

**University of Lisbon**

**Faculty of Pharmacy**



**Innovation in Cosmetics: Innovative  
Makeup Products  
Efficacy and Safety**

**Joana Isabel Batista Maia**

**Integrated Master's Degree in Pharmaceutical  
Sciences**

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**Supervisor: Professora Doutora Helena Margarida Ribeiro**

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## **4. Abbreviations List**

AAT – Alternative Animal Testing

CI – Colour Index

EPAA - European Partnership for Alternative Approaches to Animal Testing

EU – European Union

EURL–ECVAM - European Union Reference Laboratory for Validation of Alternatives to Animal Testing

NOAEL – No-observed-adverse-effect level

NPA - Natural Products Association

NGO – Non-Governmental Organization

PETA – People for the Ethical Treatment of Animals

PIF – Product Information File

R&D – Research and Development

SCCNFP – Scientific Committee on Cosmetics products and Non-food Products

SCCS - The Scientific Committee on Consumer Safety

SME – Small and Medium enterprises

## 5. Abstract

Unlike other industries that remain largely constant, the Cosmetics Industry is continuously changing. New products are created for hair, skin, makeup and personal care on a regular basis in order to meet the consumers' needs and expectations.

Cosmetic products have a lot to live up to these days, not only do they have to be innovative but also be effective and safe for the consumers and the environment.

This dissertation presents the several types of innovation within the makeup branch of the cosmetics industry.

Innovation can be done by adding new or improved ingredients to a formulation, making it different because of its properties; by changing the formulation itself, creating a product different from every other on the market, safer and easier to apply or use; by innovating the packaging, which is also becoming a huge trend because consumers are more demanding of unique, unusual and original packages that match their personality.

Technology also takes a big part in the cosmetics industry, helping to develop products closer to the consumer needs and creating new connections and experiences between consumers and products.

On a different level, cosmetics companies' mentalities are also changing. Not only consumers are becoming more responsible and aware about environmental, ethical and social issues but they demand for the industry to share their concerns and evolve in a more conscious way.

Innovation, at this pace, leads to the fast growth of the cosmetics industry. Investing in the development of a new product leads to a more complete, and varied market that provides a bigger, more effective and safer selection of products available to better suit the fast-changing consumer needs.

**Key words:** Innovation, Cosmetics, make up, efficacy, safety.

## 6. Resumo

Contrariamente a outras indústrias que se mantêm relativamente constantes, a indústria cosmética está em constante mudança e renovação. Novos produtos cosméticos são constantemente introduzidos no mercado de forma a satisfazer as necessidades e as expectativas, cada vez mais exigentes e desafiantes, dos consumidores, tornando-o assim um dos mercados mais competitivo e com maior ritmo de inovação.

Os produtos cosméticos e em particular o sector da maquilhagem é desafiado, cada vez mais, de forma a desenvolver produtos que para além de eficazes, sejam também seguros para os consumidores e para o ambiente, bem como desenvolvidos e produzidos em conformidade com os valores dos consumidores e da sociedade atual.

Existem diversas formas de inovar no sector da cosmética, sendo uma delas ao nível dos ingredientes que constituem a formulação. Desta forma, podem ser adicionados ingrediente novos, nunca usados em contexto cosmético, e cujas propriedades revolucionam o método de atuação do produto; ou simplesmente a combinação de diversos ingredientes nunca antes conjugados que aliados conferem à formulação novas ou modificadas propriedades, consideradas disruptivas e superiores em relação aos restantes produtos disponíveis no mercado.

Outra forma de inovar consiste em alterar o próprio tipo de formulação de forma a criar um produto completamente diferente. A aplicação de um tipo de formulação num contexto ou produto diferente do que é comum, com as devidas adaptações às novas funções e local de aplicação, é uma forma de inovação a este nível.

Ao nível da embalagem do produto a inovação, criatividade e diferenciação tem ganho grande relevância entre os consumidores. A forma como o produto é armazenado e a sua embalagem, transmitem muito mais do que apenas integridade e proteção, criam também um posicionamento e transmitem uma mensagem, influenciado a forma como o produto é percebido e desenvolvendo uma imagem de marca facilmente reconhecida pelos consumidores.

A tecnologia é parte intrínseca da vida em sociedade e não é exceção no que concerne o desenvolvimento de produtos cosméticos. Não só torna o processo de investigação, fabrico e armazenagem mais rápido e eficiente como contribui para a produção de produtos cada vez mais eficazes, seguros e adaptados às necessidades mais específicas dos consumidores.



Relativamente à mentalidade e aos valores da indústria cosmética e das suas marcas constituintes, estes têm também sofrido alterações de forma a inovar e se adaptarem às regras de ética, sustentabilidade ecológica e responsabilidade social que vigoram na sociedade atual. As novas gerações de consumidores são cada vez mais responsáveis e conscientes acerca de questões ambientais, éticas e sociais, exigindo que a indústria compartilhe destas mesmas preocupações e altere os seus valores de forma a que estes se harmonizem com os seus.

Desta forma, o ritmo de inovação da indústria cosmética leva ao seu rápido crescimento e desenvolvimento, tornando-a assim uma das mais dinâmicas e inovadoras do mercado.

Cada novo produto desenvolvido ou aperfeiçoado contribui para um mercado mais completo e diversificado que oferece uma maior seleção de produtos mais eficazes, seguros e em maior conformidade com as necessidades e valores dos consumidores, contribuindo assim para a harmonização da relação indústria – produto – consumidor.

**Palavras-chave:** Inovação, cosméticos, maquilhagem, eficácia, segurança.

## 7. Introduction

Cosmetics in general are not a modern invention. Civilizations have been using substances to change the appearance or accentuate some features for at least 10 000 years, and possibly a lot longer. (1)

Because it is in human nature to always strive for perfection and for new ways to express ourselves, cosmetics play an important role and shape the societies throughout the years, from ancient civilization to the modern way of lifestyle. (1)

A typical product will contain anything from 15–50 ingredients. Considering the average woman uses between 9 and 15 personal care products per day, researchers have estimated that, when combined with the addition of perfumes, women place around 515 individual chemicals on their skin each day through cosmetic use. (2)

There is a massive range of different cosmetic products on the market, all with differing combinations of ingredients, different formulations and produced and packed in different ways. (1)

## 8. Material and Methods

The present dissertation was written using resources from numerous websites like Cosmetics Europe; patent databases such as Google Patents, and Free Patent Online; scientific articles databases like NCBI and Cosmetics and Toiletries; Pubchem, a chemical substances information database; and finally, governmental websites such as the Federal Register of the USA and the European Commission website.

The scientific information resources, papers and patents date between the year of 1982 and 2017.

The key words used to discover the scientific information displayed in the dissertation were: “innovation concept”, “innovative cosmetics”, “cosmetics safety”, “cosmetics regulation in Europe” “innovative ingredients”, “colour changing lipstick patent”, “ CI45410”, “lip plumper patent”, “lip powder patent”, “pickering emulsions”, colour changing BB cream”, “encapsulated pigments patent”, “ innovative formulations”, “shade matching technique”, “cushion makeup”, “innovative packaging”, “marketing packaging”, “sustainable cosmetics”, “organic make up”, “alternative to animal testing”, and “cruelty free cosmetics”.

The information research and analysis process took place between March 2017 and September 2017, and there was a need to update the information, in particular the statistical data, in August 2017.

## 9. Innovation Concept

The concept of innovation has a wide range of definitions, but is also a very subjective term. Innovation can be defined simply as a **new idea, product or method** (3) however it can be much more than that.

It can be an improvement of something pre-existing, where a development is made on a new product in order to correct the weaknesses of a pre-existing one, incrementing value and so making it better - **evolutionary innovation**.

An example is the evolution of standard nail polish to quick-dry nail polish. Another is the development of lipstick into transfer-resistant lipstick. (4)

Innovation can also be disruptive creating new products, services or ideas without a prior invention, that are different from all there is available in the market and so, being a **revolutionary innovation**.

This type of innovation forever alters the market and it is generally associated with new entrants. The automobile was a disruptive technology for the horse-pulled wagon, for example. (4)

In both cases, there is an added value to the market, meaning they meet new requirements, unarticulated needs, or existing market needs. Innovation requires not only a scientific development process but also a creative mind to come up with something original and more effective and, therefore, new.

## 10. Innovation in Cosmetics

**“Innovation is not a buzzword in our industry: it has to be at the absolute core of what we do.” (5)**

Although innovation in the cosmetics industry is a constant process, revolutionary breakthroughs are rare. The process of innovation in the cosmetics industry is very fast and constant due to the R&D programs used to develop new products. The R&D programmes focus into consumer behaviour and beauty aspirations, the biology of skin and hair, using new innovative technologies and sustainable development methods.(6)

But ultimately what decides the pathway of innovation in cosmetics are the consumer needs and desires for the new, better and safer products designed and delivered by trusted and responsible brands (7).

The selection of products done by consumers leads the evolution of the cosmetics industry in a way that only the best ones survive and last in the market, helping to filter and develop the best and safest ingredients to humans and the environment.

This is not an effortless process. Consumer needs and desires are always changing, and what is new today is not going to be tomorrow, so the innovation in this industry must take a fast pace and be as dynamic as it can to keep consumers satisfied. Yet with every innovation the capacity to innovate further becomes more challenging but the outcome is more dazzling.

