# PRODUCT *RESPONSIBILITY*



○ unanswered ◑ partial ● complete

# Management approach

In 2006, L'Oréal implemented, on the corporate level, management that was responsible for product regulatory compliance, marketing communication assessment and consumer safety.This department consists of an international team of over 400 employees working in more than 50 countries worldwide.

These employees verify the compliance of the Group's products with local regulations and their proper follow-up after market launch. In addition, the employees working in the countries where L'Oréal has research centers assist with product development right from the initial phases. L'Oréal complies with all national regulations in every country where its products are sold. In countries with no applicable regulations, the Group adheres to European Regulations to a minimum (in terms of safety and labelling).

In order to promote the marketing of products complying with various regulations, the Group has developed internal expert systems concerning cosmetic ingredients updated in line with worldwide regulatory changes. Accessible at the formulation laboratory level, these systems are used from the initial phases of a new product in order to verify regulatory compliance with respect to the country where commercialization is being considered.

Product safety is crucial to L'Oréal, which is why the same safety requirements are applied across the globe in order to provide all consumers with products of consistent quality.

100% of the products developed by the Group undergo systematic and strict safety assessments. L'Oréal has incorporated this principle at each phase of product development.

# Customer Health and Safety

*PR1*

## LIFE CYCLE STAGES IN WHICH HEALTH AND SAFETY IMPACTS OF PRODUCTS AND SERVICES ARE ASSESSED FOR IMPROVEMENT, AND PERCENTAGE OF SIGNIFICANT PRODUCTS AND SERVICES CATEGORIES SUBJECT TO SUCH PROCEDURES

The L'Oréal Group is fully committed to complying with international regulations relative to the safety assessment of cosmetic products and their constituent ingredients. For example, in Europe, L'Oréal complies with the requirements of European Directive 76/768/EEC on cosmetic products and the European REACH regulations (EC regulation 1907/2006). In addition to these requirements, for more than 10 years the Group has implemented a systematic assessment process for all products marketed worldwide, including parts of the world where regulations are weak or even non-existent.

### 1. SAFETY ASSESSMENT, AT THE CORE OF THE DEVELOPMENT OF NEW PRODUCTS

Assessing the safety of products intended for consumer use is a prerequisite for commercializing any L'Oréal Group product.

This assessment is not performed once, but is repeated throughout product development, from the initial phase right through to commercialization. It requires examining the safety of both individual product ingredients and the finished product.

### Assessing the safety of substance included in the composition of products from their initial phases through to their marketing

Each substance included as an ingredient in a cosmetic product (100% of the substances) is subject to a safety assessment performed by a toxicologist.

Firstly, the toxicologist analyses all available data relative to this substance (physicochemical characteristics, bibliographic and experimental data) in order to determine its toxicological profile. If necessary, the toxicologist decides to generate new data to complete the existing file (see the paragraph entitled 'Moving towards a new assessment procedure'). Then the toxicologist takes potential consumer exposure into account. This exposure is related to the percentage of substances used in cosmetic products and the type of cosmetic product in question (which will determine parameters such as the exposed surface, the length of time in contact with the skin, exposure to the sun, etc.).

As a result, toxicologists assess the safety of each specific use of a substance included in a finished product. For example, the use of the same concentration of an ingredient in a mascara and in a sun care product can result in very different levels of human exposure. The assessment teams also consider other aspects of a product's life cycle: how long the ingredient remains on the skin, its exposure to sunlight, the risk of skin reactions, the possible improper use of the product, etc.

Using this information, the Group's toxicologists determine the concentration of a substance that enables it to be used in total safety. This concentration corresponds to a level of ingredient use that is at least 100 times less than the level considered to be safe under experimental conditions of use given the toxicological profile of and exposure to the substance. All this information becomes an integral part of the regulatory file compiled for all substances.

This assessment goes hand in hand with product development. In fact, the safety assessment of a substance begins as soon as its incorporation into a future product is envisaged. At this point, the formulator (the manufacturer of the future cosmetic products) asks his «reference toxicologist» if the incorporation of this substance is possible from consumer safety point of view.

With each phase in the product's development that could lead to changes in the composition of the formula, the formulator verifies that those changes are possible from the point of view of consumer safety.

