THE WORLD OF THE

COSMETICS INDUSTRY

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DR KOZIEJ

Centrum Kosmetyków Dr Piotr Koziej

[Cosmetic Center, Piotr Koziej PhD] is the laboratory which offers state-of-the art technologies, professional equipment and long term experience of medical doctors specialized in various areas of medicine. We provide comprehensive research services on cosmetic and home cleaning products. Our laboratory provides testing of standard products, as well as products of special use, professional products, sensitive products and products for children.

Safety assessment – assessment of the impact of a given cosmetic product on the human health safety, performed in compliance with the most recent guidelines of the European Union

Microbiological tests – as set forth in the Cosmetic Products Act and COLIPA guidelines, these are tests which confirm the biocidal action of cosmetic products, house cleaning products and other goods, and which are performed with methods defined in Polish and European standards

Challenge test – carried out pursuant to the applicable European Pharmacopoeias or PN EN ISO 11930:2012; in agreement with the client, depending on specific needs and the purpose of the test, we may introduce modifications to the research method and establish individually effectiveness criteria

Dermatological tests:

- Patch Test – dermatological test (open, semi-open and closed)
- Photo Patch Tests – phototoxicity and photoallergy assessment
- Tests of skin tolerance in the spot of application

Usage tests:

- Individual selection of test subjects, depending on product characteristics and intended use; large groups of subjects (as recommended by the manufacturer)
- Skin tolerance to the product on the spot of application
- Individual, subjective assessment by each research subjects of:
  – the utility value of the product;
  – the action of the product as declared by the manufacturer.
- Tests may also be carried out under the supervision of another MD specialists, e.g. in dermatology, gynecology, ophthalmology, allergology or in other areas.

Apparatus testing:

- An objective assessment of the impact of tested products on the skin condition and of the declared utility values of the preparations
- Courage&Khazaka apparatus – tested parameters: hydration, TEWL, sebum (lubrication), pH level, pigmentation (blush and discolorations), temperature, elasticity. Results are elaborated in the form of charts, tables and descriptions and photos.
- Miravex Antera 3D ™ and VisiofaceQuick apparatuses – tested parameters: size and depth of wrinkles, color (rush and discolorations), smoothening, pore level, UV. Results are elaborated in the form of charts, tables and descriptions and photos.
- Thermographic testing - a thermic assessment of the skin, which shows the blood flow in the hypodermis. It is most often used to check the advancement of cellulite and the effects of its treatment

UV coefficient assessment (UVA and UVB):

- UV coefficient testing with the *in vivo* method, in compliance with COLIPA Guidelines (2007 Guideline), BOOTS Guidelines (2008 revision) or FDA ones:
  - UVB – SPF coefficient testing
  - UVA - UVA/UVB coefficient testing
  - Photostability testing
  - Water resistance testing
  - Phototoxicity and photoallergy testing
- A quick testing useful in formula definition (results in only 3 days)
- UV coefficient testing with the *in vitro* method; methodology based on COLIPA procedures and FDA standards:
  - UVB – SPF (in-vitro) coefficient testing
  - UVA – PPD coefficient testing

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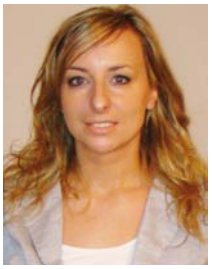

Teresa Kubsz-Miller
Editor of issue „The World of the Cosmetics Industry"

Dear Readers

We invite you to read this year's first issue of " The World of the Cosmetics Industry" magazine.

For some time now the Polish cosmetics market has been preparing for changes which will come into effect on 13 July 2013. So, specially for you, we have prepared a section devoted to Good Manufacturing Practice in the production of cosmetics, to remind you once again what changes the new regulation will bring.

As always, the magazine also includes many interesting articles related to production, quality control, and raw materials in cosmetics.

Taking numerous domestic and foreign fairs into account, the magazine is also being issued in English.

Enjoy the reading

Teresa Kubsz-Miller

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A specialist quarterly targeted at cosmetics industry producers, as well as suppliers who offer products and services within the cosmetics field.
The magazine is addressed to process and production engineers, automatic systems specialists, heads of production, control and quality assurance divisions, heads of logistics and procurement divisions and product development divisions at cosmetics companies. The magazine is also targeted at product managers, sales and marketing directors, chief decision makers in purchasing departments, university professors and other faculty members, representatives of industry organizations and institutes, as well as private individuals.

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Selecting and verifying methods of neutralization of antimicrobial properties of cosmetics

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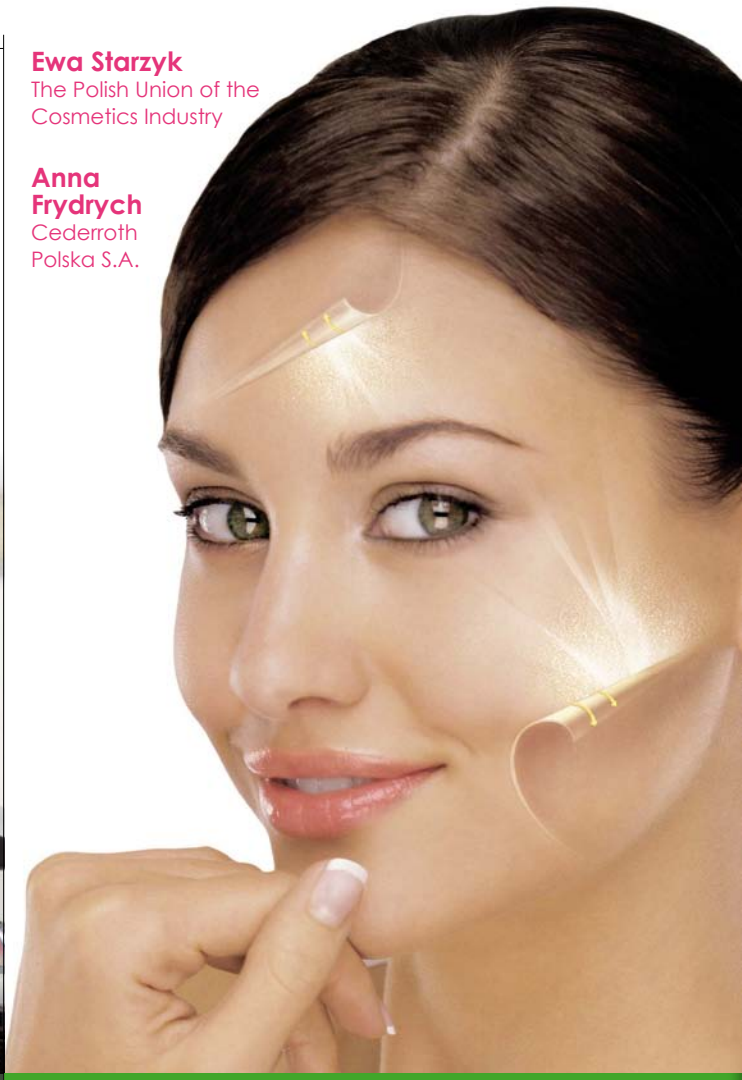

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The approaching changes in the cosmetics industry

Sylwia Stokowska
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Precisely Right.

For quite some time now the producers of cosmetic products have been following legislative developments at the EU level in an attempt to adapt to the upcoming changes, which will become effective from 11th July 2013 with the entry into force of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products. During the transition period the producers are sparing no efforts to come up to the expectations and requirements of the new law. Let me briefly explore the changes that the new regulation will bring about.

In general, the upcoming regulation on cosmetic products will transfer responsibility for the quality of cosmetic products from the Ministry of Health (the National Institute of Hygiene) to producers and distributors. It will define general safety parameters to be followed by producers under the pain of legal or financial liability for any unexpected risks attributable to the use of a cosmetic product.

What do the changes involve?

Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products implements multiple changes which companies are now trying to embrace. The developments specifically address cosmetic products, as well as functions and notification procedures.

Producers will now have to establish a responsible person, and only cosmetic products for which a legal or natural person is designated as the 'responsible person' shall be placed on the market. Responsible persons will be there to ensure compliance with the relevant obligations set out in the Regulation. They will ensure that the finished product is safe, and that good manufacturing practice is in place. They will also monitor product documentation, and coordinate sampling and testing operations. Responsible persons shall also handle all notification-related issues in the EU, and will monitor compliance with the restrictions on raw materials or CMRs, the use of which is limited or entirely prohibited. Responsible persons will also monitor the use of nanomaterials, which have to be notified within the Community, and will make sure that the content of trace impurities poses no risk to human health. There are also provisions prohibiting animal testing. The Regulation also establishes the obligation of proper product labelling, and proof and confirmation of the effect claimed. Responsible persons will be legally obliged to make available the relevant information.

Another function stipulated in the Regulation is that of the safety assessor, who is responsible for the compilation of a cosmetic product safety report. The cosmetic product safety assessment shall be carried out by a person in possession of a university diploma in pharmacy, toxicology, or a similar discipline, and with at least several years of professional experience in the cosmetics industry. Safety assessors are required to regularly follow online databases (Chembank) listing ingredients of cosmetic products. Cosmetic product safety reports should be updated to reflect all amendments to the applicable laws, as well as all modifications in composition, function and packaging, and all other product information.

In the light of the EC Regulation, the role of Safety Assessors is to protect producers as the final link in the chain of legal defence and product security. They also uphold the rights of consumers, acting as independent entities established under the EU law. But first and foremost, Safety Assessors help protect the law and are legally responsible for the cosmetic product safety report.

Under the Regulation, distributors will also have some new responsibilities to fulfil, and will have to ensure that all labelling information is provided, all language requirements are met, and that the date of minimum durability has not expired, if applicable.

Obligations of distributors

Distributors shall ensure that while a product is under their responsibility, storage and transport conditions do not jeopardize its compliance with the requirements set out in the Regulation. They shall also, further to a reasonable request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the product with the requirements listed under paragraph 2 of the Regulation, in language which can be easily understood by that authority. The distributor shall also identify the distributor or the responsible person from whom, and the distributors to whom, the cosmetic product was supplied. This obligation shall persist for a period of 3 years from the date on which the batch of the cosmetic product was made available to the distributor.

Product notification

The product notification procedure will change dramatically. Cosmetic products will now be subject to mandatory notification by electronic means, via the Cosmetic Products Notification Portal (CPNP), by providing data on: the category of the cosmetic product and its name or names, enabling its specific

identification, as well as the name and address of the responsible person where the product information file is readily accessible. The country of origin needs to be submitted in the case of import, along with the Member State in which the cosmetic product is to be placed on the market, as well as the contact details of a physical person to be contacted in the case of necessity. It is also necessary to provide information on the presence of substances in the form of nanomaterials, and the name and number of the Chemical Abstracts Service (CAS) or the EC number of substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR), of category 1A or 1B, and the frame formulation allowing for prompt and appropriate medical treatment.

The responsible person shall notify the Commission of the original labelling, and a photograph of the corresponding packaging shall be provided. The notification obligation shall also rest with distributors who translate, at their own initiative, any element of the labelling in order to comply with national law.

Another important change was introduced in the indications concerning the durability for use of a cosmetic product. Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products there shall be an indication of the period of time after opening that the cosmetic product is safe and can be used without any harm to the consumer. This information shall be indicated, except where the concept of durability after opening is not relevant, by the symbol shown in point 2 of Annex VII, followed by the period (in months and/or years).

Cosmetic product:	Individuals, titles	Substances:
Good Manufacturing Practice – GMP (harmonized standard)	Responsible person Product identification in a supply chain	CMR Nanomaterials
Notification	Obligations of distributors	Lists of ingredients
Labelling, PAO	Safety assessor	
Cosmetic product safety report		

Table 1. List of key new developments introduced with Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products

Changes in production – GMP according to ISO 22716

Changes can be expected in key departments of each and every company operating in the cosmetics industry, and the production departments will be affected most as the new laws implement very detailed and specific requirements in this area. These new developments will be introduced for the first time ever, and will be accompanied by detailed guidelines set out in the harmonized standard ISO 22716, applicable specifically to the cosmetics industry.

Many companies have succeeded in implementing GMP smoothly; other market players were forced to redevelop their infrastructure to fit in with the guidelines. There are multiple new production documents to add, addressing cleanliness issues in individual production areas, as well as guidelines for raw materials, packaging and finished products.

Those companies which have previously implemented and maintained the requirements of ISO 9001 standards will find they have some GMP elements already in place, and will only have to extend and add some new production-related solutions.

EN ISO 22716:2007	EN ISO 9001:2008
A system based on production, control and QA procedures to guarantee that the finished products meet specific quality requirements.	The standard sets out general Requirements intended to be used by all organizations, irrespective of their type, size and the product delivered.
Objective: safe product	Objective: satisfaction of customer requirements
Scope: Production, control, storage and shipment of cosmetic products	Scope: Overall process, including design & development
-	Management review
-	Quality Manual
-	Quality Policy
-	Designated person

Table 2: EN ISO 22716:2007 v. EN ISO 9001:2008

Note that the GMP requirements are primarily focused on business units dealing with the production, control, storage and shipment of cosmetic products. R&D and finished product distribution are outside the scope of GMP. The key guidelines address the following issues:

- staff: each employee should be competent and skilful in the production, control storage and shipment of products of suitable quality.
- premises: all rooms should be properly designed and used to maintain appropriate cleanliness, and to facilitate the storage and protection of semi-finished products and finished products.
- equipment: each piece of equipment should be used as intended; it is important to use equipment which is easy to clean or disinfect:
- raw materials and packaging materials: third-party raw materials and packaging materials should meet specific acceptance criteria corresponding to the quality of finished products.
- production and packaging: measures should be taken at every stage of production and packaging to make sure that the finished product meets specific criteria.
- finished products: should meet specific acceptability criteria. Finished products should be stored, shipped and returned in a manner which guarantees that their quality is maintained.

The documentation of each company should be tailored to the nature of its business activity and to the type of the finished product. There should be a record-keeping system in place in each organization to properly document all measures and actions that refer to the system's implementation and maintenance.

With the growing legal requirements towards producers of cosmetic products, the expectations of final users have also risen in terms of quality and declared compliance with GMP. The guidelines listed in the standard are obligatory, but the certification is voluntary and is the simplest and most convenient way for producers to prove the compliance of their cosmetic products with the applicable legal requirements.