The process of innovation can occur in many ways, some companies are returning to traditional substances to create new formulations and on the other end, other companies are using materials at a molecular level, and using some innovative technologies imported from other science fields to develop a whole new generation of products.(6)

## 10.1. Statistic data

By 2018, the global beauty industry will be valued at \$461 billion, according to forecasts from Research and Markets.(8)

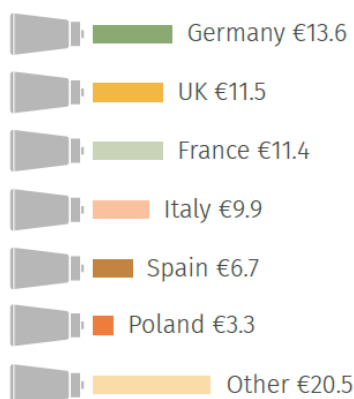
Europe is the main producer of cosmetic products. In 2016, the European cosmetics market was valued at 77 billion euros, making Europe the largest market for cosmetic products in the world, followed by the United States with 64 billion euros and China with 41 billion euros. (6)



**Figure 1:** Global market for cosmetic products (6)

Within Europe, Germany is the country with the largest market for cosmetic products, valued at €13,6 billion in 2016, followed by UK with €11.5 billion, France with €11.4 billion, and finally Italy and Spain with €9.9 billion and €6.7 billion respectively. (6)

### EUROPEAN MARKET FOR COSMETIC PRODUCTS (RSP BASIS, € BILLION)

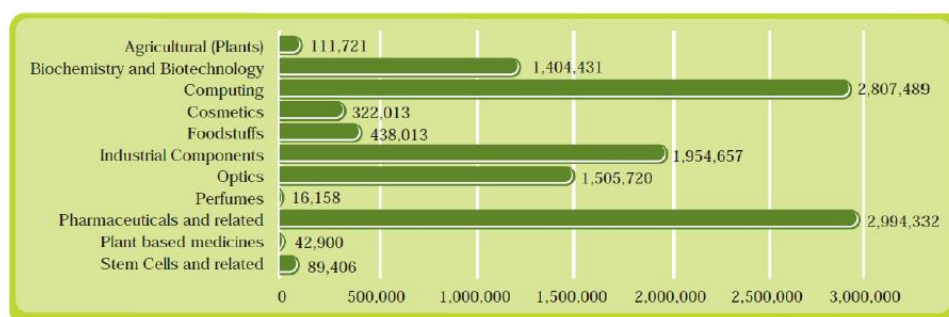


**Figure 2:** European market for cosmetic products (6)

The cosmetics industry is one of the fastest, most innovative business sectors in the world and that is due to its large investments in R&D (research and development). European Companies spent approximately €1.27 billion in R&D in 2014. In fact, that is the key for a company to keep ahead of the competition: investing in R&D.

The more and better products are launched, the more successful an industry is. So, the best way to measure how innovative a business sector is, is by analyzing the patent activity.(9)

When compared to the pharmaceutical industry or the computing industry for example, the cosmetics industry may not be the most innovative, but is still at the top of the chart by being the 7<sup>th</sup> most innovative business sector.



Source: Trends in patent activity in the cosmetics and perfume sectors. Information note 1. Union for Ethical BioTrade

**Figure 3:** Number of patent publications between 1990 and January 2010 for a range of different sectors (10)

In 2009, over 2,600 patents were awarded to the EU cosmetics industry, an estimated 10% of all patents granted in the EU and in 2011, the number rose to 6,000 patents filed by the European cosmetics industry.(9)

These numbers then translate to new or reformulated products.

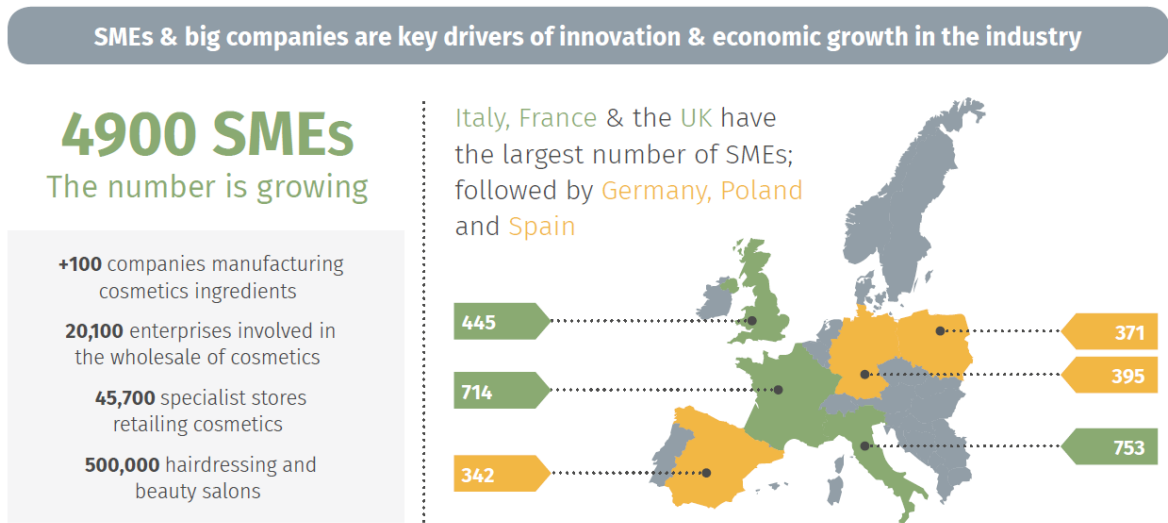
Innovation in the cosmetics industry is not short-term. It normally takes over 5 years of innovative research and formulation to bring a new product to the market.(11)

On average, a big company has around 10 000 products on their portfolio and reformulate around 25% to 30% of them per year, 10% of which are related to new ingredients patented. These new ingredients can be new to the market meaning they were never used before in any sector or can be ingredients already used in other sectors but never used for a cosmetic purpose. These companies introduce around 80 new ingredients to their portfolio every year.(9)

A smaller company like a SME has a portfolio of around 40 to 160 products and introduce about 22 new ones per year.

SMEs are small and medium size enterprises and are key players of economic growth and innovation. While there are more than 5,000 enterprises manufacturing cosmetics in Europe, the clear majority of these companies are SMEs.

In 2016, there were 4,900 SMEs in Europe, mostly located in Italy (753), France (714) and the UK (445). (6)



**Figure 4:** SME distribution in Europe (6)

European cosmetics and personal care industry employs approximately 27,700 scientists from a wide range of disciplines and possesses at least 33 scientific innovation facilities in Europe carrying research in relation to cosmetics.(11)



**Figure 5:** Number and location of scientific innovation facilities in Europe carrying out research in relation to cosmetics (6)



## 10.2. Consumer Safety

Consumer safety is the determinant goal for the manufacture and sale of cosmetics in Europe, and also, the number one priority for consumers. A product can have amazing efficacy and be innovative but if the consumers don't trust the safety of that product they're not going to use it, so the innovative process is useless.

For a new product to be introduced on the market it's mandatory to have the safety tests done. Safety assessments of cosmetic ingredients and products are based on evaluations of the risk they pose.

Risk is defined as the probability of harm in relation to dose and exposure, and is often confused with hazard. Hazard is the intrinsic property of a substance, thing or situation to cause harm. Risk is the likelihood that harm will actually occur.

This conceptual difference can explain how one substance can be used safely despite its hazardous properties. Scientists formulating cosmetics assess the risk of a certain substance and make sure that it's dose in the product is used correctly and safely. Then there is a double verification of safety done by a qualified safety assessor who performs a 'risk assessment' on each and every product before it is placed on the market. (12)

The safety assessment must pay special attention to where the product is meant to be applied (e.g. eyes, mouth or scalp) and which population group is expected to use it as well. (8)

According to the EU Cosmetics Regulation, it's the joint responsibility of the European Commission and the cosmetics industry to perform a risk-based safety evaluation of cosmetics products.

European Commission requests a scientific advice and a written safety evaluation of substances and products to an independent expert group called The Scientific Committee on Consumer Safety (SCCS) so that a decision can be taken regarding the usage of the product. Then the European Commission decides to put or not the ingredient on the annexes list of the substances prohibited in cosmetic products (annex II of the Regulation (EC) No1223/2009 of the European parliament and of the council). This list contains all the ingredients that could potentially cause damage to human health making them forbidden or restricted to use in cosmetic products.

The cosmetics industry also requires a highly qualified safety assessor to produce a written safety evaluation of its products and ingredients. In addition to that,

manufacturers are required to produce a Product Information File (PIF), which is a unique dossier per product, covering two main elements: safety and efficacy. (7)

To meet their obligations under the EU Cosmetics Regulation, companies must fulfil specific duties before placing a product on the market. These include not only the Safety assessment and the PIF, but also the usage of the same rules for ingredients and labelling must be applied for all the European Union members creating a single market. This will allow a product to move freely within the European Union with the same labelling, packaging and safety regulations applied creating a harmonized market.(8)

## 10.3. Types of Innovation

There are so many ways to innovate that the possibilities are endless. However, in the cosmetics world there are five fundamental areas where intellectuals focus their efforts and creativity.