### Assessing the safety of finished cosmetic product before marketing

The toxicologists also assess the consumer's tolerance to a finished cosmetic product. This assessment also occurs during the initial phase of composition. In fact, toxicologists have acquired the necessary expertise to determine the formula on paper and identify possible interactions and interrelationships between substances.

This assessment makes use of existing bibliographic and experimental data and can require new studies to be implemented if necessary. The new studies can be in vitro tests or clinical trials conducted with volunteer subjects. The clinical trails on volunteers are only performed when it has been previously determined that the product safety is satisfactory for the volunteers, given that the purpose of these trials is to verify that the target population tolerates the product prior to commercialization.

The assessment of product safety is finalized when a safety certificate endorsed by a toxicologist involved with a file is issued. The issued certificate and the file are systematically present for all commercialized products.

### Safety of cosmetic products and impact on assessing safety

Finally, after commercialization, L'Oréal continues to assess the use and tolerance of its products on the market worldwide through the international safety of cosmetic products network. This network uses strict and recognized methods to collect, verify and analyse the adverse effects related to a product's use.

This tool helps identify exceptionally «abnormal» cases of intolerance on the market. In such cases, additional investigations may be offered to the consumers in question. The product file is then re-examined to identify the cause of the intolerance and, if necessary, take appropriate measures such as reprinting of labelling if unsuitable, adding warning labels or modifying the composition of the formula if required.

This information is used to update the files for substances that may be found to cause intolerance and of their corresponding cosmetic products.

↳ For more information on safety of cosmetic products at L'Oréal, please refer to chapter PR2 of the present sheet

## 2. L'ORÉAL ADAPTS ITS ASSESSMENT METHODS

Because the L'Oréal Group has anticipated and invested in the development of new safety assessment methods for almost 30 years, this safety assessment process has been able to adapt to an increasingly more restrictive regulatory context, prohibiting, among others, the use of animals to test product safety.

A new regulatory framework, the 7th amendment to the European Cosmetic Directive, entered into effect in 2004. In 2009, it imposed a ban for March 2013 on the use of animal testing to assess the safety of finished cosmetic products and substances intended for cosmetic use in Europe.

In this regulatory context, a new paradigm, similar in extent to that of eco-design, was developed within Research & Innovation for the safety assessment of ingredients and products. Innovation is now defined by the recognition of high-performance cosmetic ingredients that are initially selected for having no impact on health and the environment.

This capacity results from L'Oréal's investment in creating tools to help predict the impact of raw materials and finished products on human health and the environment, without the use of animal testing (predictive methods).

**The following were the main steps involved in creating the L'Oréal Group's expertise in safety assessment based on predictive methods:**

- 1995: ECVAM/COLIPA validation study of in vitro phototoxicity test.
  Amalthée Award for alternative methods (OPAL).
- 1997: Acquisition of Episkin SNC, an industrial center for skin engineering.
  Introduction of Langerhans cells into reconstructed skin (4th European framework program).
- 1998: The EpiSkin model is validated for the assessment of cutaneous corrosion.
- 1999: COLIPA instructions on in vitro percutaneous absorption.
- 2005: Participation in the SENS-IT-IV assessment of alternative methods for allergens (6th European framework program). Founding member of EPAA (European Partnership for Alternative Approaches to Animal Testing).
- 2006: Validation of the SkinEthic RHE model for the assessment of cutaneous corrosion.
- 2006: Acquisition of SkinEthic, leader in the production and commercialization of reconstructed skin.
- 2007: Validation of the Episkin model for cutaneous irritation.
- 2008: Validation of the SkinEthic RHE for cutaneous irritation.
- 2009: L'Oréal's disclosure of its predictive method strategy during the 7th International Congress on alternative methods in Rome.
- 2010: Entry of the HCE model for corneal reconstruction into the validation phase for ocular irritation.
- 2010: Implementation of the SkinEthic RHE and EpiSkin methods for cutaneous irritation in the new OCDE TG 439 guideline.
- 2011: Production of 130,000 units of reconstructed tissue (skin and cornea) in Gerland.
- 2012: Production of 150,000 units of reconstructed tissue (skin and cornea) in Gerland.

↳ For more information on predictive assessment at L'Oréal, please refer to: *http://www.loreal.com/Article.aspx?topcode=CorpTopic_RI_Security_PredictiveAssessment*

The prediction capacity of these tools grows each day with the advances that occur in tissue engineering technologies, modern biology, mathematical modelling, computer calculations and century-long database development.