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New regulations will affect the relationship between manufacturers and distributors of cosmetic products

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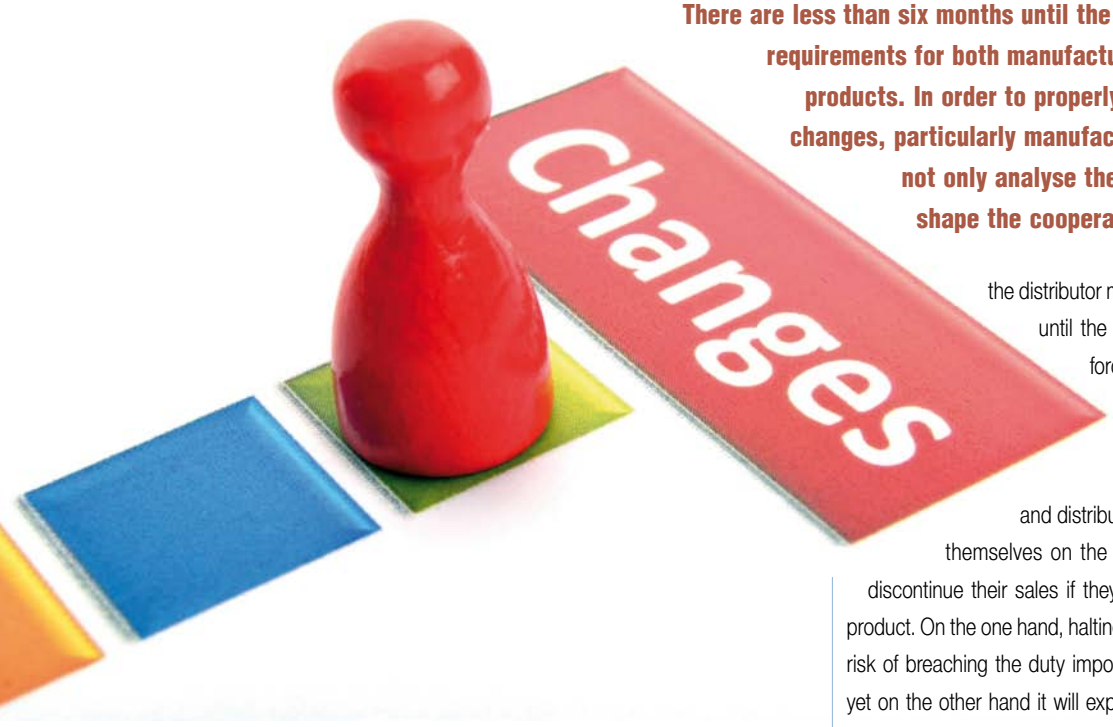
I Domański Zakrzewski Palinka



There are less than six months until the introduction of several new legal requirements for both manufacturers and distributors of cosmetic products. In order to properly prepare their businesses for the changes, particularly manufacturers of cosmetic products must not only analyse their operations but also adequately shape the cooperation with their business partners.

Early morning on 11 July 2013 manufacturers and distributors of cosmetic products will wake up to a new legal reality. The scale of changes is reflected in an increased volume of the regulations. Compared to the current Act on Cosmetics, the new regulation (without annexes) will contain 100% provisions more. The new regulations will not only define the current duties in more detail, but also impose a number of new requirements. The purpose of this article is to present exemplified regulations that significantly affect the relationship between manufacturers and distributors, and to identify solutions to enhance legal safety of the conducted activity.

Halting product distribution

One of the main purposes of the new regulation is to ensure a high level of human health protection. Thus, both the manufacturer/responsible person1 and the distributor must pay attention whether the cosmetic products they offer fulfil the requirements. If the products are found not to comply with the regulations, the distributor must among other things halt the distribution until the products comply with the requirements in force. Such a situation may occur for instance if the packaging indicates incorrect details of the responsible person.

As a result of the duties of manufacturers and distributors being so shaped, distributors may find themselves on the horns of a dilemma whether they should discontinue their sales if they have doubts as to legal compliance of a product. On the one hand, halting the distribution will allow them to avoid the risk of breaching the duty imposed under Regulation (EC) No 1223/2009, yet on the other hand it will expose them to direct financial losses in case of unjustified actions. A decision to halt the distribution will obviously impact the business of the manufacturer. The described problem may prove to be important especially in terms of the relationship between businesses operating in different countries (for example, a French manufacturer selling cosmetic products to a Polish distributor). The practice of the administration authorities in different Member States may differ considerably. The labelling in the Member State of the manufacturer may be regarded by local authorities as correct while in the Member State of the registered office of the distributor it would be questioned, at least initially, which entails additional doubts and risks.

The above issues lead to a conclusion that the existing agreements in the manufacturer – distributor relationship require a detailed analysis or need additional provisions to regulate steps to be taken in case of doubts as to compliance of products with regulations. Consideration should be particularly made of:

- the manner of clarifying doubts whether the cosmetic products being the subject-matter of the agreement fulfil the requirements;

[1] It is worth noting that, in general, for cosmetic products manufactured within the Community (and not exported or imported back to the Community), the responsible person will implicitly be the manufacturer established within the Community unless it designates, by written mandate, another legal person or individual to act as the responsible person. Therefore, all comments on the manufacturer will further on apply to a situation where the manufacturer is concurrently the person responsible for its cosmetic products.

- the arrangements concerning remedy measures to be taken (for example, guidelines defining the acceptable level of interference in product labelling by the distributor); and
- the contractual penalties if the distribution is halted without sound reason.

Serious undesirable effects

Yet another area of changes are the duties relating to all signals about adverse reaction to cosmetic products. The requirements concerning the notification of serious undesirable effects apply to both distributors and manufacturers. Serious undesirable effects must be reported by these entities to competent administration authorities. The scope of information that must mandatorily be reported has been defined broadly since it includes not only information which is known to the entity but also information which may reasonably be expected to be known to the said entity. Such wording leaves a lot of discretion in evaluating whether a given entity fulfilled its duties.

The above problem may easily have relevance in the manufacturer – distributor relationship. Naturally, these two entities exchange a lot of trading information, including information relating to product opinions. This may also include information about events qualified as serious undesirable effects, for example the distributor being notified by a customer about the occurrence of undesirable effects after the application of the product. The source of potential problems may be incorrect communication, for example the distributor sending a communication to the e-mail address of the manufacturer's employee who has been on a long parental leave. There are doubts whether in such a situation the manufacturer could have reasonably been expected to know and thus report a serious undesirable effect? The decision of the public administration authority is difficult to foresee. Measures may however be indicated to mitigate legal risk. For example, one of the solutions would be to draw up relevant clauses to agreements concluded with distributors to provide clearly how to communicate information that may concern serious undesirable effects and which will concurrently obligate the other party to the agreement to act strictly in accordance with the accepted procedure. Once such actions have been taken, it will be much easier to substantiate before the competent authorities that in the analysed situation the entity did fulfil its duties and it could have not been expected to know about the notification of serious undesirable effects.

Personal data protection

The issue concerning the duty to report severe undesirable effects is closely related to yet another area of legal regulations which will become increasingly important for the cosmetic products sector. Information about side effects of cosmetic products communicated by customers will often not be qualified as serious undesirable effects. However, such information will be very often related to the health condition and will contain customer data, such as for instance name and surname, address, e-mail address. This means that in order to process these data, personal data protection requirements will have to be fulfilled. These requirements are very restrictive since often they will concern the so-called sensitive personal data (relating among other things to the health condition). It should be emphasized that the requirements for this type of data are not identical with the requirements when gathering ordinary personal data (for example when filling in consumer questionnaires or marketing forms). It is important to be ready in advance to receive such personal data, by knowing applicable legal requirements and establishing relevant company operating procedures.

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In the manufacturer-distributor contractual relationship, an issue that is also worth noting is the exchange of personal data, particularly sensitive data, which will allow avoiding situations when the processing of information would expose both the disclosing party and the recipient to legal liability. This is particularly important in terms of the sanctions which may be imposed in Poland for breach of personal data protection regulations since the Act on Personal Data Protection sets forth restrictive penalties, including deprivation of liberty.

Sanctions in Poland

Notwithstanding the sanctions under the personal data protection regulations, all parties interested in the cosmetics sector are waiting for the identification of sanctions for breach of Regulation (EC) No 1223/2009. The interest in this matter is understandable, particularly considering the lack of clarity as to interpretation of the duties imposed under new regulations. Apart from the generally described powers of the administration authorities, for instance powers to order withdrawal of a given product from the market, Member States are obligated to establish appropriate sanctions. However, as at the end of January 2013, according to the information from the Office of the Chief Sanitary Inspector Office, work is currently only at an early stage in the legislative process. This means that it is difficult to define precisely at present what sanctions will be established and when they are going to be adopted in Poland.

Summary

In order to fulfil new requirements and meet business targets at the same time, it will be necessary not only to implement changes in one's own company but also to optimally shape cooperation with business partners. In practice, this means that existing procedures will have to be reviewed or new procedures will have to be established. The existing and future agreements with business partners should also be analysed. There are less than six months to take relevant action.

□

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Analyses and recommendations for entrepreneurs regarding the new legal norms for cosmetics can also be found at http://blog.dzp.pl/pharma.

PRODUCT CLAIMS

– CRITERIA AND USE

Laura Błażko
Quality Manager

2013 is important for the cosmetics industry because of the entry into force of Regulation (EC) no. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

Regulation 1223/2009/EC replaces Directive 76/768/EEC implemented by the current Act on cosmetics and will be a new primary regulation applying to the market of cosmetic products.

Product claims are an important part of Regulation 1223/2009/EC, which in article 20 states that:

The Commission shall, in cooperation with Member States, establish an action plan regarding claims used, and fix priorities for determining common criteria justifying the use of a claim.

Criteria for claims which may be used in respect to the properties of cosmetic products will be established in detail in an additional document (another regulation). The document will establish common criteria, and compliance with them will be monitored during controls by market surveillance authorities.

As standard, the claim is any information about a cosmetic product published for marketing purposes and regarding content, nature, product properties, effects, efficacy, etc. The claim can be comprised of elements such as text, images, pictures, signs and pictograms used in product labelling (i.e. on the package, label and attached product leaflet) or in advertising materials (e.g. in points of sale or various media).

Regulations and rules on good market practice equally refer both to individual claims and all information about the cosmetic product, which includes all elements used by companies to provide consumers with information.

Because the cosmetics industry widely uses product claims that serve as the primary marketing tool, to create a competitive edge and encourage consumers to purchase products, regulations regarding claims focus great interest and are closely observed by the manufacturers and distributors of cosmetic products.

Based on the currently developing proposal of the European Commission, claims used with regard to cosmetic products will have to meet the following common criteria:

- Legal compliance;
- Truthfulness;
- Evidence support;
- Honesty;
- Fairness;
- Allow informed decisions.

The common criteria listed above are of equal importance. The common criteria apply to all types of claims.

The document presents the following explanations of the above-listed criteria:

Legal compliance

Claims on cosmetic products should be compliant with all applicable legal requirements and must not be misleading to the consumer. The person responsible for claims should also consider relevant self-regulation systems for marketing communications. Claims which indicate that a product has a specific benefit when this benefit is mere compliance with minimum legal requirements shall not be allowed.

Also, claims that indicate that the product has been approved by an authority shall not be allowed since a cosmetic product is allowed onto the market without any governmental approval. Equally, a CE mark should not be applied on cosmetic products.

The acceptability of a claim should be based on the reasonable expectations of an average consumer in a given market.

Truthfulness

Neither the general presentation of the cosmetic product nor individual claims made for the product shall be based on false or irrelevant information. If the claim states that the product contains a specific ingredient, the ingredient must be present. Claims on ingredients referring to the properties of a specific ingredient should not imply that the finished product has the same properties when it does not. Moreover, marketing information must not imply that the expressed opinions are objective statements, unless the opinion is supported with objective evidence.

Evidence support

Claims for cosmetic products, whether explicit or implicit, must be supported by adequate and appropriate, verifiable evidence regardless of the methodology used to support the claim, including adequate expert opinion. This applies to new or established claims regardless of the type of evidence support.

The responsible person shall determine the appropriate and sufficient methodology to support the claim, and make decisions on the choice of evidence support. Supporting evidence can be of different forms and if necessary has to be included in the product information file.

The responsible person must have appropriate and sufficient scientific evidence to justify explicit or implicit claims. S/he may consult an expert to provide appropriate support. The responsible person must also ensure that the evidence support is still applicable when the product formulation changes. Evidence for claim substantiation has to take into account best practice.

If studies are being used as evidence, they must be relevant to the product and to the benefit claimed, must follow well-designed and well-conducted methodologies (valid, reliable and reproducible), and must respect ethical considerations.

The level of evidence or substantiation should be consistent with the type of claim. A high level of evidence or substantiation is particularly vital for claims where lack of efficacy may cause a safety hazard, e.g. sun protection claims. On the other hand, claims that are clearly exaggerated, and which are not to be taken literally by the average consumer (hyperbole), or abstract statements will not usually need substantiation.

A claim which transfers ingredient properties to the properties of the finished product must be supported by adequate and appropriate evidence, e.g. demonstrating the presence of the ingredient at an effective concentration, etc. The acceptability of the claim should be based on the level of evidence, taking into account all available studies, data and information. Types of

evidence may differ depending on the nature of the claim and commonly available general knowledge.

Honesty

Presentations of a product's performance must not go beyond the available supporting evidence. Neither the general presentation of a cosmetic product nor individual claims made for the product shall imply, by suggested action or by omission, that the product has characteristics or functions which it does not have.

Claims should not attribute to the product specific (i.e. unique) characteristics if similar products possess the same characteristics. If the action of a product depends on specific conditions, for example use with other products, this must be clearly stated.

Fairness

Claims for cosmetic products shall be objective and shall not denigrate the competition, nor shall they denigrate ingredients safely and legally used in cosmetic products. In addition, claims for cosmetic products shall not create confusion with the product of a competitor.

Claims for cosmetic products can be of a comparative nature provided that they are compliant with Directive 2006/114/EC on misleading and comparative advertising, and with national regulations implementing this directive.

Allow informed decisions

Claims addressed to consumers should be clear and understandable to the average consumer, as they are an integral part of products and should provide information allowing consumers and specialists to make an informed decision.

Marketing messages must take into account the capacity of potential users (the population of a relevant member state or part of the population, e.g. consumers of different ages and genders, or professionals) to understand the message. Marketing messages should be clear, precise, relevant and understandable by the target audience.