This includes innovation in **ingredients**, by adding new, never used or improved ingredients to a certain formulation, differentiating it based on the properties of its content.

Another way to innovate is to come up with a unique **formulation**, different from every other on the market, safer and easier to apply or use.

**Packaging** is also becoming a huge trend and consumers are more demanding of unique, un-usual and original packages that meet their own personality, turning an “ok, normal and boring” product to a “fun, never seen, interesting” one.

**Technology** takes a big part in the cosmetics industry, helping to develop products closer to the consumer needs and creating new connections and experiences between consumers and products.

Lastly, cosmetics companies’ **mentalities** are also changing. Not only are consumers becoming more responsible and aware about environmental, ethical and social issues but they demand for the industry to share their concerns and evolve in a more conscious way.

## **10.3.1. Innovative Ingredients**

Ingredient level innovation is done at the core of the product and will influence its main purpose. In the innovation levels of a product, innovation in its ingredients is the primary level, followed by the innovation in the formulation, packaging and marketing. The complexity required to innovate is superior at this stage requiring several efficacy and safety tests for its use to be allowed in the product.

From synthetic, mineral or vegetal origin, the range of ingredients available allows the development of innovative, complex and stable formulations.

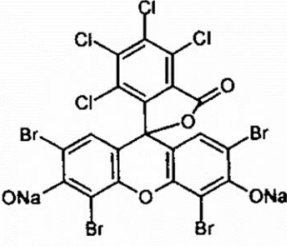
Ingredient selection is dictated by the EU Cosmetics Regulation, which lays down all rules for product and ingredient safety assessments. It lists all substances that must not be used due to their toxicity; substances that can only be used in specific circumstances; and the substances approved for use in cosmetics like colouring agents, preservatives and UV filters.

### **10.3.1.1. Colour Changing Lipstick**

This product is a lipstick that changes its colour when in contact with the human lips or skin. According to the CN 102366354 A patent of this type of product this variation of colouring is due to the change of the pH value when the lipstick comes in contact with the human lips. (14)

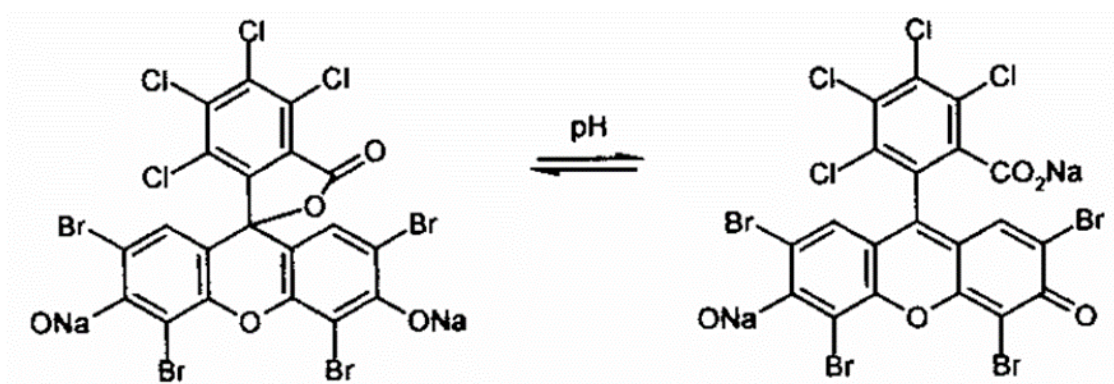
Other than the visual effect of colour changing, the product claims also include the prevention of chapped lips, a durable colour, pleasant fragrance and capabilities of moisturizing and softening skins.(14)

The ingredient responsible for this colour change of the lipstick is a colourant with the CI 45410.

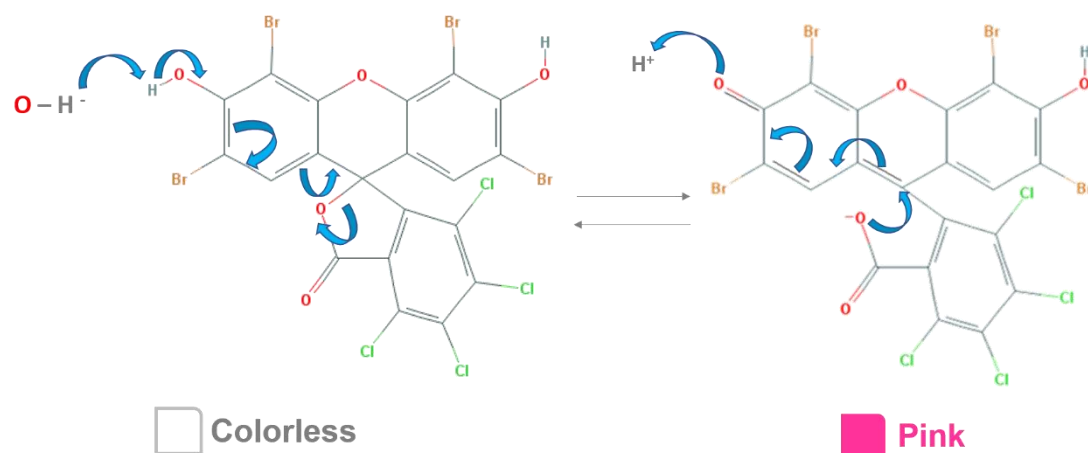
CI 45410	
CAS Number	18472-87-2 / 13473-26-2
EINECS	242-355-6 / 236-747-6
IUPAC Name	3,4,5,6-Tetrachloro-2-(1,4,5,8-tetrabromo-6-hydroxy-3-oxoxanthen-9-yl) benzoic acid, and its insoluble barium, strontium and zirconium lakes, salts and pigments.
Restriction (applies to EU only)	not more than 1 % 2-(6-hydroxy-3-oxo-3H xanthen-9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
Functions	Cosmetic colorant
colour	Pink/red
Molecular formula	C <sub>20</sub> H <sub>2</sub> Br <sub>4</sub> Cl <sub>4</sub> O <sub>5</sub> Na <sub>2</sub>
Molecular structure	
Melting point	>300°C
pKa*	4.29 (* Although the molecule contains two ionisable groups, only one pKa is reported)
Solubility and stability	In water and organic solvents

**Table 1:** CI 45410 information (15)(16)(17)

This pigment is colourless when isolated from water and can be mixed into an oil- or a wax-based product, like lipstick, resulting in a colourless finished product as well. When it comes in contact with moisture, the change in solubility and pH causes this pigment to gain a pink shade. This variation of colour can be different from person to person depending on their natural lip and skin pigmentation and of course pH value. The amount of CI 45410, along with the other dyes used, will also determine the final shade.(18)



**Figure 6:** CI 45410 pH depending chemical reaction (16)



**Figure 7:** CI 45410 colour changing mechanism

The molecule has two forms depending on the pH and lipophilicity of the medium, thus having two different absorption spectrums.

When the pH value of the medium is higher (basic), the predominant form of the molecule is the open one (pink), because it absorbs more in the visible part of the light spectrum due to its larger conjugation. This means that an individual with skin and lips with higher pH value experiences the presence of a more vibrant colour.

This colourant (CI 45410) is a fluorescein-based dye that was approved in 1982 for use in drugs and cosmetics, except the eye area and mainly used in lipsticks or blushers. (17) These agents emit light after excitation because the wave length of the emitted light is usually longer than the one of the incident light. This type of pigment, used in the colour changing lipstick, is called eosin dye used in cosmetic to stain the skin, producing a pink shade which, beside the colour, also confer long-wear properties to the lipstick.(18) (19)

The INCI name of this pigment can vary according to the geographical area in question. To identify the colorants allowed for use in European Union, the INCI name **CI 45410** must be used.

“To identify the certified colorant (acid form) for labeling purposes in the US, the INCI name **Red 27** must be used. To identify the certified salt of Red 27 extended on an appropriate substrate in compliance with Code of federal regulations (section 21CFR82.1051), the INCI name **Red 27 Lake** must be used.”(20)

“To identify the certified colorant (Red 27 sodium salt) for labeling purposes in the US, the INCI name Red 28 must be used. To identify the certified salt of **Red 28**

extended on an appropriate substrate in compliance with Code of federal regulations (section 21CFR82.1051), the INCI name **Red 28 Lake** must be used.”(20)

Concerning the safety of this colourant, according to the Cosmetics Europe, the Federal Register, and the Government of Canada, there are some concerns to be considered.

These two regulatory agencies analysed the CI 45410 and emitted their opinion.

