

# Packaging Evaluation and Safety Assessment of a Cosmetic Product

ANCA MARIA JUNCAN\*

Lucian Blaga University, Faculty of Medicine, Preclinical Department, 2A Lucian Blaga Str., 550169, Sibiu, Romania

*The aim of this study was the development and formulating of a cosmetic product for bodycare and the assessment of compatibility tests performed on the product, transfered into a polyethylene (PE) cosmetic bottle. Sample of cosmetic cream were stored using 200 ml PE plastic bottles with PP (Polypropylene) cap. The developed cosmetic formulation was monitored under accelerated stability studies, performed over a period of 30 days while maintaining the product at 4, 20 and 40°C. Quality control initial, and after initiating the accelerated stability test was performed for the developed cosmetic formulation.*

**Keywords:** cosmetic product, cosmetic packaging, accelerated stability test

Cosmetics are commercially available products, that are used to improve the appearance of the skin [1, 2].

In such a competitive market like the cosmetics, product packaging and aesthetics takes a leading role in the marketing and interaction between brand and consumer processes [3,4].

A typical *oil in water* (o/w) formulation might contain ingredients such as water, glycerin, stearic acid, mineral oil, triethanolamine, cetyl alcohol, carbomers and preserved with parabens and antioxidants, which mostly occur in mixtures in cosmetic formulations. In cosmetics there are added reducing agents and free radical scavengers, known generically as antioxidants [5, 6].

Firstly, for a developed cosmetic formula to fulfill all the requirements, it is necessary to have a suitable vehicle (that encompasses emulsions, emollients, moisturizers, preservatives, perfumes, colorants) and to include in its formulation all the active ingredients (UV filters, botanical or biotechnological extracts), necessary to attain what is claimed by its advertising [5, 7, 8].

Cosmetics are regulated in the European Union by Regulation (EC) No 1223/2009. The main objectives of this regulation are to create a set of rules that all cosmetics comply with and to ensure a high level of protection for human health. One of the requirements of the regulation is that prior to placing the product on the market a safety assessment is carried out. The regulation specifies that this safety assessment should be in the form of a cosmetic product safety report [9].

Packaging material is the primary packaging which is in direct contact with the product. Annex I of Regulation (EC) No 1223/2009 requires that the cosmetic safety assessor considers the characteristics, purity and stability of the packaging. The safety evaluation of the cosmetic product has to take into account the possibility that the substances from packaging can migrate into the product and their possible effect on human health.

Primary packaging materials for cosmetics have to be carefully developed or must be selected from amongst materials already on the market. A basic requirement of packaging is the protection of the contents of the pack. In particular there must be an adequate barrier against water vapor, UV light, oxygen and CO<sub>2</sub>. Furthermore it must be assured that no components or ingredients of the packaging can migrate into the product, and there must be no adsorption or absorption of components from the product into the packaging. In addition the packaging must be non-hazardous, i.e. it must not contain any toxic substances, as well as not being able to release any substance into the product which may be in a potentially toxic concentration [10, 11].

The cosmetic packaging market can be segmented based on types, applications, materials, and geography. Different types of cosmetic packaging, with various innovations, are introduced in the market. The types of cosmetic packaging material include paper, plastic, glass, metal and others (fig. 1) [12].



Fig. 1. Cosmetic Packaging Market Segmentation

\* email: [ancamaria.juncan@ulbsibiu.ro](mailto:ancamaria.juncan@ulbsibiu.ro)

Packaging can be defined as a co-ordinated system of preparing goods for transport, distribution, storage and end-use and a package provides a means of ensuring the safe delivery of a product to the final consumer, in a safe condition at minimum cost. Fundamentally, the main functions of a packaging can be summarized as, follows:

- to contain the product
- to prevent spillage or leakage of the product
- to protect the product against mechanical and environmental damage
- to identify the product manufacturer
- to display *product-use* instructions, where applicable
- to enhance product sales appeal, through design and graphics.