In addition, the European Commission is developing detailed criteria for other selected types of claims

EU Member States and the European Commission have decided that this will particularly refer to criteria for the use of claims such as «natural» and «organic». For that purpose, the International Organization for Standardization (ISO) is developing an international standard which will be later adopted as a European standard (EN). The new standard will establish conditions to be met by the ingredients of cosmetics or cosmetic products defined as natural or organic. The European Commission is also working on the criteria for claims containing the words "free from..." and health claims.

Marketers of cosmetic products are fully responsible for the compliance of the product with current regulations, including product information. The adoption of new regulations and guidelines will be followed by changes in their enforcement, so manufacturers and distributors should closely analyse these documents, with special focus on the form of the future acts and possible consequences.

The cosmetics industry has exclusive influence on the market depiction that will be presented by the European Commission in 2016, and the potential need for the implementation of additional regulations.

As laid down in Regulation 1223/2009/EC of the European Parliament and of the Council:

Art. 6 (labelling):
The Member States shall take all necessary measures to ensure that in the labelling, making available on the market, and advertising of cosmetic products, text, names, trade marks, pictures or other signs shall not be used to imply that these products have characteristics which they do not have.

Art. 20:
By 11 July 2016, the Commission shall submit to the European Parliament and the Council a report regarding the use of claims on the basis of the common criteria (...) If the report concludes that claims used in respect of cosmetic products are not in conformity with the common criteria, the Commission shall take appropriate measures to ensure compliance in cooperation with the Member States.

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GMP – practical guidelines

Katarzyna Kostrzewa
Consultant Intertek

Batch-to-batch repeatability

Producers are required to prove that each and every batch they produce complies with the requirements listed in the relevant product specifications, and that the production procedures have been observed.
This involves the obligation to keep and supervise records and to run product tests.

The majority of production industries are allowed to accept raw materials based on standardized quality certificates, while in the cosmetics industry the condition precedent is that the testing methods used by suppliers have been accepted in advance, and that the manufacturers of raw materials have been successfully audited. The recipient sets the scope of audit procedures at the production facility, and the supplier is expected to consent to have the audit performed.

Full identification of process and products

Apart from the labelling of raw materials, packaging and finished products, is it necessary to correctly label equipment and premises. Containers in the storage area should be labelled individually – a joint label per palette will not be enough.

- Product status: released / currently tested / non-compliant must be stated on each packaging entered into storage. Apart from the name, the marking of premises should include a cleanliness status: contaminated / during cleaning and disinfection / clean and disinfected.
- Apart from the name and the code, the marking of equipment should include the cleanliness status and the technical status, e.g. date of the last and of the next calibration / adjustment.
- Dedicated procedures should be in place to supervise the functionality and cleanliness of the equipment, and of the measuring instruments in particular.

Control of changes

"Internal organization and scope of tasks related to the planned change of a single or several GMP operations to make sure that all products subject to production, packaging, control and storage correspond to the predefined acceptance criteria."

Changes should be controlled according to the "cleanliness of lines" procedure: The control should take place in-between each subsequent production run, according to a checklist, to make sure that the following items are checked prior to the beginning of subsequent production runs:

- tanks / containers used in the previous production run have been removed
- labels used in the previous production run have been removed so that they cannot be accidentally attached to new tanks and throughout the process
- cardboard boxes have been removed
- finished products made in the last production run have been removed
- documents referring to the previously made products have been removed
- waste bins have been emptied
- measurement instruments have been reset
- all minor equipment pieces used in the previous production run have been removed

Records from precious verifications should be kept. The verification check must be entrusted to another person.

Sampling raw materials

Raw materials can only be sampled by authorized and trained employees, using specific sampling methods. The collected quantity of raw materials should be sufficient to run the scheduled tests and to prepare a counter sample. All due diligence must be exercised while collecting samples to avoid contamination and deterioration of the quality of the raw material. Samples should be properly labelled with: name or code, batch number, sampling date, container ID from which the sample was collected, and the place at which the sample was taken.

It can be difficult to determine the place where the sampling took place, and the best solution would be to arrange for a separate sampling room. Samples should be kept at a dedicated place, under specific conditions.

Quality Control Laboratory

The Quality Control Laboratory is mainly intended for the running of appropriate tests:

- release of materials for use
- testing finished products before they are released for sale

Reagents, solutions, reference standards and culture media should be properly labelled (name, concentration, shelf-life, prepared by, first opened on, storage conditions)

Tests should be performed according to accepted analytical methods. Acceptance criteria should be defined for raw materials, packaging, product mass, and finished products

The test results should be analysed in detail. The causes of non-compliance, if any, should be identified by analysing the process of raw material acceptance, sampling, production and testing. Each re-testing should be reasonably justified

Training

Under ISO 22716 it is obligatory to train all employees working in the cosmetics industry, both in production departments and in administration and management. Training records should be enclosed to and kept in personnel files.

It would be advisable to consider non-obligatory certification for compliance with the ISO 22716 standard. Accredited certification and registration for compliance with ISO 22716 is a token of the company's engagement in the quality and safety of products, and its dedication to continuous development. Certification means the company has implemented and uses an effective production management system that fulfils the strict requirements of an independent external audit. ISO 22716 consolidates the company's image among customers, employees and shareholders. The standard is recognized all over the world, which means that it also makes the company and its brand more recognizable. □

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Modern methods of testing sunscreen products

PASSAGE COSMETICS LABORATORY

Sunscreen products occupy a significant place in the sales statistics of cosmetics for personal care. On the cosmetics market, we can observe a trend towards higher sun protection factors (SPF) in the available sunscreen products. What regulations are sunscreens subject to? How are these cosmetics tested, and what properties must a sunscreen product have in order to meet the requirements of current legal norms?

Apart from the requirements resulting from the Cosmetics Act, from the perspective of the upcoming months one ought to mention further obligations resulting from the entry into force of the Regulation (EC) No. 1223/2009 of the European Parliament and of the Council. As in the case of all cosmetics, this new regulation requires that a number of necessary elements (safety report including a calculated safety margin, information regarding the packaging, surface of application etc.) be added to the dossier of every sunscreen product. It is also necessary to abide by the recommendations of the European Commission from September 22, 2006, document no. 4089, "Commission recommendation regarding the efficacy of sunscreen products and the claims made relating thereto". Further on in this article, when discussing Commission recommendations, the authors will be referring to this document. As the Directorate General for Health and Consumers (SANCO) informs us, the Commission's recommendations are not legally binding, but it is expected that the industry will adopt them because of their significance. Also important is the reference to the relevant articles regarding the safety of cosmetic products placed on the market, as well as claims made about the product. Both the "old" regulations and the new Regulation No. 1223/2009 (Article 20) state that it is forbidden "...to imply that these products have characteristics or functions which they do not have". When interpreting regulations defined in this way, it must be clearly stated that if we wish to place a cosmetic product with a defined sun protection factor (SPF) on the market, the appropriate tests must be carried out first, confirming such a level of protection. In item 16 of the Commission's recommendations from September 22, 2006, the European Committee for Standardisation has been authorised to establish European standards which would allow the determination of the sun protection factor and UVA protection factor of sunscreen products. As a result, over the last 2 years three norms, numbered 24442, 24443 and 24444, pertaining to the analysis of sunscreen products, have been developed and published.

The EN ISO 24444:2010 norm "Cosmetics – Sun protection test methods – *In vivo* determination of the sun protection factor (SPF)" has the status of a Polish Norm since January 2011. This norm is based on the same principle

of SPF determination as the earlier COLIPA guidelines. The test is carried out on healthy volunteers and consists in comparing the minimal erythemal dose of UV radiation for skin protected with the tested product and the minimal erythemal dose for unprotected skin. The norm specifies: the radiation source (a suitable xenon lamp or its equivalent), the criteria for volunteer selection, the amount of product to be applied, the area and skin surface to be irradiated and the interpretation of test results. It is also clearly specified that the study report, apart from the basic product data and the expected SPF value, should also contain accurate information about the volunteers participating in the study (identification code, phototype, age and sex), a description of the UV source, information about the standards used, data regarding the erythemal doses for protected and unprotected skin together with the calculation of means and statistical parameters of the test, as well as the date and name of the person performing the test.

The ISO 24442 norm "Cosmetics – Sun protection test methods - ***In vivo*** determination of sunscreen UVA protection" describes the determination of the UVA protection factor (UVA PF) through tests carried out on healthy volunteers. The principle of the test is very similar to the one described in the PN-EN ISO 24444 norm (***in vivo*** SPF determination). The difference is that the test criterion is not erythema but persistent pigment darkening (PPD) of the volunteers' skin. Furthermore, the UV source, often fitted with a special filter, gives off very low amounts of UVB radiation (the UVB amount cannot exceed 0,1% of the total UV radiation as converted into energy units). This method is now used less and less, since the following norm has been issued:

PN-EN ISO 24443:2012 "Determination of sunscreen UVA photoprotection ***in vitro***". This is an ***in vitro*** procedure – without the participation of volunteers, using special measuring devices and PMMA plates of a defined size and „roughness". The test consists of precisely applying samples of the analysed product on a poly(methyl methacrylate) plate and measuring the light spectrum in the 290-400 nm range before and after irradiation with a dose of UV rays. The paradox here is that the norm title refers to an „***in vitro***" determination, since one must know the sun protection factor determined ***in vivo*** (SPF ***in vivo***) in order to perform the test and carry out all the calculations. Comparing the theoretically calculated SPF***in vitro*** to the actually determined SPF***in vivo*** is necessary to obtain the „C" value needed to correctly calculate the initial UVA protection and the dose of UV with which the plate should be irradiated. The authors of the norm make it clear that the calculated SPF***in vitro*** cannot be presented as the definite result of SPF determination. This proviso is probably due to the Commission's recommendations, which state plainly that procedures which do not require volunteers are to be given priority over ***in vivo*** methods. However, it must be remarked that although nearly seven years have elapsed since the Commission's recommendations were issued, as yet no norm has been developed which would allow the ***in vivo*** method of SPF determination to be replaced with another norm, one which would not require the participation of volunteers.

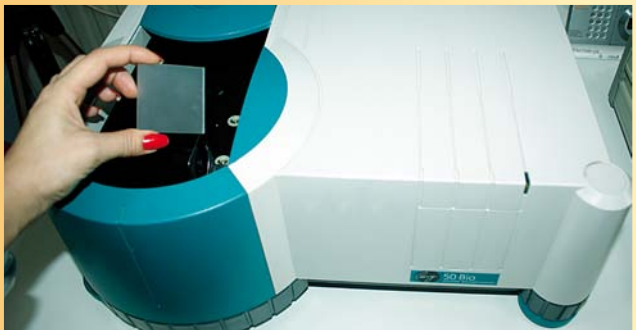
The Commission's recommendations from 2006 also include determining the critical wavelength (at least 370 nm) and assessing the UVA/UVB protection ratio (at least 1/3). The critical wavelength is the wavelength for which the section under the integrated optical density curve starting at 290 nm is equal to 90 % of the integrated section between 290 and 400 nm. Previously, the UVA protection factor (UVA PF) was determined using the method published in the COLIPA guidelines in 2011, entitled „Method for ***in vitro*** determination of UVA

Sample of tested cosmetic is applied on a PMMA plate

protection". The enclosed calculation sheet makes it possible to calculate the critical wavelength and UVA PF. The test procedures described by the COLIPA guidelines and by the PN-EN ISO 24443:2012 norm are very similar, except that the COLIPA methodology also mentions the „critical wavelength" parameter, not included in the norm. This is an important parameter which permits a simple and quick assessment of whether the given sunscreen product will give us sufficient protection not only against UVB, but also against UVA rays.

On the basis of test results gathered using the methods described above, we can label products in accordance with the Commission's recommendations. Four categories of sun protection are distinguished: low, medium, high and very high. The next step is assigning the appropriate sun protection factor (SPF). This factor is assigned on the basis of test results (6, 10, 15, 20, 25, 30, 50 or 50+). It is also necessary to confirm that the product has the required UVA/UVB protection ratio of at least 1/3.

The last important point to be raised is the water resistance of sunscreen products. The testing procedure has been described in the COLIPA booklet „Guidelines for evaluating sun product water resistance". The testing process consists of applying the tested product to the volunteer's skin and, subsequently, two twenty-minute immersions in a spa pool or jacuzzi. The immersion parameters are highly standardised, including water quality and its temperature, no bubbles and no towelling. The two immersions are separated by a 15-minute period of drying time. After the second immersion, the skin is allowed to dry completely, and afterwards the SPF of the product is measured again, using the standard method of SPF determination. The procedure also involves the use of a control water resistant product with a SPF of 12/15. The test results are interpreted as follows: if the SPF after the water immersion procedure is higher than 50% of the initial value, the product is considered water resistant. A stricter test also exists for products labelled as „very water



PMMA plate is inserted into the light path of the spectrophotometer

Exposure of a volunteer during SPF measurement

resistant". It consists of four twenty-minute immersions separated by fifteen-minute breaks. If the SPF after such an immersion sequence is higher than 50% of the initial value, the product can be labelled as "very water resistant".

An interesting and relatively frequently used method of assessing the efficacy of sun protection is the Boots star rating system. This method, last verified in 2008, consists in calculating the UVA/UVB ratio for the tested product before and after irradiation with UV rays. The test is performed using rough PMMA plates and a wavelength-dependent optical density curve is generated in the 290-400 nm spectrum. Afterwards, the ratio of sections under the curve is calculated for UVA (320-400 nm) and UVB (290-320 nm). Each time, the plate is exposed to the same dose of UV radiation (17.5 J/cm2), the equivalent of a ca. 1 hour-long exposure to solar radiation. The optical density spectrum is then measured a second time and the UVA/UVB ratio is calculated. Table 1 shows a list of Boots star ratings depending on the test results.

	Initial UVA/UVB ratio			
UVA/UVB ratio after exposure		0,6-0,79	0,8-0,89	0,9-
	0,57-0,75	***	***	***
	0,76-0,85	***	****	****
	0,86-	***	****	*****

Obviously, one- and two-star products are missing from the table. This is because of the recent changes in the recommendations regarding the minimal protection offered by sunscreen products. Since the requirements have been elevated, one- and two-star products are, in practice, no longer treated as sunscreen products at all.

Also worth mentioning are the so-called SPF calculators. These special programs make it possible to calculate the basic parameters (SPF, UVA/UVB) of a sunscreen product based on the percentage of individual ingredients functioning as UV filters. These calculations are often confirmed in *in vivo* studies and form a good basis for the actual SPF measurements.