According to the **Federal Register**, it is categorized as photo genotoxic. This pigment is known to be an extremely efficient photodynamic sensitizer whose photo-excitation results in the formation of free radicals and singlet oxygen. These highly reactive species attack cellular components such as lipids, proteins and nucleic acids and have proved to be mutagenic in bacterial assays. In addition, in vitro studies using mammalian cells have shown that CI 45410 sensitizes photooxidation of guanine bases in cellular DNA, a lesion known to be mutagenic.(17)

**Cosmetics Europe** considered the information provided on the compound largely incomplete, confusing and controversial, not conforming with SCCNFP (Scientific Committee on Cosmetic products and Non-Food Products) notes of guidance. (16)

According to the data provided and analysed by the SCCS, the CI 45410 was considered to be non-irritating to skin. However, skin staining caused by this pigment would have masked any irritant erythema. Therefore, some irritant potential has not been excluded. When applied to the ocular area, the CI 45410 was considered irritating. (21)

Concerning the mutagenicity, the genotoxicity of this colourant was investigated for the 3 endpoints of genotoxicity: gene mutations, chromosome aberrations and aneuploidy. (21)

The induction of gene mutations was studied in in vitro tests. According to them, this pigment did not induce gene mutations in bacteria nor in cultured mammalian cells. Mice exposure to CI 45410 did not result in an increase in erythrocytes with micronuclei Chromosomal aberrations and aneuploidy were not investigated with in vitro tests. (21)

It was considered that CI 45410 has no genotoxic potential and additional tests are unnecessary which is contradictory to the Federal Register opinion. (21)

The SCCS considered 50 mg/kg/day as the NOAEL for sub-chronic toxicity. In the developmental toxicity study, the NOAEL for maternal toxicity was 50 mg/kg/day. (21)

Based on the data provided, the SCCS (Scientific Committee on Consumer Safety) opinion about CI 45401 is that the formulations don't represent a risk to the health of the consumer. (21)

According to the Environment Canada Domestic Substance List and the Canada, the CI 45410 is classified as expected to be toxic or harmful and it is suspected to be an environmental toxin, persistent and bio accumulative in wildlife. (22)

Despite some long-term safety concerns and contradictory information about the mutagenicity, it was approved by the Federal Register and Cosmetics Europe as a certifiable colour additive for colouring drugs and cosmetics except for the eye area and with the restriction of not more than 1% used in the formulation. (16)(17)

Product example:



**Figure 8:** Colour changing lipstick (23)



### 10.3.1.2. Lip Plumper

In the field of lip makeup, the main expectation of lipstick users is the modification of the visual appearance of the lips, generally in terms of coloration, gloss/matte effect and, increasingly often, volume.(24)

To obtain a volumizing effect on the lips there are two alternatives currently available to users. The first alternative involves recourse to cosmetic surgery and, with regard to its invasive nature, is therefore not adopted by the vast majority of users. The second alternative consists on applying a makeup film on the lips, of one or more materials capable of giving a suitable optical effect of fuller lips. (24)

The present invention consists of a water-based composition that includes one or more blood circulation enhancing substances responsible for the volumizing effect on the lips and comprises organic solvents and emollients.(25)

The product is claimed to alter the lips appearance, making them look fuller, fleshier and redder, and, depending on the ingredients other than the blood circulation enhancers, it can also colour the lips or give them a shine or matte finish. Other perceived benefits include stimulating collagen production and moisturizing. (24)(25)

The blood circulation enhancing substances work by irritating the skin of the lips making them swell slightly and look redder because of the dilatation of the blood vessels. (26)

According to the US 2007/0243150 A1 patent, the array of ingredients to achieve a vasodilation effect include blood circulation enhancers, like palmitoyl oligopeptide, benzylnicotinate, menthone glycerine acetal and also cinnamon, wintergreen, forms of capsaicin, niacin, which is type of B vitamin that has vasodilation properties, caffeine, ginger and menthol.(27)(25)

In preferred embodiments, water comprises more than 50% of the composition by volume, and the solvents, emulsifiers, and thickeners, about 25% to about 35%. Finally, the blood circulation promoters comprise about 2% to about 4% of this composition.(25)

Also, many lip plumper products contain ingredients with reflective properties that give them a high shine, which enhances the plumping effect and make it last longer. Despite this, the only way to get a long-lasting effect is through reapplication, but eventually, the lips may become irritated. (26)

Because lip plumper work by irritating the skin they should be used with care. Used too often, they may cause lips to peel or even develop ulcers.(27) Also, if the lip skin is already irritated the situation can aggravate and the lips can become dryer, split, peel, crack and even bleed, specially the top lip, which is often thinner than the bottom one. (26)

People who are prone to allergies are more likely to have a strong reaction to the ingredients in a lip plumper, which may cause pain, stinging, and even a rash around the mouth.(26)

More recently, L'OREAL invented a new method of plumping lips. (28)

According to the US 8628758 B2 patent, the invention relates to a process for making up the lips, "comprising at least one step of placing in contact on the surface of said lips: a first anhydrous composition containing at least one water-soluble organic acid, a second anhydrous composition that is different from the first containing at least one alkali metal carbonate, alkali metal bicarbonate, alkaline-earth metal bicarbonate, or alkaline-earth metal carbonate, and an aqueous medium separate from the first anhydrous composition and the second anhydrous composition.(28)"

The placing in contact of the organic acid and the alkali metal or alkaline-earth metal carbonate or bicarbonate with an aqueous medium generates CO<sub>2</sub>, which leading to an effervescence reaction. (28)

According to the embodiment, the aqueous medium can be the user's saliva or it may also be water applied by the user to the surface of the lips. This water or aqueous medium may be applied before, after or simultaneously with the organic acid and/or the carbonate or bicarbonate.(28)

The inventors have found that when this effervescent reaction takes place on the surface of the lips, which is manifested by a bubbly effect and also by a slight tingling, it increases significantly the volume of the lips and intensifies their natural flesh tone.(28)

Concerning the safety of the product, it is considered to be safe when used in the correct way and not excessively. (28)

To meet their obligations under the EU Cosmetics Regulation, companies must fulfil specific duties before placing a product on the market. These include a safety assessment and the PIF (Product Information File) which is a file that contain all the information about the product, mainly, the safety and efficacy.

This type of invention has been placed and has not been withdrawn from the market, so according to the European Commission, it fulfils all the safety requirements to be commercialized and used safely.

Product example:



Figure 9: Lip plumper examples (29)

## 10.3.2. Innovative Formulation

Formulation can simply be defined as a mixture prepared according to a formula. Innovation in this case means coming up with a new or reformulated formula inexistent in the market. This area has so many different notable examples of innovation. Imagine something as simple as a lipstick, you picture it being a bright colour like pink or red, in a black and gold case, with that classic lipstick shape. Well today a lipstick can be so much more, you now have a million colours, from the classic red to the green, blue, and even black. You have glittered lipstick, fluorescent lipstick, matte lipstick, nail polish like lipstick, colour changing lipstick and the list goes on. Nowadays you can imagine a product and think that it is impossible that it exists just to find out that it not only exists but it's available on the market.

### 10.3.2.1. Colour changing BB cream

**“Colour changing composition in O/W emulsion form in the form of oleosomes”**

Consumers of tinted creams and care products are nowadays looking for products which can combine both but look less like makeup and more like care products. (30)

BB cream stands for blemish balm, blemish base and beauty balm. When compared to a tinted formulation like a foundation and a skin care product, the BB cream falls somewhere in the middle of both having the coverage power of the foundation and the moisturizing power of the skincare product.

Cosmetic compositions, especially foundations, are commonly used to give the skin an aesthetic colour, but also to hide skin imperfections such as redness and/or marks. In this regard, many formulations have been developed to date.

The present invention relates to cosmetic compositions that contain a blend of microencapsulated colorants that produce a natural, textured tone effect that is imperceptible in the product external appearance and packaging, and only appears when the product is applied to a keratin material, in particular the skin. Also, this type of formulations is also appreciated by certain consumers for its playful nature. (30)

To obtain the visual effect of the absence of colour, the pigments are encapsulated in microcapsules or spherules constituting a shell around the pigment preventing it to blend with the rest of the formulation. When the product is applied in the

skin there is a certain pressure exerted leading to the rupture of the microcapsules thus revealing immediately their colour.(30)

According to the invention, the "colour changing formulation" means a composition wherein the colour before application is different from the colour after application, this difference being visible to the naked eyes.(31)

"The pigments are preferably encapsulated in microcapsules which are both resistant to the other raw materials present in the composition and flexible enough to be able to break under shear during application and to deliver the hoped-for colour." (30)

The colour changing formulation using encapsulated pigments has multiple cosmetic applications, from BB cream to foundations, lip balm, eyeliner, mascara, and many other types of liquid formulations.(31)

The colour changing formulation is described as an oil-in-water emulsion. It's formed from oleosomes which are coloured oily globules provided with a lamellar liquid crystal coating. These are preferable from 10  $\mu\text{m}$  to 800  $\mu\text{m}$  and are dispersed in an aqueous phase. For skin application, like the present BB cream, the average preferable size is less than 400  $\mu\text{m}$ .(31)

A microcapsule consists, according to the WO 2015/003641 patent, preferably of an inner core surrounded by at least two layers in which the colourant is entrapped. (31)

The core is uncoloured and made of an organic material like monosaccharide-polyol (preferably mannitol) having ideally a size ranging from 500 nm to 150  $\mu\text{m}$  in diameter. Surrounding the core there is at least two layers, comprising an organic inner layer and an organic outer layer of different colours in which the pigment is entrapped.(31)

The inner layer, is the closest from the core and contain at least one colorant, preferably iron oxide(s) and at least one polymer derived binder and a lipid based material.(31)

The outer layer with an ideal thickness of 5  $\mu\text{m}$  to 500  $\mu\text{m}$ , comprises titanium dioxide particles, and at least one polymer derived binder and one lipid-based material as well. (31)