The most important aspect in packaging design and development, is the physical form of the product itself. In the area of cosmetics and toiletries this may be a mobile liquid (e.g. perfumes), a viscous liquid (e.g. shampoo), a free-flowing powder (e.g. talc), an emulsion (e.g. lotions and creams) or a solid (e.g. soap). In addition, it is also important to know whether the material to be packaged has any particular requirements, imposed by factors such as volatility, corrosiveness, odour, density and moisture sensitivity. Lastly, the effects of environmental conditions on the product should be understood and consideration to factors such as temperature, relative humidity, and exposure to air, light and water, should be given [13, 14].

A key element is the packaging component itself- the bottle, tube, vial, carton, plastic sleeve, etc. - *that houses* the product. The industry's focus on innovation now goes beyond the products themselves to the packaging components, with many more innovative packaging ideas, shapes, styles, and materials [15, 16].

Packaging of a cosmetic product requires high-performance materials that function as a barrier to the outer environment. The development of new materials that can fulfill the desired functions can open new opportunities for the packaging industry [12, 17, 18]. The desired materials must be strong with active components that can be modified based on the content and environment. The materials should also be able to extend the shelf life of the

contents and help stocking of the final products. The development of new packaging materials desired functionalities can help in driving the market growth [12].

## Experimental part

### Materials and methods

#### Preparation of the Regenerating Hand and Body Lotion

The ingredients used in the developed cosmetic formulation were: deionised water; Glycerin; Caprylyl Glycol, Glycerin, Glyceryl Caprylate, Phenylpropanol; Tocopherol, Helianthus Annuus (Sunflower) Seed Oil (Biesterfeld Spezialchemie Romania S.R.L.); Glycerin, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sucrose Laurate, Aqua (Alfa Chemicals Ltd, UK); Glyceryl Stearate (Ashland Specialty Chemical, USA); Cetearyl Alcohol (BASF SRL, Romania); Butyrospermum Parkii; Theobroma Cacao Butter; Simmondsia Chinensis Oil; squalane (Sophim, France); Alcohol, Water and Onopordum Acanthium Flower/Leaf/Stem Extract (Gattefosse, France); Mel Extract (Naturex, France). Table 1 shows the composition of the developed anti-aging cream.

Manufacturing procedure: Phase A (aqueous Phase) was heated up to 78° C and xanthan gum (phase A1) was dispersed. Phase B was heated up to 78° C. Phase B was emulsified into Phase A under stirring and homogenized for 1-2 min., using an ultra turrax (T-50-digital-ULTRA-TURRAX, IKA, Germany). Medium stirring was performed for cooling down. Phase C (Water and Onopordum Acanthium Flower/Leaf/Stem Extract and Mel Extract) were added below 40°C and cooling down was performed under stirring.

#### Packaging of the cosmetic product

Samples of cosmetic cream were stored using 200 mL PE (Polyethylene) plastic bottles with PP (Polypropylene) caps. Technical specification of the cosmetic bottle and cap are presented in table 2, respectively, table 3. Figure 2. shows the technical specification of the cosmetic bottle and cap ensemble, respectively the technical scheme of the cosmetic bottle and cap ensemble.

**Table 1**  
FORMULATION OF THE REGENERATING HAND AND BODY LOTION

Phase	Product	INCI	Function	%*
<b>A</b>	SUCRAGEL AOF	Glycerin, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sucrose Laurate, Aqua	emulsifier/ thickener	D
	Cerasynt SD	Glyceryl Stearate	emollient	E
	Lanette D	Cetearyl Alcohol	emollient	E
	Karite CP	Butyrospermum Parkii	emollient	E
	Cacao Butter	Theobroma Cacao Butter	emollient	E
	Jojoba Oil	Simmondsia Chinensis Oil	emollient	E
	Phytosqualan	Squalane	emollient	E
	dermofeel® TOCO 70 non- GMO	Tocopherol, Helianthus Annuus (Sunflower) Seed Oil	antioxidant	F
<b>A1</b>	Keltrol RD	Xanthan Gum	thickener, stabiliser	F
<b>B</b>	Deionised Water	Aqua	base	A
	dermoganics® Glycerin	Glycerin	humectant/solvent	E
	dermosoft® LP	Caprylyl Glycol, Glycerin, Glyceryl Caprylate, Phenylpropanol	preservative	F
<b>C</b>	GATULINE® SKIN-REPAIR BIO	Alcohol, Water and Onopordum Acanthium Flower/Leaf/Stem Extract	active ingredient	E
	Honey LG	Mel Extract	active ingredient	E