Conclusion

Although new norms have appeared in recent years with the aim of facilitating the testing of sunscreen products, we still lack an effective *in vitro* method which would require neither the use of complicated apparatus nor the participation of volunteers. Also lacking are clearly formulated and valid legal regulations regarding the labelling and testing of cosmetic sunbathing products.

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Translation by: www.besttext.pl

Stem cells – what are they?

Should people be afraid of them? Where are they applicable in contemporary cosmetology?

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Microscopic stem cells have given rise to a huge and constantly growing debate. A number of people consider studies on stem cells as a key solution to a series of treatments, e.g. cancer therapies, organ cultures and immune system repair. However, others regard them as the opening of Pandora's Box, which will depreciate human life.

– Thomas Scott Christopher

Stem cells – an issue talked about by every scientist or person associated with the medical and biotech sectors, or genetic engineering. Certainly, the quotation from a book by T.S. Christopher entitled "The time of stem cells. A brief introduction to the forthcoming medical revolution" perfectly describes the atmosphere accompanying the phenomenon of stem cells. In fact, is this a breakthrough that will improve the quality of human life, or will it turn out to be a dead end in the struggle for youth? It is hard to answer the question now and, in reality, time alone will tell us whether following this pathway has been a good choice. One cannot indiscriminately opt for any of the two options since every For and Against hides inside itself a grain of truth. Indeed, let us define more precisely what stem cells are, how they work, and where they can be applied.

Stem cells are cells that possess two features essential for the human organism, i.e. a capacity for proliferation and differentiation. Due to their massive proliferative potential, stem cells are able to undergo an unlimited number of divisions. This leads to the condition in which the human organism is able to regenerate on its own. The differentiative ability enables the stem cell to gain vital functions needed for normal functioning of, and building, a given organ in which it is present. The stem cell proliferative potential can be divided into several subtypes, namely:

- Totipotent – capable of developing into any cell type present in an organism
- Pluripotent – capable of transforming into any other cell type present in an organism except for a placenta cell
- Multipotent – capable of initiating the development of several cell types of similar properties and embryonic origin
- Unipotent – capable of generating only one type of cells; they are precursors

With regard to their origin stem cells may be divided into two groups:

- Embryonic Stem Cells (ESC)
- Somatic stem cells, which are present in the tissues of adult organisms

The cosmetics industry is involved mainly with stem cells found in the basement membrane of the epidermis, in the dermis, and in totipotent plant cells. Due to ethical aspects, contemporary European law prohibits the use of cells and tissues of human origin in cosmetic products. Fortunately, biotechnology has coped with this problem by using plant-derived cells. Each part of a plant, i.e. stem, leaves, flowers and seeds, are formed out of stem cells originated from a small connective tissue located at the apical end of the stem. Contrary to animal organisms, all plant stem cells exert totipotent effects. Given that, a plant can develop itself over years, maintaining regenerative properties in each of its organs. In order to make the most of the potential accumulated in the stem cells, a technology allowing for their multiple divisions ought to be implemented. Tissue and cell cultures serve this purpose. However, frequent misleading associations of both these culture types as a unity have

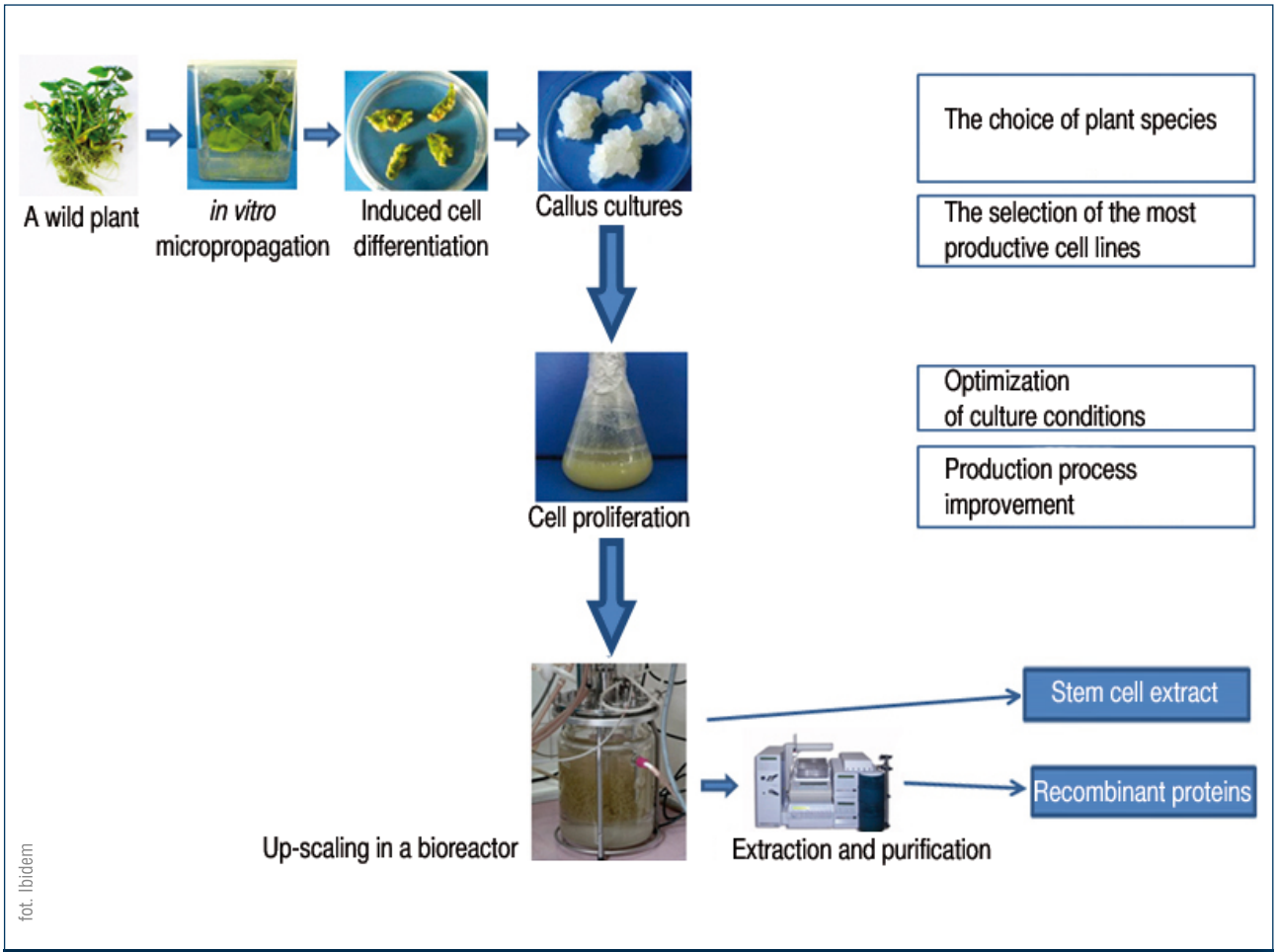

Figure. 1. Schematic diagram presenting the generation of plant stem cells

been reported. Specifically, the tissue cultures should be attributed to spatial cultures, i.e. organ cultures, cell and tissue models and constructs, aggregate cultures and spheroids. On the other hand, the cell cultures cover cultures of dispersed cells in primary cultures, in monolayer cell system cultures, as well as in suspensions. There are many techniques used for the multiplication of stem cells, and even a brief description of all of them is unfeasible within the scope of this paper.

Undoubtedly, micropropagation is one of the key methods used for the multiplication of pure plant tissue cultures. This is an ***in vitro*** technique used for massive vegetative reproduction of plants. The advantage of this technique is its high reproduction ratio, as well as the genotype and phenotype homogeneity of the offspring. Owing to isolation and the fact that the process is carried out under sterile and pathogen-free conditions, the standardization of traits among plants is extraordinarily precise.

There are a number of micropropagation types, with the main ones as follows:

Shoot tip culture – the growth of shoot tips, the formation of a root, and, finally, the adaptation to ex vitro conditions occurs

The stimulation of lateral bud development – stem nodes play the role of explants. Due to the isolation of stem nodes, the dormant lateral buds stimulate plant regeneration (growth renewal) and shoot formation. This method is based on an organized ***in vitro*** development, which was ascribed to them as early as at the ***in vivo*** stage.

Indirect shoot organogenesis – this is manifested by the differentiation and multiplication of explant cells with the formation of callus followed by plant reconstruction.

A general schematic representation can make the whole process more easily understandable (Fig. 1).

The use of stem cells in the cosmetics industry

Certainly, the properties of plant stem cells are highly desired in the cosmetics market. The cosmetics industry places its faith and makes great plans as to their ability to regenerate and differentiate themselves. Cosmetic products based on simple chemical compounds cannot meet numerous clients' demands any more. Youthfulness and beautiful appearance are issues desired by everybody and everybody would do their best to find a method of putting the clocks back even a little. Plastic surgery and dermocosmetic procedures are quite expensive and, by their invasive nature, bear a high risk. The use of totipotent cells' inert power in cosmetic products constitutes a competitive option contrasted with a scalpel. However, in order to play their role, stem cells require a special storage technique until they come into contact with human skin.

In the case of cosmetic preparations, stem cells, generated as a result of micropropagation, are exposed to high pressure. The next step is based on cell membrane digestion resulting in cell breakdown, followed by the release

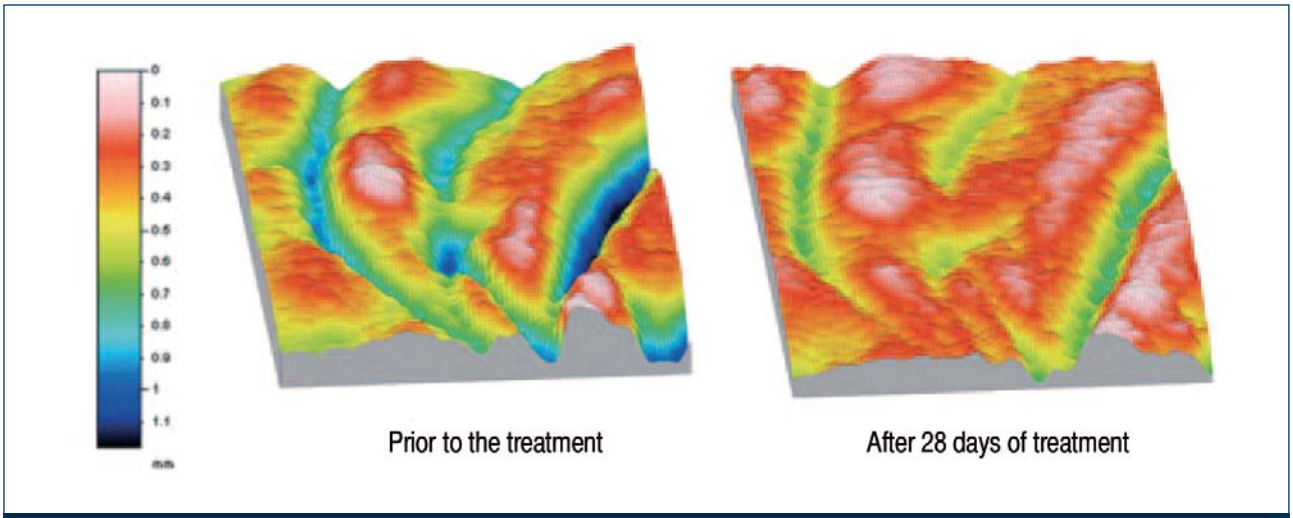

Figure 2. 3-dimensional photographs presenting the diminution of wrinkles after a 4-week treatment

of its contents into the milieu. At the end, the final product is encapsulated in liposomes, resembling a water bubble surrounded by a double phospholipid membrane. Because of that, the stem cell contents can easily be introduced into the cosmetic emulsion.

The penetrative ability of a liposome is strictly correlated with the particular plant species from which stem cells have been harvested. For instance, liposomes containing hyaluronic acid originated from algae stem cells would penetrate into the dermis. In contrast, liposomes containing ginseng stem cells would penetrate into the basal membrane of the epidermis in order to stimulate reparatory processes and normal keratinisation in there.

In order to prove the efficacy of stem cell use in cosmetic products, clinical tests were conducted with the participation of twenty volunteers for four weeks. A preparation containing a 2% extract obtained from apple stem cells was applied onto the region of so-called crow's feet. Depth of wrinkles was studied with the use of the PRIMOS system. Measurements were taken after two and four weeks (Fig. 2). Also, photographs were taken that visualized the pre- and post-treatment depth of the wrinkles (Fig. 3).

As you can see in the above images, the efficacy results in the case of products containing plant stem cell extracts speak for themselves. Considerable wrinkle smoothing and complexion lightening are easily perceivable.

Regardless of a common use, either in medicine or in cosmetology, stem cells still cause a lot of controversy. Biotechnology, including genetic engineering, is becoming a more and more intrinsic aspect of our lives. Bearing in mind the present rate of development, such a state is inevitable. Mechanisms connected to the presence of these cells in human organisms still need to be elucidated. Nevertheless, contemporary studies on them shed a positive light on their future.

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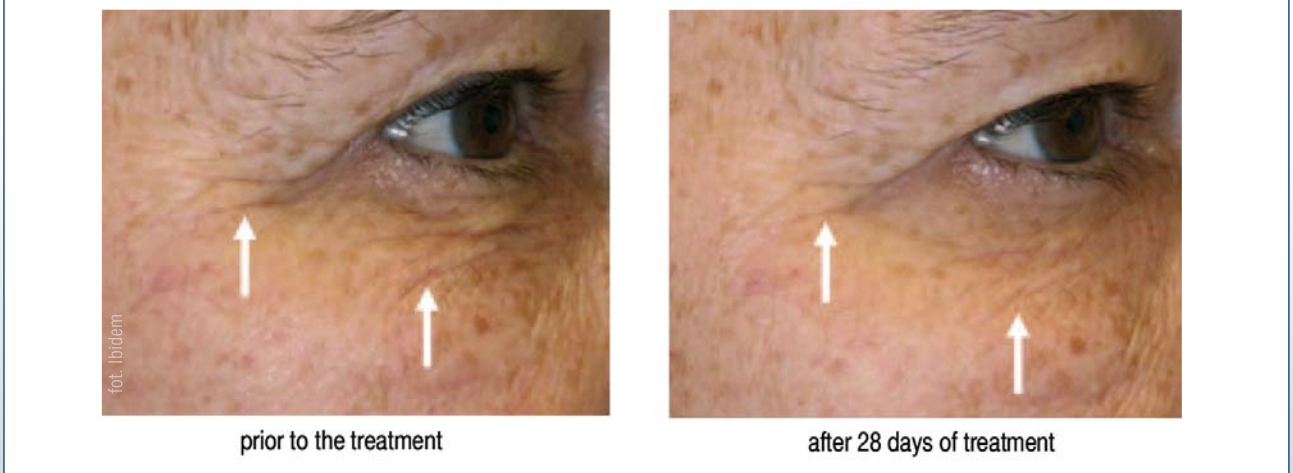

Figure 3. Pre- and post-treatment volunteer's photographs

EVELINE COSMETICS

is the biggest Polish producer and exporter of cosmetics. Within last **30 years** the company has developed strong position in over 70 countries all over the world. It offers wide range of make-up, facial and body daily care products to its clients.