Preferably, the microcapsule according to the invention, and in particular the external layer(s) comprise(s) hydrophilic polymers selected from the group consisting of

polysaccharides and derivatives, acrylic or methacrylic acid homopolymers or copolymers or salts and esters thereof, and their mixture.(31)

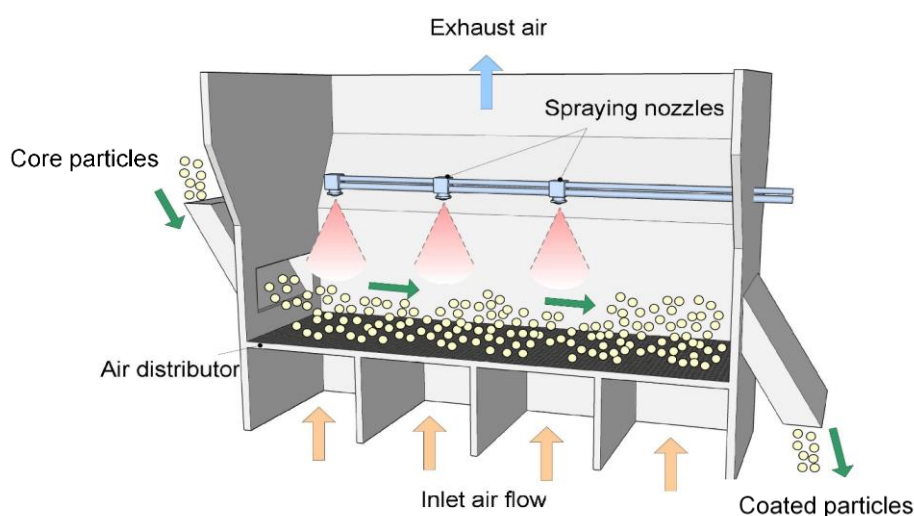
Optionally but preferably, additional coloured layers can be added forming a multi layered microcapsule.(31)

There are several methods to produce the microcapsules within the coating or encapsulation domain, including pelletization, granulation and coating.(31)

For example, the microcapsules may be obtained by comprising a mixture of compounds like actives pigments, polymers and solvents, and drying to form capsules as disclosed in WO01/35933 and WO2011/027960, or a method comprising granulation and coating by spray drying as disclosed in FR2841155, or by fluidized bed technology.(31)

According to the WO 2015/003641 patent at least one layer of the microcapsules is obtained by fluid bed process, in particular the outer layer but most preferably all the layers. (31)

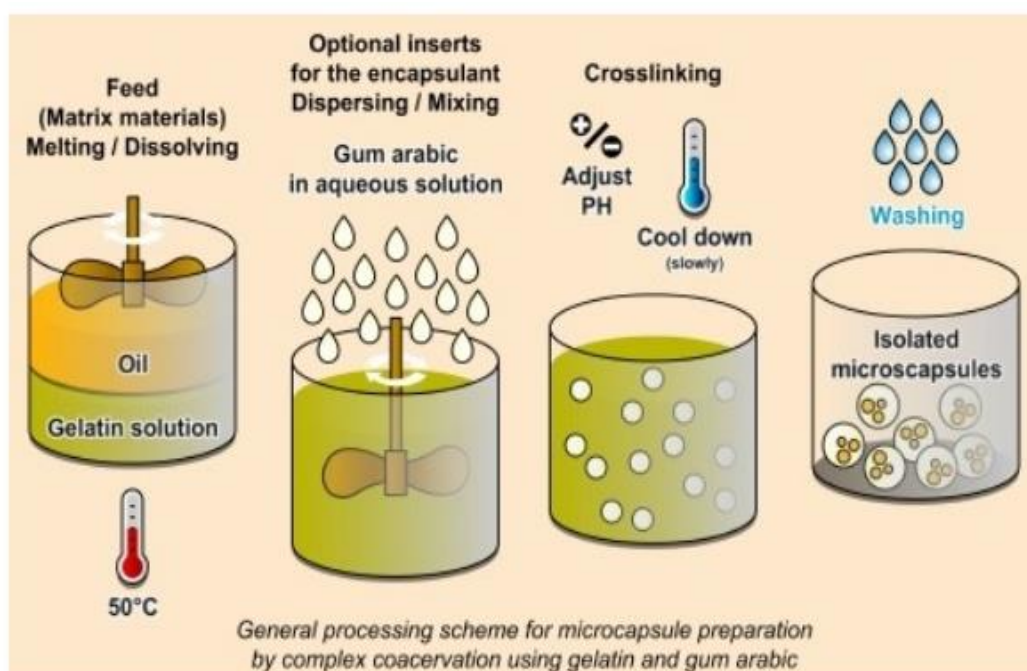
Spray coating in a fluidized bed system produces an even surface coating the material by the application of a film. In this method, the particles having different shapes and sizes are moved around in the fluidized bed and simultaneously sprayed with a liquid. The aqueous or organic solution evaporates and the solids it contains form the coating layer, leading to microcapsule layers advantageously regular, concentric and with a homogenous thickness.(32)(31)



**Figure 10:** Fluidized Bed method (33)

A specific feature of the fluid bed process is that the coated particles are better encapsulated when compared to spray drying, where the matrix with the core material is randomly dispersed in a polymer.(31)

A previous patent also mentioned another method for the encapsulation of the pigments. In the WO 2004075679 A2 patent, the preferred process of encapsulation is by coacervation. This process consists on the separation of a liquid phase of a coating material from a polymeric solution and wrapping of that phase as a uniform layer around the suspended core particles, forming micro-sized droplets. A complex of colloidal material is added to the external phase in such a way that a deposit is formed around each droplet thereby forming an outer wall or shell. (34)(35)



**Figure 11:** Complex Coacervation method (36)

After obtaining the microcapsules they are then dispersed in a water based cream which contain the care ingredients of the BB cream while the coloured particles are encapsulated in the oleosomes, making the final product an oil in water emulsion.

The final product, is claimed to provide a very strong moisturizing sensation, creamy texture with very comfortable feeling during application, and sheer natural makeup result after application. (31)

All these features help to deliver a very good balance of skincare efficacy perception (creamy and moist) as well as makeup efficacy (proper coverage and natural radiance). Advantageously, an appropriate sunscreen agent may be added.(31)

The microcapsules are intended to rupture and release the encapsulated pigment when physical forces are applied. However, colorant-containing microcapsules are not always stable, and can burst spontaneously and gradually release the colorant without any force being applied. This rupture of the microcapsules often results from a softening of the external layer and leads to the release of the pigments entrapped. Consequently, the bulk appearance becomes greyish which is not very attractive for the consumer.(30)(31)

This release phenomenon is more probable to occur, particularly in an Oil-in-Water type emulsion. Colour bleed occurs when a dye or pigment migrates through or off the microcapsules because of the contact with moisture and/or other ingredients in a formulation such as alcohols or glycols, surfactants, silicones, oils, preservatives, salts and other components typically found in cosmetic formulations that causes the destabilization of the microcapsules by softening its external layer. (31)

Also, this type of formulation has few stability under long periods of time and elevated temperatures and pressure, particularly it remains the need to dispose of emulsions which remain stable over a prolonged time e.g. during 2 months at room temperature and even at 37°C or 45°C, which can be a challenge in countries with a large temperature amplitude.(30)(31)

To improve the appearance of the final product, the inventors of the WO 2013107776 A2 patent, have found that the use of reflective particles dispersed in an oil, coat the microcapsules of pigments and act as a mirror, thus making it possible to reduce the visibility in bulk of the encapsulated pigments, giving the composition a nacreous white appearance and luminous effect which is more attractive for the consumer. (30)



Product example:

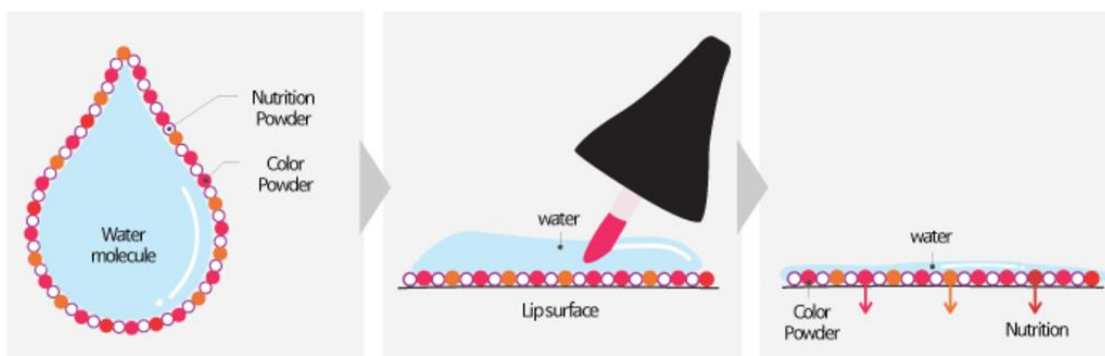


**Figure 12:** L'Oréal nude magique BB cream (36)

### 10.3.2.2. Powder Lipstick

This invention consists of a lipstick in the form of a powder. This coloured powder has the interesting property of turning to liquid when in contact with the lips or the skin.

This type of composition is prepared as a loose powder composition but contain a fairly elevated level of water. When applied in the skin or lips the powder releases the water, and the formulation becomes liquid on the skin.



