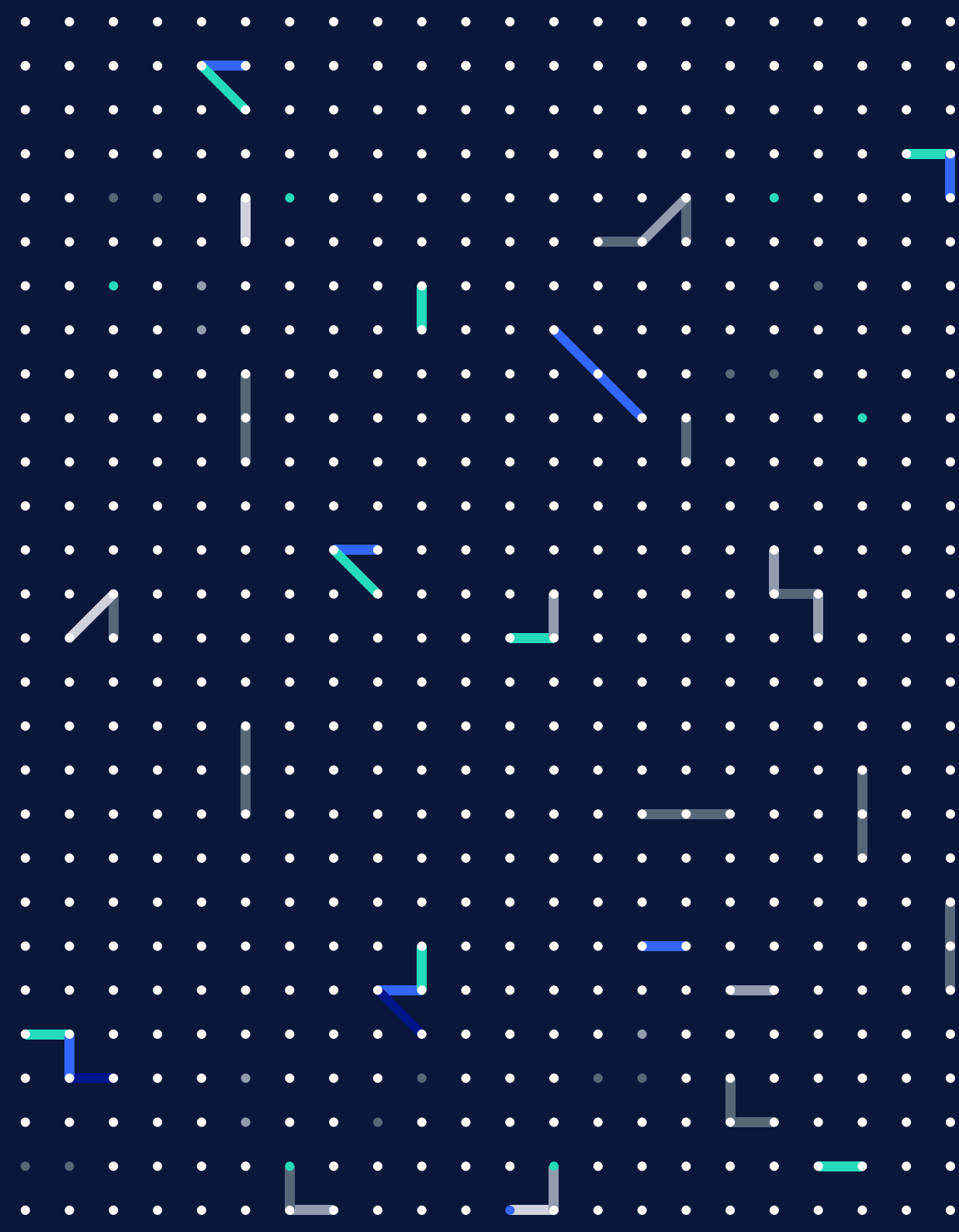info@cremeglobal.com
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Cosmetics Europe

The aim of this project was to provide quantitative information on habits and practices of consumers in the European Union.

In setting up this study Colipa's aim was to provide quantitative information on habits and practices of consumers in the European Union. In order to make use of the most up-to-date investigative methods of consumer habits' tracking and of the most appropriate information technology methods, Creme Ltd. was chosen to perform the data analysis and statistical modeling project.

**Cosmetics Europe
Case Study**

Providing quantitative information on habits and practices of consumers in the European Union

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