In the process of cosmetics production latest achievements of worldwide cosmetology are used. Familiarity with consumers' needs, products innovativeness and balanced price-quality ratio decides on the brand's strong position on the market. The brand's strength is proved by annual total sale of almost **70 million pieces of cosmetics**, where 80% out of it is exported.

EVELINE COSMETICS

celebrating 30 years

we create the beauty of your skin

EVELINE COSMETICS gained clients' trust through the years of experience, high quality of products and guarantee of effectiveness. It is a modern company responding quickly to markettrends, consumers' needs and expectations.

The line of comprehensive anti-cellulite, slimming and shaping silhouette cosmetics – **Slim Extreme**, the leader in sales of cosmetics in its category*, was the unchallenged sales hit within the last few years.

An innovative series ***bio*Hyaluron 4D** has also gained a strong market position since it was launched. It owes its success to unique formula, combining the effects of hyaluronic acid and plant stem cells.

Following global trends, Eveline Cosmetics laboratories developed multifunction **BB creams**.

Blemish Base series combines the advantages of care cream and foundation.

Creams from **Diamonds & 24k Gold™** series are the real „touch of luxury". Formulas rich in 24-carat gold and real diamond. Clients all over the world love this cream for its innovativeness.

Professional nail treatments **Nail Therapy** and **Art Scenic** line of facial make-up cosmetics are also produced by Eveline Cosmetics.

BLACK men's line is the novelty on Polish market. Technologically advanced formulas with original French fragrance ensure immediate and comprehensive skin regeneration after shaving.

*Nielsen, May – June 2012, anti-cellulite and slimming cosmetics.

www.eveline.eu www.slimextreme.eu

20th anniversary of the Polish Association of Cosmetics and Home Care Products Producers

The Polish Association of Cosmetics and Home Care Products Producers, the only Polish organization in its sector operating based on the synergy of the cosmetics and home care products industries, has a twenty-year-long history!
The Association celebrated this important anniversary on 14 December 2012 at the Primate's Palace in Warsaw.

The mission of the Association is to promote, develop and protect the interests of the cosmetics and home care products industries in Poland.

Members of the Association receive:
- support when facing unjustified restrictions
- information necessary to comply with legal and administrative obligations
- facilitation in the execution of everyday professional duties
- help in crisis situations
- individual advice from experts

The Association is an organization with a real influence on European Union and Polish legislative processes. It has been actively operating in the EU forum as a member of European organizations such as AISE and Cosmetics Europe, and as a participant in the expert groups of the European Commission. It prevents unjustified restrictions that may be experienced by the industries, and carries out educational activities.

The celebration of the 20th anniversary of the Association was held under the auspices of the following institutions:
- Ministry of the Economy
- Bureau for Chemical Substances
- Our Earth Foundation
- EPS Media Publishing House, publishing the bimonthly „Chemia i Biznes"
- Farmacom Publishing House, publisher of the quarterly „The World of the Cosmetics Industry."

This was an excellent opportunity to recapitulate two decades of operation and to discuss the challenges which are faced today by the cosmetics industry, and producers of home care products and biocides.

The celebration gathered Members of the Association, Chief Executive Officers from the member companies, representatives of administrative

authorities, the media, experts from the cosmetics and home care products industries, and partners and friends of the Association.

The honoured guest, Mr. Jerzy Majchrzak, Director of the Department for Innovation and Industry at the Ministry of the Economy, added splendour with his speech to celebrate the Association's anniversary.

Anna Oborska, General Director of the Association, gave a brief presentation of the past years of its operation. Among the many achievements of the Association, special attention was drawn to the model of cooperation that was successfully worked-out over all those years. Today, the Association is a special platform on which market competitors can safely exist by following partnership rules. Another milestone was the previously mentioned presence of the Association in European institutions, such as Cosmetics Europe (the Association is a member of the CE Board), A.I.S.E. and the European Commission. Special emphasis was put on the fact that direct participation in expert groups of the European Commission offers an exceptional chance to put forward initiatives of the Association to the EC without an intermediate party, and it also keeps the Association updated in terms of risks to the industry resulting from changing legislation, and such information is passed directly to member companies.

Over the 20 years of its operation in the market, the Association has become an opinion-making and expert body. The anniversary celebration was also an opportunity to talk about training, workshops, publications and cooperation with the media.

The presentation of a film about the Association, showing future but also the present activities of the Association, was an important moment of the anniversary celebration.

During the ceremony, Ms Lidia Wąsowicz, General Director at the Bureau for Chemical Substances, read a letter of congratulations from Inspector Jerzy Majka. In his letter, Mr Majka underlined the vital role of the Association as a representative of a large group of cosmetics and home care products producers in establishing legislation, and he also expressed acknowledgement of the cooperation between the Bureau and the Association. „For us you are a model Association which almost perfectly represents the interests of the industry in contacts with our bureau... Your remarks have many times been taken into consideration during talks held at an international level," said Inspector Majka in his letter.

At the ceremony the Association had the privilege to host guests and listen to lectures from leading experts in the cosmetics and home care products industries, including those representing administrative authorities and the scientific environment. Presentations on the past and future of the cosmetics and home care products industries were given by:

- Dr. Chris Flower – member of the Board for Cosmetics Europe, Director-General of the CTPA, „Trends in the cosmetics industry"
- Valérie Séjourné – Director for Communications Affairs at AISE, „Sustainable development as a chance for the future"
- Dr. Andrzej Kalski – Bureau for Chemical Substances „Product safety in the past and today – what we are aiming at"

One of the key moments of the ceremony was acknowledging people with special merit in the Association, i.e. former Presidents of the Board. Distinctions were given by Hanna Jabłońska, who is current President of the Board, to Krzysztof Studziński, Irena Gadomska and Małgorzata Wadzińska.

For more information about the activity of the Association visit our website www.czystepiekno.pl

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Selecting and verifying methods of neutralization of antimicrobial properties of cosmetics

Piotr Nowaczyk, Dorota Merlak
Argenta Mikrobiologia Sp. z o.o. Sp. K.

The microbiological purity of cosmetics constitutes a serious problem for the cosmetics industry, as many raw materials used in cosmetic products are an ideal growth medium for microorganisms. The presence of microorganisms results in lower quality of the products, alters their properties, and poses a health risk to their users.

Prevention of microbiological contamination of cosmetics is achieved by adding appropriate preservatives to the product's formulation. The antimicrobial properties of the formulation should always be taken into account in microbiological assays of the product by selecting and verifying the methods of neutralization of these properties. Only once these requirements have been met may all the necessary tests checking the quality criteria of the product be conducted.

Types of preservatives and neutralizers used in cosmetic products

Preservatives are chemical substances endowed with microbiocidal or microbiostatic activity, which inhibit the growth of bacteria, yeasts and moulds, and significantly delay the process of deterioration of the quality of the product. Higher preservative concentrations used against microbes increase the microbicidal effect. The main role of preservatives is protecting cosmetic products from harmful microbial activity, starting from production, through storage, transportation and use [1, 3, 4]. It is vital that preservatives be used only to protect cosmetic products and not to solve production problems.

The choice of preservative or preservation system should not be random or based mainly on the reliability of the company providing the producer of cosmetics with preservatives, but should instead be based on the knowledge possessed by the formulation developer and the microbiologist. The type of physicochemical properties of the cosmetic, active substances among its ingredients, other ingredients exerting microbiostatic activity, as well as package type and estimated expiry date should all be taken into consideration.

There are many chemical substances used as preservatives. The chemical structure of the preservative used is less important than its mechanism of action, which is based on microbial protein denaturation and inhibition of the activity of microbial enzymes. Some of these preservatives, such as alcohol, quaternary ammonium compounds, phenols, acids and their salts, interact with plasma membranes, while isothiazolines, aldehydes, mercury and halogen derivatives react directly with cellular components. The compounds exert various types of antimicrobial activity against Gram-positive and Gram-negative bacteria, as well as yeasts and moulds, and thus preservatives used in the formulation often act synergistically, leading to a combined antimicrobial effect [1].

In microbiological studies aimed at selecting and verifying the method of neutralization of the antimicrobial properties of a cosmetic, the type of preservative used in the studied cosmetic is of great importance. Knowledge of the preservatives used in the formulation [1, 3, 4] helps to establish the range of action of the chemical compound used to neutralize the antimicrobial properties of the preservatives. The ISO standards currently in force [2, 5–10] contain appropriate annexes with lists of preservatives and their respective neutralizing agents necessary for the neutralization of the antimicrobial activity of these preservatives, and are shown as an overview in Table 1.

Selecting and verifying methods of neutralization of the antimicrobial properties of a cosmetic

Proper selection and verification of the methods of neutralization of antimicrobial properties of a product is of critical importance in the entire procedure finally leading to product release and introduction on the market. The published ISO standards [2, 5–10] regarding microbiological assays for each type of microorganisms describe the two stages of an assay. Stage one includes culturing of the assayed formulation on a non-selective broth medium in order to allow the microorganisms to multiply while avoiding the risk of growth inhibition by the ingredients of selective differentiation media. The enriched broth medium used may contain neutralizers if the assayed sample exhibits antimicrobial properties. However, in such a case the efficacy of neutralization should be demonstrated. Stage two, the proper isolation of microorganisms, should be conducted on a differentiation medium and be followed by identification of the studied microorganisms. It is critically important to neutralize the effect of any possible growth inhibition against microorganisms present in the sample in order to enable detection of live microorganisms. Regardless of the adopted procedure, neutralization of the

antimicrobial properties of the product should always be verified and validated [2, 5–10]. All procedures should comply with the general guidelines defined in the PN-EN ISO 21148:2009 standard [6].

Selecting and verifying the methods of neutralization of antimicrobial properties of the product should be based on a correctly performed validation using inocula of test strains at correct cell densities. The lists of test strains indicated for the assays can be found in appropriate standards [2, 5–10]. Guidelines in force [2, 5–10] indicate the correct method by which to prepare properly calibrated suspensions of test strains [6 — Annex C]. The correctness of preparation of appropriate inocula at a defined cell density must always be verified by culturing the suspension on a solid medium using the pour-plate technique and counting the colonies that grow. When using commercially available ready-to-use preparations of test strains at predefined cell densities (confirmed by appropriate certificates), it is vital to always follow the instructions provided by the producer. Using ready-to-use preparations significantly shortens the time of cell suspension calibration. When using commercial suspensions, a max. 3rd passage should be introduced into the sample.

The validation test involves the concurrent preparation of two sample types: validation and control samples. According to the standards in force [2, 5–10], the validation sample should contain the tested formulation (1g or 1 ml), a specific volume of validated broth medium with neutralizer, and 0.1 ml of diluted test strain suspension at a density of 100–500 CFU/ml (10 to 50 CFU per 1 ml or 1 g of product) [5, 7 (section covering the detection of mesophilic aerobic bacteria), 8–10] or 1000–3000 CFU/ml [7: section covering the estimation of the number of mesophilic aerobic bacteria] (100 to 300 CFU per 1 ml or 1 gram of product). When filtration is employed, at least 1 g or 1 ml of the tested product should be filtered, followed by the transfer of the filter to a tube (flask) containing validated broth medium. The control sample should contain 1 g or 1 ml of the tested product and a specified volume of validated broth medium with neutralizer. After incubation at an appropriate temperature for an appropriate time, the cultures should be passaged to selective media (dedicated to specific microorganisms and defined by the standards in force [2, 5–10]) and, after reincubation in appropriate conditions, the results of the obtained microbial growth should be interpreted. Interpretation of validation results includes several issues. First of all, it is necessary to confirm that the initially calibrated microbial suspension used in the test contains the correct number of CFU/ml after dilution. A correct neutralization process and detection of microorganisms is confirmed when a microorganism-specific growth is obtained on the validation plate, but no growth of the tested microorganisms is observed on the control plate. Neutralization and detection of microorganisms are also considered validated when bacterial growth is observed on both the validation plate and the control plate, but this indicates product contamination. If no growth on the validation plate occurs, the product still exerts its antimicrobial activity, which indicates the need for modifying the assay by increasing the volume of broth medium while maintaining the initial amount of the product, by introducing a sufficient amount of neutralizer to the medium, or by combining both procedures, which would allow microbial growth. If the isolation of microorganisms is not possible even when a higher neutralizer concentration is added and a greater volume of enrichment broth medium is used, this indicates that the tested formulation is probably not susceptible to contamination with a given microorganism. It is important to include all information regarding the methods, neutralizing agents and validation procedure applied in the study report.

Preservatives	Chemical compounds capable of neutralization of the antimicrobial activity of preservatives
phenol derivatives: parabens, phenoxyethanol, phenylethanol etc., anilides	lecithin, polysorbate 80, oxyethylenated fatty alcohols, nonionic surfactants
quaternary ammonium compounds, cationic surfactants	lecithin, saponin, polysorbate 80, sodium dodecyl sulfate, oxyethylenated fatty alcohols
aldehydes, formaldehyde releasers	glycine, histidine
oxidizing compounds	sodium thiosulfate
isothiazolinones, imidazoles	lecithin, saponin, amines, sulfates, mercaptans, sodium hydrogen sulfate (IV), sodium thioglycolate
biguanides	lecithin, saponin, polysorbate 80
metal salts (Cu, Zn, Hg), organomercury compounds	sodium hydrogen sulfate, L-cysteine, thiol compounds, thiolglycolic acid

Tab. 1. Agents neutralizing the antimicrobial activity of preservatives [ref. 2, 5–10]

Conclusions

Developing the final formulation of a cosmetic requires extensive knowledge and labour. In the preparation of a cosmetic, as well as its monitoring during production and use, microbiological assays conducted by the producing company or commercial quality control laboratories are of critical importance. The assays cover many aspects of the product. One of them is the discussed correct selection and verification of the methods of neutralization of antimicrobial properties of a cosmetic. In conclusion, correctly conducted microbiological tests are the foundation for a quality product and its safety for end users.