**Figure 13:** Lip powder structure and functioning (37)

This product besides playful is also versatile and can be used as a blush. It provides the advantages of a powder, such as portability and ease of application and absorption of oils by the contained powders. Having also the added advantage of containing a large amount of water, allowing the delivery of valuable water-soluble actives and also providing a cool moisture when applied.

The composition of the invention is substantially oil-free, containing less than about 1% of an oil component, being particularly useful for individuals with oily skin, it is also well adapted for use in hot weather when an oily product is particularly undesirable. In addition, the powder, upon application onto the skin and/or lips, provides an advantageous release of a cool moisture, which can be further prolonged by the addition of menthol or other cooling components to the formulation.

Lipsticks of this type, when applied over a conventional lipstick, can convert the lipstick to a matte finish.

Powder-to-liquid compositions are known in the art, as oil in water powder emulsions called Pickering emulsions.

A Pickering emulsion is an emulsion stabilized by solid particles like silica which adsorb onto the interface between the two phases.

When oil and water are mixed, small oil droplets are formed and dispersed throughout the water. These droplets will coalesce to decrease the amount of energy in the system, however, when solid particles are added to the mixture, they will bind to the surface of the interface and prevent the droplets from coalescing, thus causing the emulsion to be more stable and separate the two phases.

The powder used for this purpose is porous silicone-coated fumed silica. The more silica particles present, the more water the composition can hold. However, silica particles, when present in large quantities, confer a dry and gritty feeling on the skin. To prevent this effect, water-soluble actives or skin-conditioning agents may be added to the water phase.

This specific composition contains pigment powders, to add colour to the formulation. The powder ingredients used include, inorganic pigments, preferably iron and titanium oxides and also transparent metal oxide-coated silica beads.

The powder compositions are prepared, in general terms, by combining all the components of the aqueous phase, including actives, if any, and the water-soluble polymer. The dry components i.e., the silica particles, additional powder components, and pigment powders, are combined and pulverized separately. The aqueous phase is then added into the dry phase and blended thoroughly. Alternatively, additional powders can be blended in at the end of the process.(38)

Product example:



**Figure 14:** Lip powder example (RiRe) (39)

### 10.3.3. Innovative Technology

Nowadays technology is everywhere. It's almost impossible to imagine any aspect of our lives that doesn't involve it. Not talking about just about computers, that era was just the beginning, technology merged with our daily life in a way that we can no longer dissociate from it. From our phones to our cars, from work to our home, technology enhances our lives, bringing us closer to information, entertainment, and to each other. (40)

Technology refers to knowledge, tools, techniques and systems to serve a bigger purpose of making life easier and better. (41)

R&D teams of the cosmetics industry companies are growing and diversifying, and suddenly there's not only chemists working in the lab but an entire team of engineers, marketers and scientists of so many different areas working together to return the most outstanding ideas and make the cosmetics industry continue to grow and evolve.

Technology, whether on a smartphone, an app or in a new scientific technology, creates new connections and experiences between consumers and products.(42)

Consumers, products and companies are developing closer relationships, being personalization one of the biggest concerns of the companies. Consumers want to feel special and expect products particularly designed for their needs.

There is no doubt that the most interindividual variation is the skin colour, and when it comes to makeup, finding the perfect foundation shade can, sometimes, be very difficult.

L'Oréal developed the Shade matching technique that allows women to find their ideal shade of foundation. (42)

After 10-12 months of experiments, they created a machine that was able diagnose the skin type and condition, create the correct foundation formula for it, put the product into the formula blender and package the final product in a customizable and personal way, thus creating a totally personalized product in only a few minutes.(42)

The system performs using reflectance spectrophotometry which is a non-invasive technique that can analyse the skin tone. (42)

The technique is performed by illuminating the surface to be analysed, in this case, the skin, with a light of a specific spectrum and recording the spectral response of the surface.(43)

The relationship between the intensity of light hitting the surface and the one it reflects is called percentage reflectance. This value is then calculated for each wavelength in the visible spectrum, thus defining the spectral behaviour of the surface under examination. (43)

The spectral behaviour is characteristic of the material and can translate to the exact skin tone of the subject submitting the evaluation. (43)

After obtaining the skin tone information, the skin hydration and nutrition is also measured, thus creating the skin care part of the formulation also adapted to the individual needs of the consumer.

The final formula developed is finally blended and packaged in a customizable way creating a final product adapted to the exact skin type and colour of the consumer and that meets the needs for a perfect tone matching foundation.

## **10.3.4. Innovative Packaging**

Packaging is one of the most important aspects of a product. It's what makes the product sellable. It not only transmits all the relevant and obligatory information about the product but also creates the desire and need to own it. The packaging of the product is going to speak for it. In analogy, it's like the makeup of the product, it might be a daily makeup, an evening makeup or even no makeup at all, but it will influence the consumer's wants and create a perception of the brand's positioning in the market.

### **10.3.4.1. Cushion makeup**

The cushion make-up concept originated in Korea being first launched in March 2008 and then replicated by the other countries. It is estimated that about 55-70 million units of cushion make-up have been sold worldwide.(44)

This type of packaging can be adapted for multiple purposes. From the most common, as a foundation, to a cushion blush, lip cushion and even hair retouch cushion. It is definitely a revolutionary way of packaging the already existing types of formulations.(44)

It is basically a liquid foundation immersed in a sponge. This sponge is a urethane foam that contains and preserves the liquid make-up. The saturated sponge is then packaged in the lower compartment of an air tight compact case together with an applicator puff used to apply the product on the skin. (44)

The foundation type cushion has many technical similarities to the Blemish Balm or Beauty Balm (BB) Cream and Colour Control/Correcting (CC) Cream technology which are products designed to feel lighter on the skin and provide a more natural appearance than the conventional foundation. (44)

The application is fairly simple, the consumer first presses the applicator puff onto the foundation sponge to dispense the liquid product and then, pat and press gently onto the face until the desired effect is achieved. (44)

The cushion foundations are generally all water-in-silicone or multiple phase emulsions.

Silicone-based emulsifiers can impart the same benefits as water-in-oil emulsions without most of the drawbacks associated with these systems, such as greasy feel,

difficult and costly manufacturing and less formulation flexibility when compared to oil-in-water systems. (44)

An external silicone phase has advantages for the product design of cushion foundations. The viscosity range of this type of formulation can vary from a thin liquid to a thick cream by varying the concentration of the internal aqueous phase. In this case, a thin liquid is required to utilize the pad applicator and for the final product to be easily spread onto the skin. (44)

Sebum control powders are also part of the ingredients in cushion foundations and are claimed to take care of excessive sebum and oil on skin and suppress greasiness for a shine-free effect, creating a semi-matte finish desirable for the customer. (44)

The foundation formulation is then impregnated within a very porous sponge until it's completely saturated. (44)

The sponge is made of urethane foam and is highly porous holding up to 800,000 individual pores. It prevents the sedimentation of the lower viscosity particles of the formulation and sets in the lower compartment of the compact. (44)

Inside the cushion package is also stored a polyurethane puff used to smear the foundation on the skin. (44)

The puff is placed in contact with the cushion sponge to transfer the liquid foundation by capillarity. Then, by patting or gently stamping, the foundation is transferred onto the skin in the desired dose. Multiple layers of foundation can be built by reapplying the product, giving more coverage to the skin. (44)

Although the puff applicator is claimed to be anti-bacterial, the sponge is only semi-protected from the surrounding air and may be prone to addition of bacteria because of the continuous contact with the skin of the applicator. (44)

The puff is stored in a second compartment of the compact separated of the cushion sponge by a lid. This separation will prevent the foundation from prematurely drying out. (44)

The compact is designed for refills to be added, which are sold to replace the old cushion with a new cushion, when the product expires after 12 months or as the cushion dries out. (44)

This type of packaging can also be used as a blush by replacing the foundation for a tinted cream which is also impregnated in the sponge and applied on the cheeks. The sponge can also be adapted for the tip of a lip pen to deliver lip balm and used even for hair products such as hair roots retouchers using the same principle of a product impregnated sponge. (44)

Product example:



**Figure 15:** Foundation Cushion (45)(46)



**Figure 16:** Blush Cushion (47)





**Figure 17:** Skin corrective cushions (46)



**Figure 18:** Lipstick cushion (48)



**Figure 19:** Hair retoucher cushion (49)

### **10.3.4.2. Cool/funny/different packaging**

The packaging is a very important aspect, particularly for cosmetics and personal care products. It can help position a product, engage the consumer and convey the correct, or incorrect message to the consumer, shaping the consumer's purchasing decisions.(50)

The type of packaging imports functionality and application options and will influence the formulation of the product, which has to be adapted for the correct packaging. (50)

The basic function of the packaging is to protect the product and also communicate that the value is protected as well.

The container stores the product so that it is not degraded through storage, shipping and handling. Degradation and damage can be caused by various causes like biological, chemical, physical and thermal causes and damage caused by human interaction. So, it is a very important aspect for the certification of the product quality.(51)

In addition to protecting the product, packaging also plays a big role in marketing cosmetic products.