**\*Legend:**  
A > 50 %  
25 % < B ≤ 50 %  
10 % < C ≤ 25 %  
5 % < D ≤ 10 %  
1% < E ≤ 5%  
0,1% < F ≤ 1%  
G ≤ 0.1%

Tehmical Specification Cosmetic bottle 200 ml	
Total high	154±1mm
Bottles neck high	32±0.3mm
Inner diameter of the bottles neck	18.6±0.2mm
External diameter of the bottles neck	21.5±0.2mm
Diameter on the coil	23.8±0.2mm
Wall thickness	0.9±0.1mm
Label application high	84±1mm
Label application	middle of the labelling space deviation ±1mm tolerance between the beginning and end of the label±0.5mm
Weight labelled bottle	22±1g
Total Volume	220ml±5
Useful Volume	200ml
Raw material	34% HDPE (high-density polyethylene) 66% LDPE (low-density polyethylene)
Colour	white

**Table 2**  
TEHNIICAL SPECIFICATION OF THE  
COSMETIC BOTTLE

**Table 3**  
TEHNIICAL SPECIFICATION OF THE COSMETIC BOTTLE CAP

Tehmical Specification Cosmetic bottle cap	
Raw material	PP HP 500 N
Colour	White
<i>Dimensions</i>	
Total high	33.7± 0.3 mm
Thickness of the capsule	2.3±0.2 mm
External diameter at the base	29.8±0.3 mm
Diameter at the top of the thread	22.8±0.2 mm
Diameter at the bottom of the thread	25.5±0.3 mm
Weight	5.5±0.3 g

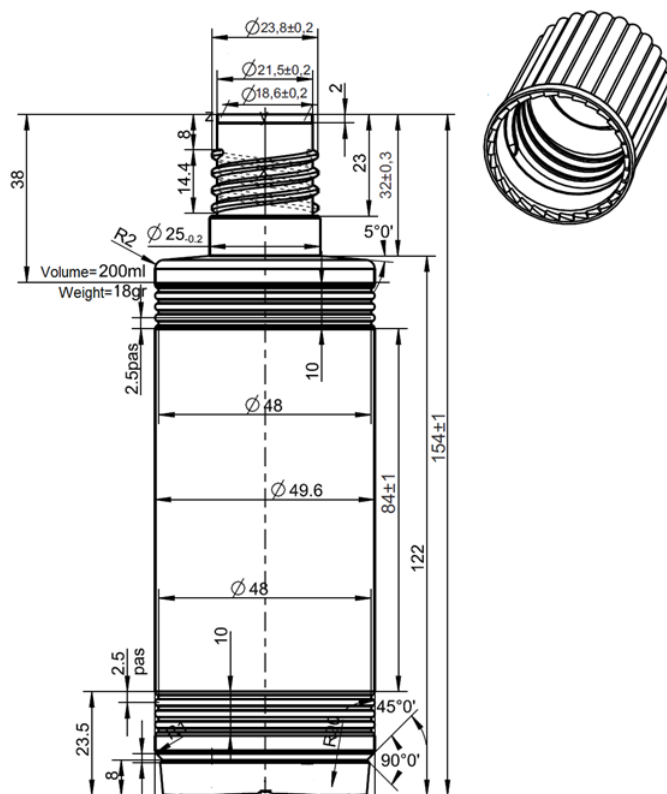


Fig. 2. Tehnical scheme of the cosmetic bottle and cap ensemble

### Accelerated Stability Test

Compatibility tests should be performed on the product, once transferred to the final container. The container-content relationship should be explored for all the packaging materials, as the final quality of the products is always the result of a delicate balance between these two components. Despite the importance of these aspects,

there isn't enough information about the possible chemical-physical interactions between formulation and packaging, because, differing from food packaging, the cosmetic one is not regulated and, to date, appropriate guidelines are still missing [19].