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List of methods used for preservative effectiveness testing

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There are many methods used for this purpose, e.g. the disc diffusion method or the microdilution method. They have been precisely designed for antimicrobial susceptibility testing, but after modifications can also be use for testing preservatives. These techniques, when modified according to recommendations by EUCAST, can also be used for testing the declared effects of cosmetic products, including certain properties, e.g. skin cleansing.

Cosmetics, first of all, have to be gentle and safe for the skin, as well as have efficient action against pathogens as they are a perfect growth medium for them. Cosmetic products have to be free from pathogenic microorganisms, not only immediately after manufacture but also during the entire shelf life. It is vital to meet these requirements, otherwise the quality of cosmetics may deteriorate, and also the product may cause serious infections in humans. These quality standards can be met using various preservatives. The correct determination of preservative concentration is very important, as excessive doses may have negative effects on human health. Preservatives may cause allergies which can lead to other serious conditions. Therefore, the amount of preservative added should be as low as possible, but should ensure the antimicrobial effect of the substance. However, the effectiveness of the preservative depends on many factors, such as the presence of other ingredients in the cosmetic product, storage conditions and package type. For this reason the effectiveness of preservatives has to be confirmed by many individual tests. Thus, which method is better if we consider such aspects as cost-effectiveness, short time and simplicity of procedure?

The disc diffusion method

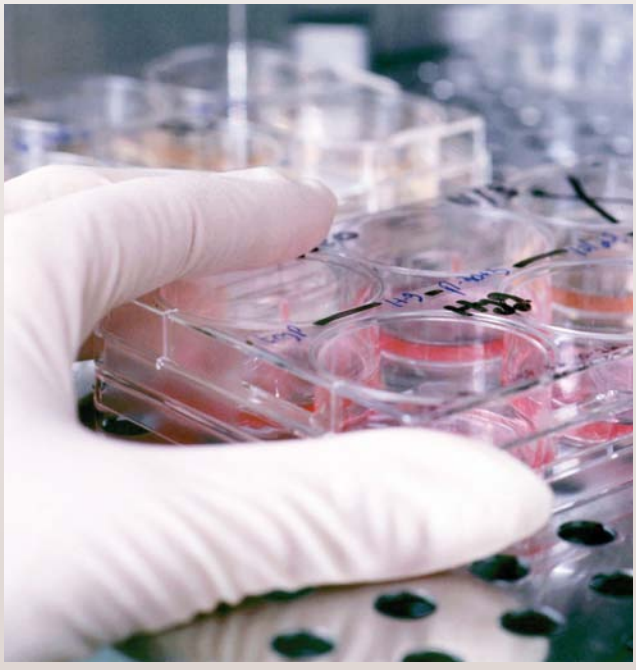
Is also known as the Kirby-Bauer protocol (to commemorate the scientists who standardized it). Many organizations appreciate the advantages it offers. Most often this method is used for testing drug resistance. The method relies on the diffusion of the product applied on a disc to the medium. The growth inhibition zones are visible around the disc. The concentration of the test substance decreases with the increasing distance from the application site. It has been assumed that the bacterial susceptibility to a given product

Size of growth inhibition zones for *Staphylococcus aureus* ATCC 25923

Size of growth inhibition zones for *Klebsiella pneumoniae* (196)

Factor	Effect of factor on the final test result
Turbidity of inoculum	• Optimum turbidity: 0.5 on the McFarland scale (might be higher for certain bacterial species); • Turbidity too low: due to microbial susceptibility, the growth inhibition zone will be larger than it should be; as a result the wrong strain description may be given (resistant bacterial strains may be categorized as susceptible); • Turbidity too high: similar to the description above – the growth inhibition zone will be smaller than it would be in the correct experiment (susceptible bacterial strains might be categorized as resistant).
Incubation temperature	• Optimum temperature: 35°C (EUCAST guidelines recommend ±1°C tolerance); • Temperature too low: the growth inhibition zone will be larger than it should be because of the need for longer incubation time.
Incubation time	• Optimum time: 16-18h (in special cases read-out can be done after 6 h, but the result should be confirmed after the required time has elapsed).
Preparation technique	• EUCAST recommends following closely the "15-15-15 minutes" rule, which means that the application of microbial suspension on a disc, the application of discs and the beginning of incubation should be done in 15-minute intervals. If this rule is not followed and intervals are extended, growth inhibition zones of microorganisms may be formed incorrectly.
Thickness of agar growth medium	• Optimum thickness: 4 mm, it has been assumed that this requires pouring 20 cm3 of medium onto a plate through a special pump. • Medium layer too thin: the size of the growth inhibition zone might by larger than it should be; • Medium layer too thick: similar to above – the size of the growth inhibition zone might be smaller.
Application and number of discs	• Optimum: it has been assumed that not more than 5 discs should be applied on a 9-10 cm diameter plate. When discs are applied correctly the unacceptable overlapping of growth inhibition zones and malformation of zones on the plate margin is avoided. Otherwise, the read-out might be difficult or result interpretation incorrect. • Paper discs are chosen according to the recommendations by the National Consultant for Medical Microbiology.
Amount and concentration of substance applied on a disc	• The size of the inhibition zone depends on the concentration of tested substance on the disc. Discs can absorb a limited amount of substance. The concentration of antibiotic in discs used in the EUCAST methodology is provided in method descriptions and tables for limit values of susceptibility to drugs. Discs with a different concentration of antibiotic should not be used. If the method is modified for the purpose of testing preservative effectiveness, the substance that is present on the disc and provided on the list published by EUCAST should be used as a reference standard.
Composition of growth medium	• Standard: Mueller-Hinton agar (M-H) with supplementation depending on the culture, e.g. blood for streptococci. • Growth medium is decisive for the growth scale of microorganisms, rate of diffusion and activity of the tested product. EUCAST does not recommend any specific manufacturer of M-H agar.
Read-out method	• Correct (according to recommendations by EUCAST): zones should be read from the back of the plate against a dark background and illuminated with reflected light, with the plate held 30 cm from the eye.

Tab.1. The effect of various factors on the correct performance in the disc diffusion method



is directly proportional to the size of the microbial growth inhibition zone. The effect of individual factors on the disc diffusion procedure is presented in table 1. Current recommendations that apply in Poland can be found on the website of the National Consultant for Medical Microbiology.

Microdilution test

This is one of the first-choice methods and is used to determine the lowest concentration of product that will inhibit bacterial growth - the minimum inhibitory concentration (MIC). The method involves the preparation of a serial increasing dilutions of the tested substance in liquid medium (Mueller-Hinton), to which a relevant inoculum is added and incubated at a pre-defined temperature for a specific time (24h). The ISO standard for the MIC method defines the temperature range of 34-37°C. Reading is carried out based on macroscopic evaluation of test tubes for the growth of microorganisms in the form of turbid suspension.

The lowest concentration of substance in the test tube in which no microbial growth is observed defines the MIC value expressed in mg/l. Usually, when determining the MIC value, two parallel replicates are prepared, and if results

Disc diffusion method		Microdilution method	
Advantages	Disadvantages	Advantages	Disadvantages
standardized method – results are interpreted based on criteria published by EUCAST – easy interpretation by different microbiologists;	some tested substances poorly diffuse to agar.	quantitative result can be obtained;	labour- and time- consuming method – routine preparation of serial dilutions of tested substance for each test;
repeatable method;		reading based on visual evaluation;	relatively large space is required to carry out test for a single strain.
fast procedure.		precise method.	

Tab. 2. Overview of discussed methods

are inconsistent, the protocol is repeated until identical results are obtained. As in the disc diffusion method, the performance of the microdilution test depends on inoculum turbidity, growth medium composition, amount of added product, and incubation time and temperature. However, the volume of the liquid medium in a test tube (minimum 2 ml) should be considered instead of the thickness of the agar medium, and the amount of substance added to the first test tube instead of the amount of substance applied on the disc. As mentioned before, the MIC value indicates the minimum concentration of the product that will inhibit bacterial growth, and this means that bacteria are still able to regenerate. If we want to determine the minimum concentration of the product that will kill 99.9% of microorganisms (MBC - Minimum Bactericidal Concentration), we should use a solid M-H medium instead of a liquid medium. In this method we can use the results and dilutions obtained for the determination of the MIC value.

Both methods have advantages and disadvantages

As presented in table 2. Although semi- or fully-automated techniques are more and more frequently used, the techniques discussed above still enjoy great popularity. This is because of their availability, flexibility, and the relatively low cost of the experimental procedure – the tests can be carried out in almost any laboratory as they do not require specialist equipment and reagents. Results obtained with both methods should be correlated, but they are not always. We should remember that when choosing any method we have to focus mainly on the precision, reliability and repeatability of results. In the microdilutions method it is very easy to make a laboratory error when preparing subsequent dilutions, and this can result in the lack of repeatability of results. On the other hand, in the disc diffusion method there is low probability of a human error with a significant effect on the final result. Both methods require manual handling, but the microdilution method is more labour- and time-consuming. Moreover, it requires more space, both when preparing serial dilutions and incubating samples. Testing the susceptibility of a single strain in two replicates requires a whole set of test tubes, while in the disc diffusion method the substance can be tested using a single plate. Qualitative results can be obtained in both methods, but the microdilution method is more useful when there is a need for quantitative results. Considering the time needed for the procedure, the disc diffusion method is more convenient.

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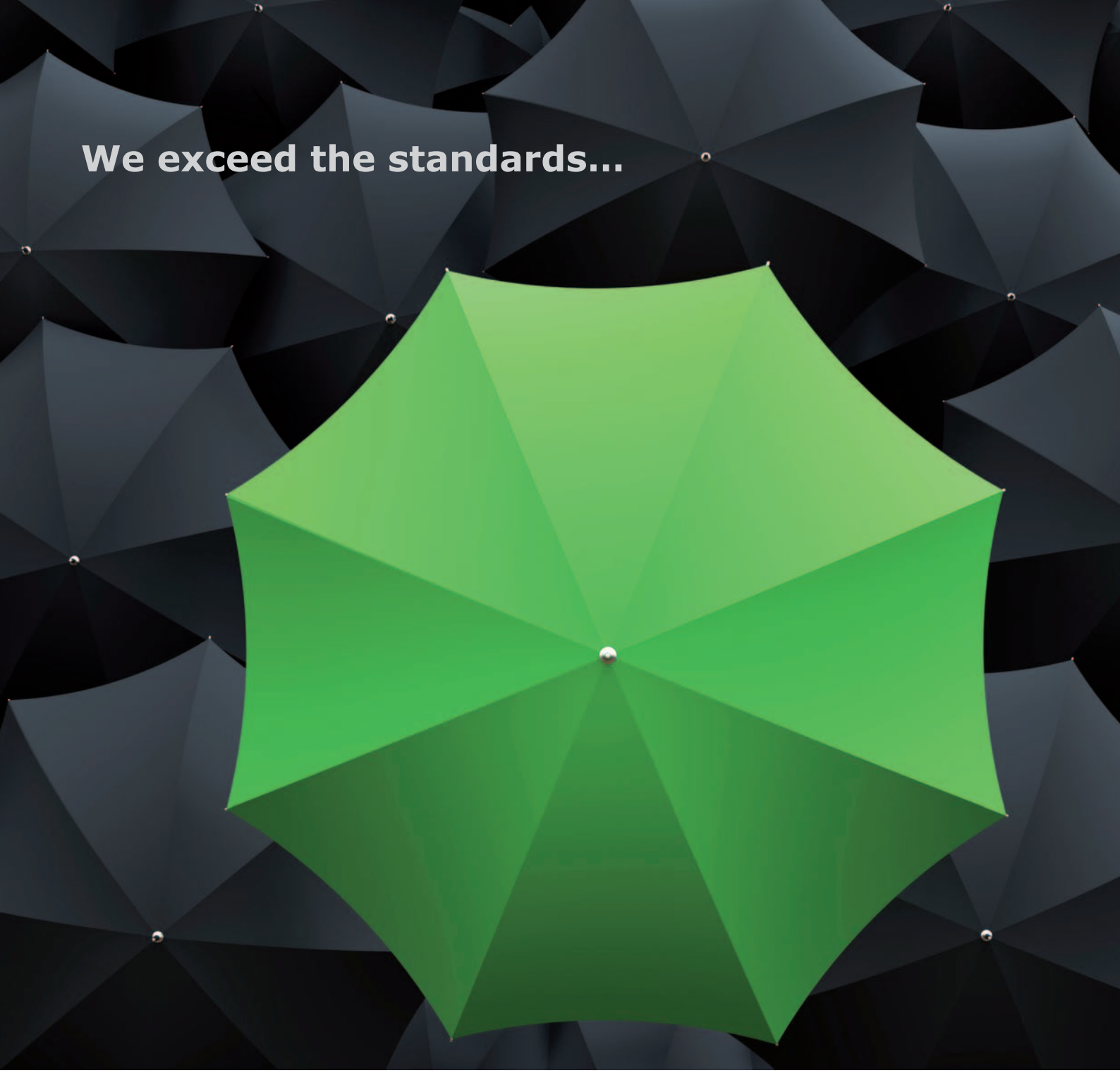

...which is a matter of course for us

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DERMOSOFT® OMP
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Biesterfeld Chemia Specjalna

Bartosz Piątkowski
Biesterfeld Chemia Specjalna

"Paraben free" is one of the most popular catch phrases found every day by thousands of consumers who make decisions on the purchase of cosmetic products. Parabens have had a bad reputation for some time, and the number of reports on their harmful effects is increasing day by day. Internet blogs are full of comments on the risk to human health associated with parabens. Most of the cited arguments are not supported by any evidence, but their cogency is powerful enough to cause a certain reaction in consumers, who reject products not containing this slogan.

Producers of cosmetics facing such consumer behaviour are searching for alternative components which may replace parabens and satisfy the expectations of end users.

Dermosoft® OMP is a perfect solution tailored to the needs of „paraben free" formulations.

Dermosoft® is a line of carefully chosen cosmetic ingredients demonstrating versatile activity. Through its multifunctional properties it allows the designers of cosmetic formulations to achieve a satisfying compromise between innovativeness and efficiency. Apart from typical properties, such as moisturizing or conditioning, the Dermosoft® OMP line also offers high antibacterial and antifungal efficiency.