Not that long ago, all beauty and care products came in two forms – a bar of soap or a product in a glass jar. The products themselves were very simple, as science had not progressed to the point where complex chemicals could be combined to create complex formulations of products or makeup. (52)

Nowadays, the situation has changed drastically. Cosmetic products are developed using modern technology and scientific knowledge and the packaging of these products are just as creative and sophisticated.(52)

Since companies are no longer limited to a standard sized and shape container for their beauty products, the possibilities are almost endless in terms of how product packaging can look. (52)

Cosmetics packaging is largely custom made to fit the specific needs of what the company wants and what costumers need. (52)

The way the product is stored and its packaging, convey much more than just integrity and protection, it also creates positioning and carry a message, influencing the way the product is perceived and developing a brand image easily recognized by consumers.

Consumers must be attracted to the packaging as much as the product itself or they will quickly lose interest. Essentially, beauty packaging should combine interesting, creative and unique shape as well as functionality to create an appealing and efficient packaging for cosmetics. (52)

Many times, product failure comes down to flawed packaging, since a good percentage of people judge products on appearance. That doesn't mean that customers are careless. It means that many people don't have the time to weigh the pros and cons of a product, so they make their decision based on the impression they get from packaging.(52)

Product example:





Figure 20: Examples of cool/funny/different packaging (53)(54)(55)(56)(57)

### **10.3.5. Innovative Company Mentality and Values**

Consumers are getting more demanding not only of innovative products but also of products that are personal to them and respect their principles.

One of the major drivers of growth in “natural” cosmetics has been the consumer trend towards healthier lifestyle. Consumer demand for natural ingredients and the increased desire for healthy lifestyles are directly affecting the market in sectors such as packaged food, personal care products and cosmetics.

Personalization and integrity are becoming the core values for consumers in the cosmetics market. Industry now has the task of meeting the consumer demands for products tailored to diverse individual factors such as age, gender, ethnicity, beliefs, geographies and climate, lifestyle, health and wellbeing.

Consumers are also becoming very conscious about the environment, and the social and ethical ramifications of consumption and production, and expect industries to share their concerns. This means a commitment to a responsible use of resources in the development and production process, across the entire value chain, which is also an opportunity for innovation on other levels of the cosmetics industry. (11)

#### **10.3.5.1. Sustainability**

Sustainable development is defined by the United Nations as meeting the needs of the present without compromising the ability of future generations to meet their own needs, based on three pillars: economic development, environmental protection and social responsibility.(58)

To reduce their environmental footprint and harmonize its values with the consumers, the cosmetics industry has been becoming a greener business. The mission statement when it comes to the environmental sustainability is “Cosmetics Europe’s mission is to shape a European operating environment conducive to long term growth and a sustainable future and to support the development of an innovative, sustainable, competitive and respected cosmetics industry in Europe, which best serves consumers”.(9)

So, industries have been developing towards more environmentally efficient manufacturing techniques and implementing protocols to reduce waste and emissions. (9)

Cosmetics Europe has developed two guidance documents for companies to implement in order to become more sustainable: “Good Sustainability Practice for the cosmetics industry” and “Ten Steps to Sustainability: all you need to know and do for a successful start” which provides practical advice for cosmetics company develop and implement an effective sustainability strategy. (9)

Many companies have been taking steps to reduce their carbon dioxide (CO<sub>2</sub>) emissions by reducing energy consumption and by powering plants with renewable energy; reducing water consumption and waste generation throughout the product life cycle and by using more sustainable materials, like recycled materials for products and packaging; and taking steps to limit the amount of waste produced. (59)

To maintain their social and environmental commitment in the supply chain, companies monitor and audit their activity, to ensure standards are met.

Companies are also taking measures to increase the use of sustainably sourced raw materials by purchasing them to suppliers who promote ethical business that provide stable revenue and support local businesses bringing benefits to producers and their communities. Also, companies promote and popularise environmentally conscious products so that more consumers become conscientious about environmental sustainability. (59)(60)

The terms “eco-friendly”, “green” and “organic” have become fundamental words for a large part of the consumers seeking for this type of products. They represent the certifications of biological agriculture, organic origin and fair trade\* to inform consumers on the origin and supply chain behind the products, and also to bring added value and justify market positioning and cost. (60)

These terms are related not only with food, but actually with every consumer goods from cars and clothing to beauty products, where makeup is included.

Organic and natural cosmetics are more than “free from; formulated without parabens” type of products. They are manufactured from natural ingredients like plant extracts, mineral oils, essences, salts and water and do not contain a certain type of ingredients such as parabens, petrochemicals and silicones. They are made under sustainable eco-friendly conditions that respect the environment thus rendering the final product more friendly to both the consumer and the environment.

The difference between “natural” and “organic” lies in the percentage of plant-based ingredients. An organic product has a minimum of 95% of all plant-based

ingredients in the formula and a minimum of 10% of all ingredients by weight must come from organic farming, while a natural product has a minimum of 50% of all plant-based ingredients in the formula and a minimum of 5% of all ingredients by weight must come from organic farming. (61)

For a product to be certified as “natural” or “organic” it must fill all the checkpoints of sustainability, from the source of its ingredients and its formulation which must be from natural, non-animal-derived products and be harmless to human health; to the R&D and manufacturing process that must be eco-friendly, ethical and do not use animal testing; and finally packaging that must include a majority of biodegradable or recycled material. (62)

This certification seal is given by a variety of independent, non-profit organizations like NPA (Natural Products Association) or ECOCERT for example, and is then displayed in the packaging label for consumers to recognise.



**Figure 21:** Examples of certification seals (57)

Eco-friendly packaging is another key factor when it comes to appealing to potential and current customers. Consumers are increasingly more aware of the impact that the products they use have on the environment and they want to reduce this impact as much as possible.(52)

As such, many consumers are actively seeking products and brands that use environmentally friendly product packaging. (52)

This type of packaging may be obtained by using recycled materials in the packaging itself, actively trying to reduce waste and increase recycling during the

manufacturing process, using less material to create the product's packaging, using bio-resins in plastics that break down faster when in a landfill and manufacturing packaging that is easy to clean and refill when the product finishes. (52)

Consumers favour companies that advertise an eco-friendly mindset on their products and practice what they preach in terms of being environmentally conscious in product manufacturing.(52)

**Note:** \* Fair trade involves purchasing raw materials or ingredients that provide stable revenue and support local businesses and the adoption of ethical business practices.



### 10.3.5.2. Alternative Animal Testing

Just like “eco-friendly” cosmetics, “cruelty-free” cosmetics are becoming more demanded. Ethical conscience is growing among consumers that expect companies to share their concerns. When this bond of trust and respect is broken, it can mean a huge loss for companies and their reputation damage can be irreversible. So, some companies are making changes to synchronize their values with the consumer's.

While some countries, such as China, require specific animal tests for cosmetic products to enter the market, the European Union, Israel, and India have banned the sale of any cosmetics or cosmetics ingredients that have been tested on animals. Still, this leaves us with 80% of the countries in the world with no laws against animal testing.(63)

Sadly, companies will continue to test on animals as long as some countries, such as China, require it and other countries, such as the U.S., allow it.(63)

On the bright side, Europe banned, in 11 September 2004, the testing of finished cosmetic products, and then, in 11 March 2009 the testing of ingredients or combination of ingredients followed, being also banned from Europe, with the exception of repeated-dose toxicity, reproductive toxicity, and toxicokinetic tests. For these specific health effects, the marketing ban applies since 11 March 2013, irrespective of the availability of alternative non-animal tests.(64)

So, the status of animal testing in relation to the cosmetics industry in the EU:

- Animal testing of cosmetics products is banned;
- Animal testing of cosmetic ingredients is banned;
- Selling cosmetic products tested on animals is banned;
- Selling cosmetic products containing ingredients tested on animals for complying with the Cosmetic Products Regulation is banned.(65)

To get this type of achievement it was necessary a lot of will, dedication and investment. For more than 20 years, the cosmetics industry's best scientists, and its strategic partners, have been dedicated to supporting the development, validation and regulatory acceptance of alternative test methods and approaches. The European Union is the best of these partners. It has been the leading body for the promotion of alternative approaches to animal testing and has created a fund of about 238 million euros for research on alternative animal test. (9)(64)

This number added to the 70 million euros invested over the years by Cosmetics Europe and a several hundreds of millions invested by individual companies own researches give a perspective of how much dedicated cosmetics industry in Europe is dedicated to innovating and fully embrace the alternative animal tests.(66)

It was firstly introduced in 1959 the principle of the **three R's**:

- Replacement of animal tests with non-animal approaches;
- Refinement of an animal test to reduce or eliminate stress or suffering;
- Reduction in the number of animals needed in a test.