By virtue of this series of predictive methods, L'Oréal was able to meet the 2009 regulatory deadline set forth by the 7th amendment to the Cosmetic Directive without negative impact on the innovation and safety of its ingredients and products.

From now on, the Group intends to build an integrated strategy of safety assessment and take part in the "toxicology of the 21st century" by continuing to develop these tools and refining their relevance. In this context, the program to simulate the first human application using a combination of predictive and in vitro tools was pursued. It pertains to certain ingredients used exclusively for cosmetic purposes.

In 2012, this integrated safety assessment strategy, along with the tools that support it, were presented by Research & Innovation at the SOT Congress in San Francisco, at the ESTIV Congress in Lisbon, at the Colama Congress in Rio de Janeiro, at the EUSAAT Congress in Linz, at the alternative method workshop in Brasilia, and at the Cosmetic Europe contact allergy workshop in Ispra.

## Predictive methods

Predictive methods combine data and tools to predict the safety of ingredients and formulas.

L'Oréal's added value in assessing the safety of its ingredients and finished products comes from the investments made in tissue engineering as well as a panel of diverse predictive methods, including statistical and mathematical models, in silico methodology and QSAR models, developed either internally or during external collaboration projects. They are used in combination to optimize their predictive capacities.

They now help perform safety assessments on raw materials thereby helping avoid the use of animal testing in 99 % of cases.

### Reconstructing tissues

L'Oréal Research has for a long time developed cellular biology and tissue engineering research aimed at reconstructing various human skin and tissue models.

**The various models have four key applications:**

- Developing an understanding of the skin without resorting to invasive clinical testing.
- Developing predictive methods and assessing the effectiveness of new active ingredients (e.g. sun filtration, photoprotection).
- Contributing to the assessment of the safety of raw materials and finished products.
- Creating, standardizing and validating alternative new predictive tests for assessing product safely.

In 2012, the commercialization of reconstructed tissue models used to assess ingredient and formula safety continued. The HCE reconstructed human corneal epithelium model has entered into the validation phase. As soon as the methods are validated, L'Oréal will make them available to manufacturers and university laboratories.

### Assessing skin irritation

Research and Innovation developed two validated methods to assess skin irritation using skin models (Episkin and RHE). The entire raw material portfolio of L'Oréal and The Body Shop has been tested using these models. This action helped deepen the understanding and enrich the database and the regulatory files of the ingredients.

### Assessing ocular irritation

The HCE reconstructed cornea model from SkinEthic is undergoing regulatory validation for ocular irritation. A study published in 2010 demonstrated the reliability of the protocol developed by L'Oréal, which has been proven on more than 400 ingredients. New ingredients are systematically tested on combinations of complementary in vitro models. Furthermore, the assessment of formulas for skin and ocular irritation continues. On the whole, since 2006, more than 12,300 formulas and 2,350 ingredients have been assessed.

## PR2

## TOTAL NUMBER OF INCIDENTS OF NON-COMPLIANCE WITH REGULATIONS AND VOLUNTARY CODES CONCERNING HEALTH AND SAFETY IMPACTS OF PRODUCTS AND SERVICES DURING THEIR LIFE CYCLE, BY TYPE OF OUTCOMES

To our knowledge, there have been no cases of non-compliance with respect to the control of compliance with regulatory requirements and voluntary codes on the health and safety impact of our products.

L'Oréal maintains a safety of cosmetic products network, with teams set up in most of the markets where it operates, including those with no existing safety of cosmetic products requirements. This network is dedicated to recording and analysing all cases of adverse effects associated with the use of one of L'Oréal's marketed products.

This network enables the company to monitor and analyse all incidents associated with the use of L'Oréal products. In 2012, this network did not register any cases of non-compliance with product safety and consumer health regulations

L'Oréal has been monitoring the safety of its commercialized products for over 25 years. This monitoring is an integral part of Group policy and internal control regulations. This strategic activity is currently performed by dedicated teams: centrally by the International Post-marketing Surveillance Department and locally by a multidisciplinary international network dedicated to this task. This network has approximately one hundred employee physicians, pharmacists, biochemists, toxicologists and scientists in 60 countries.