Dermosoft® OMP is an excellent example of versatile activity achieved through the optimal blending of several ingredients. Methylpropanediol, a highly polar substance, is able to retain water inside the skin, but is mainly a carrier for other components. Capryl glycol has been known for over 15 years, but is still a substance very often used in cosmetic formulations due to its antibacterial efficacy. Phenylpropanol is the second active ingredient, with powerful antifungal properties, enhancing the efficiency of the entire blend. At the same time, this gently-fragranced ingredient efficiently neutralizes the typical chemical odour of raw materials.

Through the use of Dermosoft® OMP manufacturers can deliver a finished product with unique self-preservation properties with no need for any additional bactericidal substances.

The moisturizing effect mentioned above is achieved through the high polarity of methylpropendiol and the content of capryl glycol, which imitates the structure of glycerine, one of the basic substances with a moisturizing effect.

Another benefit of the product is its refatting effect, i.e. preventing skin overdrying. With the amphiphilic effect of capryl glycol, Dermosoft® OMP ensures lipid protection, acting as a link between hydrophilic and lipophilic structures in the upper skin layers.

However, the major feature of this ingredient is its antifungal and antibacterial efficiency, proven in over twenty challenge tests, carried out by an independent analytical laboratory according to the recommendations of the European Pharmacopoeia.

Examples of efficiency results are presented below.

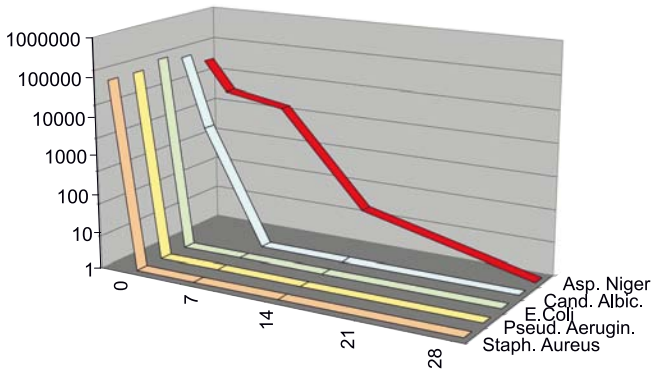


Figure 1. Test for hydrogel containing 2.5% Dermosoft® OMP

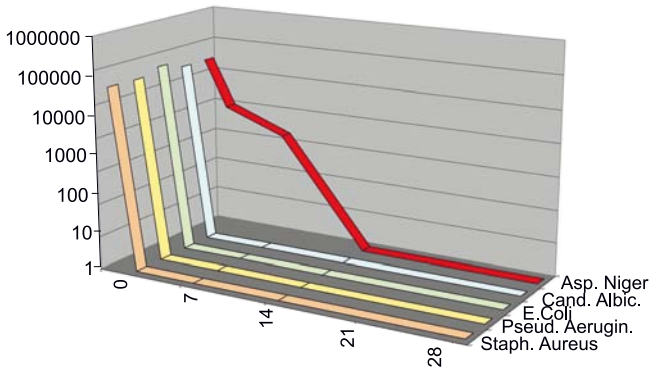
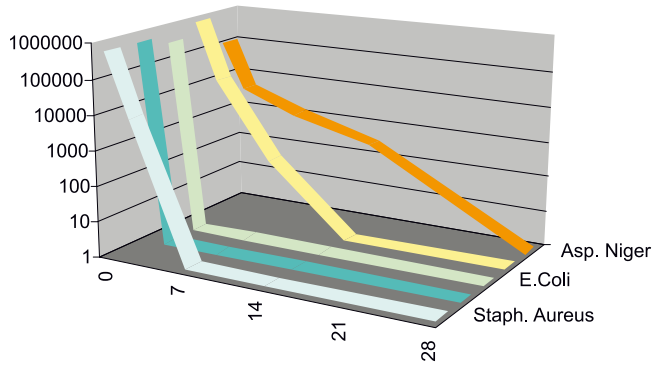
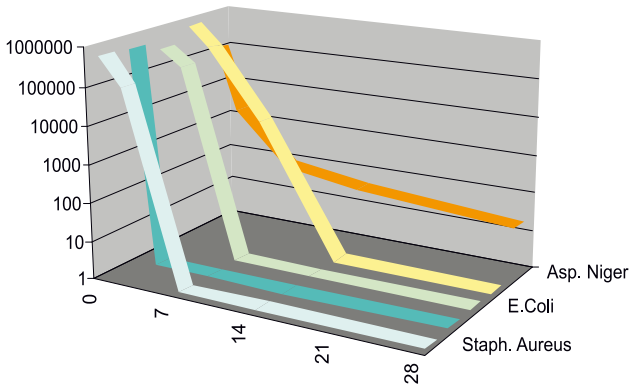


Figure 2. Test for body balm containing 3% Dermosoft® OMP

If we consider the use of Dermosoft® OMP as a replacement for parabens, it is important to compare its efficiency with the most popular paraben blends. A few examples are presented below.

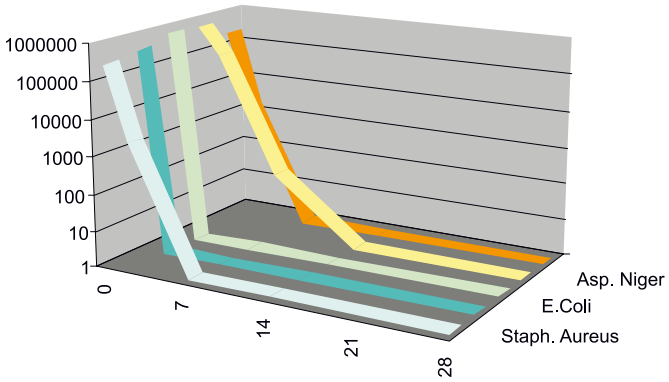


System: Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Bronopol

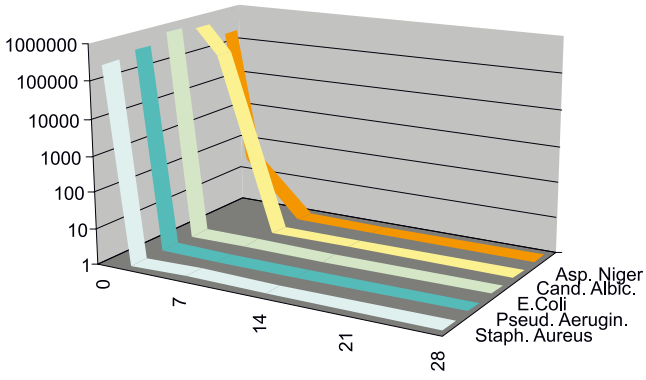


System: Dermosoft® OMP – 3%

Fig. 3. Test for shower gel for sensitive skin (pH 6) containing different preservative systems



System: Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Imidazolidinyl Urea



System: Dermosoft® OMP – 3%

Fig. 4. Test for body balm for sensitive skin (pH 7.4) containing different preservative systems

With respect to the application properties, Dermosoft® OMP maintains efficiency in a very wide range of pH, which is a strong advantage in comparison to alternative ingredients. Having a liquid consistency, it can easily be introduced in the aqueous phase, and being stable at changing temperatures it can be heated up to 80°C with no risk of efficiency loss. Dermosoft® OMP can also be used in cold processing, which makes it suitable for such applications as wet tissues.

Its excellent toxicology profile allows for application in products for children and users with sensitive skin prone to irritations.

The analysis of all the presented examples clearly demonstrates that Dermosoft® OMP is the perfect choice, both in currently used formulations as a replacement for paraben-based traditional systems, and also in new, innovative products. The efficiency, multifunctionality and ease of use of Dermosoft® OMP are advantages that will be appreciated by all designers of innovative formulations satisfying the needs of the modern cosmetics industry.

Based on materials from Dr Straetmans GmbH.

The role of metalloproteinases in skin aging process

Bożena Tyszczuk
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Dr Irena Eris

Skin aging is an inevitable process regarding every living organism. Reasons for aging may be divided into endogenous and exogenous. The former cover chronological and genetic factors, the latter – environmental ones. This type of aging is, first and foremost, photoaging connected to the exposure to solar radiation.

The process of endogenous aging is independent on every human being. We can only slightly retard its negative effects by maintaining a hygienic and healthy lifestyle, i.e. eating well, practising sports, and by taking proper care for our skin. The exogenous aging is a completely different thing. This process begins earlier than the endogenous aging and it is more apparent in persons exposed to the negative impact of external environment, e.g. in people working in the open air, in whom the symptoms of aging can be seen most rapidly (1).

Endogenous aging

Due to the endogenous aging in human skin processes occur, which mechanism of action has not been elucidated to date. A series of genetic, hormonal and environmental factors affect them. They induce changes across all the skin layers, namely epidermis, dermis and subcutaneous tissue (Fig. 1).

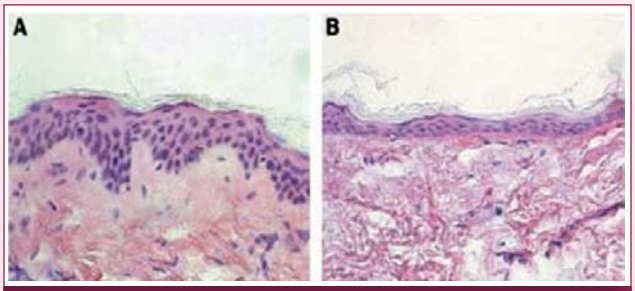

Fig. 1. Skin Cross-section in a person aged 25 years (A) and 69 years (B) visualizing histological changes in an aging skin (2)

Lesions occurring in epidermis are as follows:

- Prickle layer and granular layer atrophy as well as basal cell layer thinning;
- Reduction in the number of Langerhans cells resulting in immunity disorders;
- Reduction in the number of melanocytes and the formation of their clusters manifested by pigmentation disorders;
- Reduction in the number of sweat glands leading to skin dryness;
- Negative changes within epidermal lipids and natural moisturising factor (NMF) leading to the aggravation of skin dryness and its dehydration;
- Enhanced sensitivity to the action of external factors, e.g. soaps, detergents, UV radiation;
- Reduction in the ability to inhibit transepidermal water loss (TEWL),
- Diminution of D3 vitamin synthesis;
- Flattening the borderline between epidermis and dermis;
- The atrophy of filaments and fibres anchoring basal layer.

In turn, changes within dermis cover the following:

- Structure anomalies, e.g. degeneration, growth of rigidity and the decrease in distribution density of support fibres;
- Reduction in the number of collagen fibres, particularly type III and, to a lesser extent, type I ones;
- Reduction in the number of elastic fibres;
- Reduction in the metabolic activity of fibroblasts;
- Lesions within extracellular matrix manifested by the drop in the number of proteoglycans, glycosaminoglycans including hyaluronic acid;

- Reduction in the number of mastocytes;
- Reduction in the number of capillaries and microcirculation disorders;
- Reduction in the number of hairs and pigment content in hair (1).

Hormonal metabolism also plays a pivotal role in the aging process. After 50 years of age the function of endocrine glands gets deteriorated, which is manifested by menopause, andropause, adrenopause or somatopause. Compensation of hormonal deficiencies considerably improves the quality of life and may retard the aging of organism and skin. Familiarity with changes occurring inside an organism is essential in understanding changes developing within the skin (3).

Exogenous aging

Exogenous aging is manifested mainly by damage in elastic fibres, solar keratosis and malignant neoplasms of the skin. Such lesions are caused by external factors, predominantly by solar radiation. Lesions in the skin developing as a result of UVB radiation can be seen mostly within epidermis. Contrary to that, UVA radiation exerts its negative effect mainly on dermis, resulting in a late irreversible outcome. Over the whole life, irrespective of a season or daytime, everyone is exposed to its negative effect (1).

Hence, photoaging results from an excessive and chronic exposure to solar radiation, particularly the UVA. A considerable impact is attributed to the quantity of radiation accumulated during lifetime and to skin phototype; effects of photoaging are much more pronounced in phototype I persons compared to higher phototype persons, e.g. phototype IV.

Symptoms of postsolar skin aging are epidermal roughness and desquamation, damage of melanocytes, hypertrophy of sebaceous glands, among others. Changes based on the thickening and twisting of elastic fibres take place in dermis. Degradation of collagen and elastic fibres is due to the action of enzymes, i.e. collagenase and elastase, respectively. Fragmentation and breakdown of collagen fibres may be derived from a UV radiation-induced inflammatory process. This occurs based on the "system" of matrix metalloproteinases (MMPs). Decrease in collagen I content leads to the loss of skin firmness and the formation of distinctive deep wrinkles and creases (1).

By the stimulation of oxidative stress and the induction of receptors specific for growth factor and cytokines, UV radiation elevates activating protein 1 (AP-1) expression. This process is a stimulator for an organism to rebuild connective tissue. This process begins as a result of extracellular matrix protein degeneration. From the skin aging process point of view, the most important effect of AP-1 stimulation is the induction of metalloprotease activity (4).

Metalloproteinases

Matrix metalloproteinases (MMPs), also called metalloproteases, matrixins or collagenases, make up a group of 23 enzymes of proteolytic properties. They are endopeptidases containing a zinc atom in a molecule. Zink plays a catalytic part in them. Normally, repeating fragments, common in structure, are present in all metalloproteinanes. They are called domains. Each domain is composed of a distinct number of amino acid residues, and contains various ions, which determine its stability and enzymatic activity (8). Some domains, e.g. a propeptide or a catalytic one, and a signal peptide, reveal a common structure for all MMPs (6).

Metalloproteases are contained in all sorts of tissues and organs of human beings (5). They occur in a soluble or cell membrane-bound form. MMPs are active at neutral to slightly basic pH provided calcium ions are present in the milieu. Expression and synthesis of metalloproteases has been detected in almost all kinds of cells, namely fibroblasts, keratinocytes, macrophages, endothelial cells, dendritic cells, neurons, microglia cells, myocytes, monocytes, T lymphocytes, leukocytes, neutrophils and neoplastic cells (6).

Division of metalloproteases

- Depending on substrates metalloproteases are specific to, six groups are distinguishable as follows:
- collagenases (MMP-1, 8 and 13), which degrade type I, II, III, VI and X collagen;
- gelatinases (MMP-2, known as gelatinase A, and MMP-9, in other words gelatinase B), which are active against gelatine and collagen IV;
- stromelysin (MMP-3, 10 and 11), whose substrates are collagen and fibronectin;
- matrilysins (MMP-7 and MMP-26), which cleave fibronectin, type IV collagen and fibrinogen;
- metalloproteinases of transmembrane type (transmembrane type MMPs – MT-MMPs), with MMP-14, -15, -16, -17, -24 and -25 representatives, which activate other metalloproteases;
- a group of remaining metalloproteases covering MMP-12, -19, -20, -23, -27 and -28 (6).