This 3 principles has been a priority ever since. (65)

To continue promoting the 3Rs, the European Commission has created, in 1991, its own centre for the validation of alternative methods throughout Europe. This centre, known as the European Union Reference Laboratory for Validation of Alternatives to Animal Testing (EURL–ECVAM), plays a key role in the development, validation, and international recognition of alternative methods which reduce, refine, or replace the use of animals in testing and has become the European Union reference laboratory for alternatives to animal testing, established under the Directive 2010/63/EC on the protection of animals used for scientific purposes. (64)(67)

EPAA (European Partnership for Alternative Approaches to Animal Testing) was then created in November 2005 as a voluntary collaboration between the European Commission, European trade associations, and companies from 7 industry sectors with the purpose of facilitating the dialogue between them.(68) The sectors represented are agrochemicals, animal health, chemicals, cosmetics, fragrances, pharmaceuticals, and soaps and detergents.(67)

These partners are committed to share knowledge and resources to accelerate the development, validation and acceptance of alternative approaches to animal use in regulatory testing. (68)

EPAA partner type	Name	EPAA partner type	Name
European Commission	Directorate General: Growth	Industry	Elizabeth Arden
European Commission	Directorate General: Research and Innovation	Industry	Estée Lauder
European Commission	Directorate General: Health and Consumer Protection	Industry	Evonik–Degussa
European Commission	Directorate General: Environment	Industry	Givaudan
European Commission	Directorate General: Joint Research Centre	Industry	Glaxo SmithKline
Industry (Federation)	IFAH–Europe: International Animal Health Organization	Industry	Henkel
Industry (Federation)	CEPIC: European Chemical Industry Council	Industry	Johnson and Johnson
Industry (Federation)	Cosmetics Europe	Industry	Kanebo
Industry (Federation)	ECPA: European Crop Protection Association	Industry	Kimberly–Clark
Industry (Federation)	IFRA: International Fragrance Association	Industry	L'Oréal
Industry (Federation)	EFPIA: European Federation of Pharmaceuticals Industries and Associations	Industry	LVMH
Industry (Federation)	AISE: International Association for Soaps, Detergents, and Maintenance Products	Industry	Merck Serono
Industry	AbbVie	Industry	Merck Sharp and Dohme (MSD Animal Health)
Industry	Avon	Industry	Novartis
Industry	BASF	Industry	Novo Nordisk
Industry	Bayer	Industry	Novozymes
Industry	Beiersdorf	Industry	Pfizer
Industry	Boehringer Ingelheim	Industry	Procter and Gamble
Industry	Chanel	Industry	Reckitt Benckiser
Industry	Colgate-Palmolive	Industry	Roche (F Hoffmann–La Roche)
Industry	DSM	Industry	Sanofi–Aventis
Small & Medium Enterprises	StratiCell	Industry	SCA Hygiene Products
		Industry	Shiseido
		Industry	Svenska Cellulosa Aktiebolaget
		Industry	Symrise
		Industry	Unilever
		Industry	Zoetis

**Figure 22:** EPAA partners in November 2014 (67)

In 2012, the EPAA identified the need to reinforce international collaboration on the 3Rs, and to put emphasis on this challenge. EPAA invited members from international agencies, US-based animal welfare non-governmental organizations, India-based vaccine producers, and academics from many regions outside Europe to participate the projects and therefore contributing to the internationalization and growth of the initiative. This dynamic resulted in the creation of the **International Cooperation on Alternative Test Methods**, comprising EURL–ECVAM, the Interagency Coordinating Committee on the Validation of Alternative Methods, and other validation laboratories throughout the world contributing to the worldwide harmonization, implementation and acceptance of alternative methods for animal testing. (67)

Europe was the first continent to promote the replacement, refinement and reduction of animal testing, and the European Union's legislation (Directive 2010/63/EU is the horizontal legislation for the protection of animals used for scientific purposes) has inspired and continues to inspire several countries around the world, aiming towards better science, safer testing, and less animal testing. (67)

But how exactly will cosmetics safety be tested then? Does it mean that we will have to put human's health at risk? No, replacing animal testing will improve the quality as well as the humaneness of science.

The reasons why animal testing persists are often not scientific, actually, animal tests are 40-60% accurate, while non-animal tests are 80% accurate. So, the main reason is often bureaucratic. To implement the new alternatives and enforce their use

there is a massive bureaucratic and governmental hurdle associated being easier and more comfortable to simply do what has always been done. (69)

Tests on animals attempt to evaluate the hazards of consumer products and their ingredients. To measure toxic effects, rats, mice, guinea pigs, rabbits, and other animals are forced to swallow or inhale massive quantities of a test substance or have a chemical smeared in their eyes or on their skin. Around 500,000 animals are used in tests for cosmetic purposes every year and to test just one ingredient in a product can involve up to 1400 animals. (69)(63)

Cosmetics companies have been rejecting animal tests and replacing them for non-animal testing methods, like cell and tissue cultures, reconstructed skin grown from human cells, and computerized “structure-activity relationship” models that allow extrapolation of existing data to predict the activity of a chemical.(63)

### **Human cells and tissue**

Almost every type of human and animal cell and tissue can be grown in a laboratory. Cell culture refers to the removal of cells from an animal (including humans) or plant and their subsequent growth in a favourable artificial environment. A primary culture refers to the stage of the culture after the cells are isolated from the tissue and proliferate. After the first subculture, the primary culture becomes known as a cell line or subclone.(70)

Cell culture is one of the major tools to replace animal testing, providing excellent model systems for studying the normal physiology and biochemistry of cells like metabolic studies and aging, and the effects of compounds on the cells. So, tissues donated from human volunteers can provide a more relevant way of studying human biology effects of the substances in study than animal testing and the need for further animal sacrifice is eliminated.(70)(69)

Human tissue can be donated from surgery (e.g. biopsies, cosmetic surgery and transplants) and also after a person passed away (e.g. post-mortems). (69)

### **Computer models**

With the growing sophistication of computers, the ability to ‘model’ or replicate aspects of the human body became a reality.

Computer models of the human body such as the heart, lungs, kidneys, skin, and other systems can simulate the actual response to the organ, tissue or cell to the dosage

of the chemical compound being tested, allowing a virtual experiment based on mathematical data to be conducted. One of the underlying principles is that the biological effects of a chemical will depend on its molecular characteristics making it possible to predict toxicity without actually testing it.

The database on which such systems rely on will, of course, have come from animal experiments. But once the relation between molecular structure and activity is understood, the toxicity of any new substance can be predicted with a computer instead of an animal.

### **Human volunteers**

Rapid advances in technology have allowed the development of sophisticated scanning techniques that can be used to safely study human volunteers.(69)

An innovative technique called microdosing is being developed to replace animal testing. It requires human volunteers in which is going to be demonstrated how very small doses of potential new drugs behave in the human body. This technique studies the behaviour of drugs in humans through the administration of doses so low ("sub-therapeutic") they are unlikely to produce a systemic effect, but high enough to allow the cellular response to be studied.(71)(72)

Basically the substance in study is labelled using the radioisotope carbon-14 and is then administered to the human volunteers at levels typically about 100 times lower than the proposed therapeutic dosage. (72)

Accelerator Mass Spectrometry is the most common method for microdose analysis because of its sensibility being able to detect individual molecules radiolabelled. As Malcolm Rowland of the University of Manchester graphically put it, the technology has "the ability to detect a liquid compound even after one litre of it has been dissolved in the entire oceans of the world".(71)

These are only a few alternatives to replace animal testing leading to a more ethical and accurate way of conducting substance safety and efficacy tests. Consequently, animals don't need to be sacrificed and humans can develop their cosmetics products safely, efficiently and ethically.

Cosmetic Products with ingredients developed and tested under these circumstances are then labelled "cruelty-free". This label was created by NGO's like PETA and the Leaping Bunny, to help consumers identify products that are "really" cruelty-free.

PETA's Beauty Without Bunnies program compiles information on the testing policies of companies and publishes a list of companies that have signed a statement of assurance to confirm that they do not conduct or commission animal tests for their products, ingredients, or formulations. (63)

Consumers are key to implement this mentality change. By purchasing "cruelty-free" products from credited companies, they boycott those that do not comply with these standards, and motivate companies to adapt and innovate in this matter. (63)

## 11. Conclusion

The cosmetics industry is without a doubt one of the most fast paced and innovative industries. This is only possible due the massive investment in R&D done. The R&D programmes focus particularly into consumer behaviour and beauty aspirations and the biology of skin and hair, using and developing new innovative technologies and sustainable methods.

Investing in the development of a new product leads to a more complete, and varied market that provides a bigger, more effective and safer selection of products available to better suit the fast-changing consumer needs.

The process of innovation can occur in so many ways. From the usage of natural ingredients and ancient knowledge where traditional substances are used to create new formulations, to the development of products at a molecular level using innovative technologies imported from other science fields creating a whole new generation of products.

Innovation can be done by adding new or improved ingredients to a formulation, making it different because of its properties; by changing the formulation itself, creating a product different from every other on the market, safer and easier to apply or use; by innovating the packaging, which is also becoming a huge trend because consumers are more demanding of unique, unusual and original packages that match their personality.

Technology also takes a big part in the cosmetics industry, helping to develop products closer to the consumer needs and creating new connections and experiences between consumers and products.

Cosmetics companies' mentalities and values are also changing. Not only consumers are becoming more responsible and aware about environmental, ethical and social issues but they demand for the industry to share their concerns and evolve in a more conscious way. In the cosmetology, this results in the increasing demand and use of natural and organic ingredients in cosmetic formulations and the usage of the resources in a more conscience, efficient and waste-free way.

As a final point, innovation is not optional, is the way for a company to stay "alive" and is the fuel to the growth of the sector. Growth that will be driven by evolving demographics, new products, formats and formulations, dynamic distribution channels and technologies, and, of course, innovative thinking—all focused on one thing: the global beauty consumer.

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