The goal of this organization is to analyse and exploit the post-marketing surveillance data of all commercialized L'Oréal products to optimize their safety profile and proper use as well as to ensure continuing consumer benefit and compliance with current regulations.

In addition to working closely with the International Consumer Relations Department and the Local Consumer Opinion Department, the main assignments of the post-marketing surveillance organization are to collect and analyse adverse effects reported by consumers of their own accord, to assess each reported case and to determine whether or not the product in question was the cause. The exploitation of the post-marketing surveillance data helps detect signals and anticipate and prevent risks. It also serves as a guideline for those teams responsible for pre-marketing safety.

# Product and Service Labeling

PR3

## TYPE OF PRODUCT AND SERVICE INFORMATION REQUIRED BY PROCEDURES, AND PERCENTAGE OF SIGNIFICANT PRODUCTS AND SERVICES SUBJECT TO SUCH INFORMATION REQUIREMENTS

L'Oréal provides various types of information to its consumers: Business to Consumers **(B2C)**, its customers Business to Business **(B2B)** and authorities Business to Authorities **(B2A)**, on a voluntary **(V)** or obligatory **(O)** basis.

### 1. INFORMATION AVAILABLE TO CONSUMERS (B2C)

• ***Information on products directly available to the consumers***

**(O)** All products commercialized by the L'Oréal Group bear informative labelling that meets the regulatory obligations imposed by various countries worldwide. This labelling systematically includes, among others, the Full Ingredients Labelling (FIL) contained in the commercialized products as well as precautions for use.

**(V)** Moreover, L'Oréal also wishes to meet the expectations of most consumers and has therefore developed specific products, the sought-after characteristics of which are indicated on the packaging. As a result L'Oréal indicates on some of its products the absence of substances (e.g. parabens, sulfates, etc.) or third-party certification (e.g. by Ecocert) for organic products, developed by Mixa Bio, Sanoflore, Ushuaia Bio, etc.

In addition, L'Oréal places emphasis on eco-design actions on some of its products.

Garnier indicates on nearly all its cardboard packaging the fact that the cardboard is FSC certified (Forest Stewardship Council), accompanied by an explanatory sentence to help consumers understand the meaning of FSC.

Other brands such as Kiehl's, Fructis in the USA, Lancôme Arôma Blue, etc. indicate on their packaging that they contain, in full or in part, recycled materials.

Finally, some brands encourage consumers to sort waste in the bathroom, so that recyclable packaging can be recycled. This is the case for Fructis in France, along with Ushuaia and Biotherm.

↳ For more information on FSC, please refer to: https://ic.fsc.org/

↳ For more information on Biotherm, please refer to the article dedicated to the brand on page 28 of the Sustainable Development Report 2012.

• ***Information available via websites*** **(V)**

The L'Oréal Group brands have their dedicated websites where consumers can find additional information on their product properties and their quality.

In 2012, L'Oréal participated in environmental labelling experiments as part of the French Grenelle law. The Garnier brand assessed the environmental impact of 12 shampoos from its Ultra-Doux line on three impact indicators: CO2 emissions, water consumption and water pollution. In compliance with the conditions of these experiments, the data were intended to be made available to the consumers. The information was published on the Garner website and on the Carrefour website for six products.

• ***Information available upon request***

**(O)** Information concerning potential adverse effects following product use or composition data: in Europe: the submission of this information is obligatory within 21 days after being explicitly requested by a consumer. 100 % of requests receive replies.

**(V)** Similarly, 100 % of requests from consumer departments and relative to technical or regulatory questions (e.g. does my product contain nanomaterials? does my product contain animal extracts?, etc.) receive replies.

## 2. INFORMATION AVAILABLE TO AUTHORITIES (B2A) AND CUSTOMERS (B2B)

- **O B2A** Regulatory files for the commercialization of products or for notifications. Systematically applied: 100 % of products placed on the market meet these obligations.
- **O B2B** Transmission of product composition sheets to help physicians meet their occupational medicine obligations (INRS – French Institute of Research and Safety).
- **V B2B** Technical information provided to logistics intermediaries (transporters, warehouses) to help them comply with their own regulatory obligations. 100% of the products are covered.