Accelerated tests are developed because of the relatively short development cycle for cosmetic products, enable the prediction of stability. Stability testing should include packaging which is made of exactly the same material(s) and is as similar as possible in all other respects to the package in which the product will be marketed [20].

A simple experimental design, in order to minimize the number of trials, was employed. Polyethylene containers were filled with standard formulations and submitted to different degradation tests (photostability test and accelerated stability test) to mimic stress conditions that products can meet during their shelf life, according to European guidelines for stability tests on cosmetic products [19, 20].

The developed cosmetic formulation was monitored under accelerated stability studies. Accelerated stability tests were performed over a period of 30 days while maintaining the product at 4, 20 and 40°C.

Quality control initial, and after performing the accelerated stability test consisted of the following determinations:

- the appearance, color and odor were tested organoleptically.

- pH determination was performed using a pH meter (Mettler Toledo, Schwerzenbach, Switzerland).

### Results and discussions

The characteristics of the packaging materials that are in direct contact with the product must be assessed, as they may have an impact on the finished product's safety. Compatibility of the product with its container may be assessed as a part of the stability test. In addition to providing information on the potential migration of substances, compatibility testing will provide an indication of the lack of interactions between the product and the container and will assess possible deterioration of the product in contact with the packaging, which may also be influenced by the external environment. Correct assessment of the substance migration risk will help select the appropriate packaging material and storage conditions (which can be then indicated on the product label).

Plastics are, by far, the most commonly encountered materials in the packaging of cosmetic and toiletry products. The reasons for this are many fold but key factors such as cost, production flexibility and safety in use, have played a key role in the increasing popularity of plastics over recent years. Essentially, there are two basic types of



<i>Admissibility conditions (initial)</i>		<i>Admissibility conditions (30 days)</i>
<i>Appearance</i>	homogeneous cream	concordant
<i>Odor</i>	characteristic odor, perfumed	concordant
<i>Color</i>	White	concordant
<i>pH</i>	5.5-6.5	5.5-6.5

**Table 4**  
PHYSICO-CHEMICAL CHARACTERISTICS OF  
THE DEVELOPED CREAM

plastic material, the thermoset resins, such as phenol-formaldehyde and urea-formaldehyde, and the true thermoplastics, like polystyrene, polyethylene and polyethylene terephthalate. Thermoplastics are widely used in the production of packaging for cosmetics and toiletry products to produce containers and closures.

A cosmetic cream was developed and accelerated stability testing was performed including packaging. Accelerated stability studies performed over a period of 30 days, while maintaining the product at 4, 20 and 40°C, showed that the formulated and studied cosmetic product is stable, and there was no deterioration of the plastic container.

Quality control of the developed cosmetic cream revealed: achieving an acceptable cosmetic preparation with elegant appearance and appropriate physico-chemical and pharmacotechnical (pH, viscosity) characteristics. The determination results initial, and after 30 days are shown in table 4.

Following the protocol developed in this study, it is possible to evaluate both the behavior of the container itself, and the possible interactions between content and container in order to ensure the quality of product and the safety for consumers.

## Conclusions

In the Regulation 1223/2009, evaluation of packaging has become mandatory to assure cosmetic product safety. In fact, the safety assessment of a cosmetic product can be successfully carried out only if the hazard deriving from the use of the designed packaging for the specific product is correctly evaluated. Despite the law requirement, there is too little information about the chemical-physical characteristics of finished packaging and the possible interactions between formulation and packaging.

The accelerated stability test performed in this study for a developed cosmetic formulation for bodycare, showed that the formulated and studied cosmetic product is stable, the cosmetic product is compatible with the PE cosmetic bottle and PP cap and there was no deterioration of the packaging after the performed test. Quality control of the developed cosmetic cream revealed an acceptable cosmetic preparation with elegant appearance and appropriate physico-chemical and pharmacotechnical (pH) characteristics initial, and after 30 days.

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