*PR4*

# TOTAL NUMBER OF INCIDENTS OF NON-COMPLIANCE WITH REGULATIONS AND VOLUNTARY CODES CONCERNING PRODUCT AND SERVICE INFORMATION AND LABELING, BY TYPE OF OUTCOMES

With respect to consumer information printed on labels, the Group was made aware of questions asked by the authorities in certain countries (Singapore, Indonesia, China, Italy, etc.) concerning product names, the language used, the legibility of labels and dates printed on packaging. Answers were systematically provided and eight cases led to formal products withdrawals from the investigated points of sale.

*PR5*

# PRACTICES RELATED TO CUSTOMER SATISFACTION, INCLUDING RESULTS OF SURVEYS MEASURING CUSTOMER SATISFACTION

The Consumer Relations Department is key for the Group L'Oréal . It is responsible for upholding and protecting the reputation and image of L'Oréal and its brands, as well as adapting to changes in the behaviour of the general public and constantly improving communication with consumers.

One of the main objectives of the Consumer Relations Department is to remain easily accessible to consumers. There are specialized teams whose role consists of ensuring that all consumers can contact the Group and obtain a reply to their questions. Providing a reply to each question is a requirement that enables L'Oréal to position itself as a recognized authority on beauty.

### Missions of the Consumers Relations Department:

- **To effectively communicate with the general public:** listen, advise, support and educate are the watchwords for each consumer who enters into contact with L'Oréal.
- **To resolve disputes:** responsibly and effectively manage disputes as soon as they arise and find a solution that satisfies both consumers and L'Oréal.
- **To constantly communicate with the marketing teams:** allow them to benefit from the public's experience in order to constantly improve their products and consistently deepen their understanding of consumers.
- **To anticipate current affairs topics and ensure that awareness is raised** at L'Oréal on the subjects and issues that emerge from society.

In 2012, the Consumer Relations Department processed over 1.24 million contacts. These departments cover 63 countries and have 520 employees dedicated to consumer relations.

# Marketing Communications

## PR6

## PROGRAMS FOR ADHERENCE TO LAWS, STANDARDS, AND VOLUNTARY CODES RELATED TO MARKETING COMMUNICATIONS, INCLUDING ADVERTISING, PROMOTION, AND SPONSORSHIP

The Group has an International Product Communication Evaluation Department that assesses all product communication items and their effects; these elements include the presentation, claims and advertising images. The Department assesses the communication of each product prior to commercialisation to ensure compliance with the advertising regulations in each market.

The department is supported by a scientific director network that the Group began to implement nearly 20 years ago. Today, this network has over 200 employees from 50 countries. The assignments of this network include monitoring local marketing communication regulations and self-disciplinary codes as well as verifying that communication complies with local requirements.
The L'Oréal Code of Business Ethics (*http://www.loreal.com/Article.aspx?topcode=CorpTopic_Group_Gouv_Ethics_Charter*) ensures that responsible advertising is carried out The Group thereby ensures that its advertising and promotional materials are based on proven results and scientific data, and that the information provided is readily available to consumers. The Group has also adopted many principles from advertising guidelines on an international scale.

### UDA Charter on responsible advertisement

The UDA Charter (from the French advertisers union) on responsible advertisement covers responsible communication, marketing and confidentiality as well as social and environmental impact. Since 2007, L'Oréal (which signed this Charter and its five principles) has taken advances made in this area each year into consideration.
*http://www.uda.fr/communication-responsable/charte-uda/* (in French)

### Charter for Voluntary Commitment to Body Image

L'Oréal also fully supports the French government's Charter for Voluntary Commitment to Body Image.

### Product performance and advertisement

Advertised product performance is always supported by rigorous scientific data and sophisticated measurement techniques. Since the protocols vary from country to country, L'Oréal must constantly ensure that it takes local requirements into consideration.

## PR7

## TOTAL NUMBER OF INCIDENTS OF NON-COMPLIANCE WITH REGULATIONS AND VOLUNTARY CODES CONCERNING MARKETING COMMUNICATIONS, INCLUDING ADVERTISING, PROMOTION, AND SPONSORSHIP BY TYPE OF OUTCOMES

In 2012, L'Oréal was questioned by advertising control authorities, both judicial and self-disciplinary, and after investigation, was obliged to modify/withdraw advertisements upon which the Group had been interrogated 21 times. These figures need to be put into perspective: there were over 7,000 new formulas commercialized in 2012.