The role of metalloproteases

Metalloproteases play a pivotal role both in physiological and pathological processes in a human body. They take part in processes associated with healing wounds, scar formation, cartilage and bone rebuilding, among others. Furthermore, they participate in angiogenesis and apoptosis. Metalloproteases are also involved in pathological processes leading to neoplastic and autoimmune diseases or inflammatory states of joints (7). They take part in the aetiology of a number of skin diseases such as psoriasis, lichen planus, acne rosacea, bullous diseases, scleroderma and crural ulcerations, among others. Recent reports have been made on the involvement of metalloproteases in the aethipathology of acnes rosacea and postsolar skin aging (6).

Metalloproteinase mode of action

Metalloproteases are synthesized in an inactive form as proenzymes (proMMP). Their activation takes place in an extracellular process due to splitting off a cysteine residue. This results in changes of the molecule spatial structure consisting in the uncover of active centre containing zinc atom. The main scope of action for metalloproteases is the hydrolysis of extracellular matrix (ECM) in a tissue resorption and rebuilding process. MMPs induce a disintegration of both collagenous (fibronectin, laminin, vitronectin, agrecan, entacin, tenascin) and non-collagenous (growth factors, cell surface markers) fragments of the ECM. MMP-2 and -9, belonging to the gelitanase group, degrade type IV collagen. Dissolution of vascular basement

membrane caused by these enzymes runs along the same pathway. As a result of changes in the ECM structure, both normal and malignant cell flow is facilitated (6). MMP enzymatic activity undergoes a multidirectional regulation, for example at the stage of gene transcription with the presence of a variety of both biological factors, i.e. hormones, growth factors, cytokines, interactions between cells and ECM, and physical ones, e.g. UV radiation. The MMP activity control also occurs at the level of proenzyme activation. Metalloproteinase secretion is stimulated by vascular endothelial growth factor (VEGF), tumour necrosis factor alpha (TNF-), interleukin 1 (IL-1), E2, D2 and F2- prostaglandins and phagocytosis processes. Neoplastic cells also produce a so-called extracellular matrix metalloproteinase inducer (EMMPRIN) that stimulates fibroblasts to synthesize metalloproteases. An overstimulation of MMPs expression is prevented by their natural tissue inhibitors of matrix metalloproteinases (TIMPs) and 2-macroglobulin, a liver-derived protein of a high molecular mass, which plays an inhibitory role against all the metalloproteases. Proteolytic activity of metalloproteases is regulated by changes in the proportion between their expression level and the level of their inhibitory factors. Four classes of metalloprotease inhibitors, present in the ECM and body fluids (TIMPs-1, -2, -3 and -4), have been described to date. The most abundant tissue TIMPs are TIMP-1 and -2. Inhibition of MMP proteolytic activity occurs through the formation of complexes between active metalloprotease forms or respective proenzymes and their tissue inhibitors (6).

UV- and photoaging induced metalloprotease expression

Study results for each MMP gene expression have been reported in the literature review by T. Quan et al., with experiments both under conditions with no irradiation (control) and with a UV radiation as a causative factor. Under the former conditions, transcription of MMP8, -10, -12, -20 and -26 was not detected, while transcription of the remaining MMPs was at a detection limit, being approximately 1000- fold lower than internal control. On the other hand, MMP-14 mRNA expression level was 35-fold higher than other detectable MMPs. From among 19 MMPs present in the skin only three were to a considerable degree induced as a response to the UV radiation, namely MMP-1, MMP-3 and MMP-9.

Other studies have also confirmed that keratinocytes are a major cellular source of MMPs, including MMP-1, MMP-3 and MMP-9, in the skin exposed to UV radiation ***in vivo***. However, ***in vitro*** studies conducted on tissue cultures and a model of human skin have found that the main source of MMPs, which arise as a response to UV radiation, are fibroblasts originated from dermis. For the above mentioned ***in vivo*** and ***in vitro*** study results, this discrepancy is unclear. It is possible that cells of dermis may play an essential role in the MMP epidermal synthesis process through an indirect mechanism of action based on the release of growth factors and cytokines, which influence the MMP production in keratinocytes (9).

The effects of photoaging, i.e. damage to the collagen and elastin fibres within the ECM, are a reason for the development of wrinkles as well as skin flabbiness and loss of firmness. The atrophy of collagen fibres is the effect of the growth in the expression level of collagenases (MMP-1) and gelatinases (MMP-2), whereas elastin fibres are destroyed by elastases (MMP-2 and MMP-9) (10).

Examples of active substances used in cosmetology in order to inhibit metalloprotease-induced activity

More and more active ingredients used in anti-aging type of products appear in the market. They are products manufactured in order to prevent and alleviate the effects of exogenous aging including its peculiar form, which is photoaging.

One of such raw materials is an extract obtained from autumn pumpkin (Cucurbita pepo). A high molecular mass protein fraction, which protects elastin and collagen fibres, constitutes this raw material. ***In vitro***, it inhibits the synthesis of catepsin L and MMP-1 metalloprotease by 86% and 99%, respectively. It also reduces MMP-2 activity, an enzyme associated with degradation of both collagen and elastin fibres. Moreover, the pumpkin extract favours normal organization of network made up of elastic and collagenous fibres through the elevation of type I collagen synthesis (62% ***in vitro*** increase) and through the stimulation of the ECM cell expression (11).

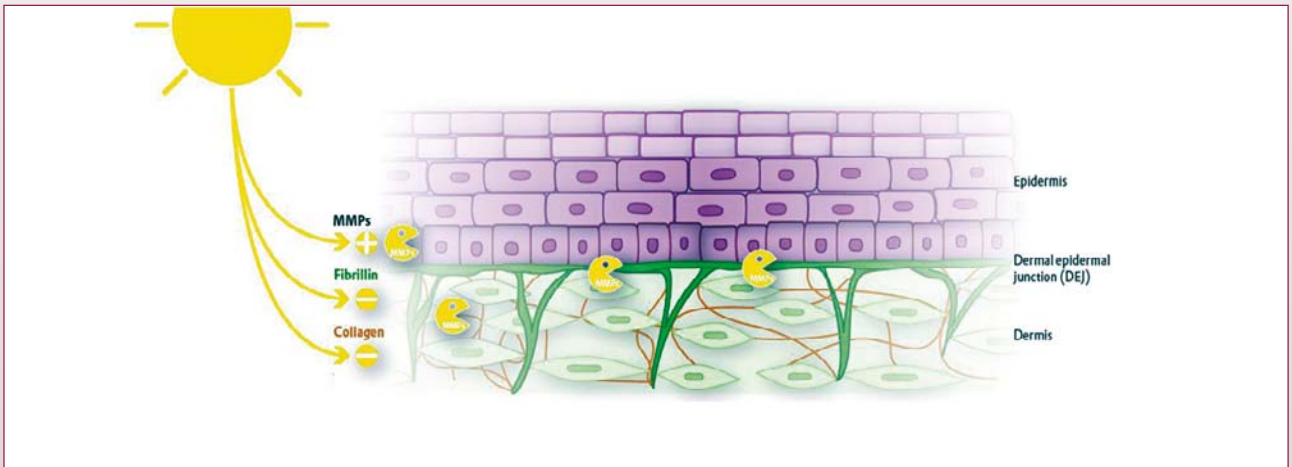

Fig. 3. A schematic representation of metalloprotease inhibitor mechanism of action according to Evonic Industries

Another example of cosmetic ingredient of TIMP nature is an extract from brown algae (Laminaria ochroleuca), also known as a 'golden algae'. It has been elaborated in order to reduce the effects of skin aging. The preparation contains -lipoic acid and vitamins, among others. Due to a high concentration of phosphatidylcholine, it promotes the rebuilding of skin lipid barrier. ***In vitro*** tests with human fibroblast culture using ELISA revealed a reduction of MMP-1 expression by 25% and 31% in the presence of L. ochroleuca extract used at concentrations 0.5% and 1%, respectively. The raw material was a protector for matrix fibres and dermal-epidermal junctions (DEJ) against cleavage by means of reduction of MMP-2, -3 and -9 synthesis levels (12).

L. ochroleuca extract neutralized the consequences of stress caused by the UVB radiation manifested by the diminution of TNF- , COX, LTB4 and IL1, IL6, IL10 (interleukins) release in ***in vitro*** culture of human keratinocytes. The results of comet assay revealed a corrective action of the extract on UV derived DNA damage. Other studies have confirmed the effect of this raw material on the stimulation of collagen and glycosaminoglycan (GAG) synthesis (13).

The action of TIMPs nature is also attributable to the following:

- peptides: Tripeptide-2, which exerts an inhibitory effect on elastase and MMP-1; Myristoyl Tetrapeptide-20 inhibiting MMP-1 and Acetyl Hexapeptide-20 inhibiting MMP-1, -2 and -9;
- lychee peel extract that inhibits MMP-1 activity;
- phenol, 4-[1E, 3S)-3-ethenyl-3, 7-dimethyl-1, 5-octadienyl, which exerts an inhibitory effect on elastase;
- common blackberry (Rubus fruticosus) leaf extract that inhibits MMP-1, -2, -9 and elastase.

Summary

Matrix metalloproteinases are present in all organs of a human organism. They are involved in a number of processes. However, their major area of action is the degradation of connective tissue protein structures. UV radiation is one of the main factors responsible for the activation of metalloproteases in the skin aging process. The effects of MMPs action are changes in the structure of dermal matrix, wrinkles, decrease in skin elasticity and firmness as well as the presence of permanent and/or transient erythema and teleangiectasia. In order to avoid or reduce the intensity of these lesions, contemporary cosmetology is still looking for novel active substances, which would not only inhibit the expression of metalloproteases, but also reduce their activity and exert an effect on the improvement of aging skin condition.

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Chemical peeling agents – not always cosmetic

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CEDERROTH

Chemical peeling agents, i.e. solutions for so-called chemabrasion are an important group of products and treatments in beauty salons and aesthetic medicine. At the same time, these products are controversial from the formal standpoint as there are no transparent legal rules governing their production and use.

Chemical peeling treatment is based on the controlled removal of epidermal cells. Depending on the type of substance used, the effective amount (concentration), which in many instances is closely correlated with the pH of the formulation, and the time of contact with the skin, a different degree (depth) of peeling can be obtained, starting with the removal of only the outer layers of the epidermis, to the complete removal of the stratum corneum, and in extreme cases, the epidermis and the upper layer of the dermis. The purpose of each peeling procedure is to stimulate the skin's regeneration processes and to accelerate cell divisions in the basal layer, as well as to stimulate the processes in the dermis, the synthesis of collagen and other extracellular matrix proteins. The strength of the end result will always depend on the depth of peeling agent.

The depth of the exfoliation and the components used are directly related to effectiveness, but also to side-effects of the treatment, which include:

- possible cytotoxic activity in the skin (e.g. typical for trichloroacetic acid or high concentrations of salicylic acid), resulting in damage and death of the living cells of the epidermis and dermis close to the dermal-epidermal junction,
- destruction of the epidermal barrier,
- severe irritation,
- risk of complications during healing - the possibility of deep scars and discolouration.

For this reason, deep exfoliation treatments and the use of prohibited substances in cosmetics should be performed solely by an experienced physician.

In the literature, especially from the medical field, the most common division of peeling agents is based on peeling depth. Usually three groups are distinguished: superficial, medium and deep. However, from a formal point of view it is an ambiguous criterion with which to qualify a peeling product or procedure as cosmetic or non-cosmetic.

The classification of peeling agents into cosmetic (use of cosmetic products and performed by beauticians) and non-cosmetic (use of products that are not cosmetics), which can be performed solely in a physician's office or by a physician (see Table) is primarily based on:

- depth of exfoliation
- type of active substances used,
- communication of the product (e.g. declared action, instruction for use).

Regulations concerning chemical peeling agents (cosmetic)

There are no specific law regulations either for chemical peeling agents (cosmetic) as a group, or for most of the compounds used in these formulas as exfoliating agents. The exception is salicylic acid, the use of which in chemical peeling agents is allowed in concentrations up to 2% (item 98 of Annex III of Directive 76/768/EEC). Annex II of the Directive regarding the use of prohibited substances in cosmetics is also an important legal limitation, in many cases clearly demarcating a border between cosmetic and non-cosmetic products. Annex II includes:

- trichloroacetic acid (TCA) - prohibited for use in cosmetics, item 10 of Annex II of Directive 76/768/EEC
- trichloroacetic acid (TCA) - prohibited for use in cosmetics, item 375 of Annex II of Directive 76/768/EEC.
- phenol - prohibited for use in cosmetics, item 1175 of Annex II of Directive 76/768/EEC.
- resorcinol (e.g. component of Jessner's Solution) - allowed only for use in hair preparations in maximum concentrations of 0.5% in shampoos and hair lotions, and 1.25% in oxidative hair dyes, item 22 of Annex III to Directive 76/768/EEC.

All the above compounds are generally used in peeling agents. However, such products cannot be classified or marketed in any case as cosmetic products.

The discussion on the issue of chemical peeling agents (cosmetic) has had quite a long history and began with an attempt to introduce restrictions on the use of alpha hydroxy acids in preparations for exfoliation.

In 2000 and 2004, the Scientific Committee on Cosmetic Products and Non-Food SCCNFP published reviews (SCCNFP/0370/00 and SCCNFP/0799/04) on the risk management of products for exfoliation based on the AHA. The Committee recommended that effective risk management should specify:

- maximum concentration of AHA in the preparation,
- the minimum pH of the preparation,
- appropriate warnings as part of a label, e.g. "Avoid eye contact" and "after using AHA products protect the skin from UV radiation"

SCCNFP stated that glycolic acid may be safely used in a concentration of 4% and a pH of ⩾ 3.8 and lactic acid in a concentration of 2.5% and a pH of ⩾ 5

These are, however, very low concentrations compared to those used in the products on the market, in particular those for professional use.

In 2005, the European Commission presented a legislative proposal which envisaged the inclusion of two alpha hydroxy acids, glycolic and lactic acids, to Annex III of Directive 76/768/EEC, which are on the list of restricted substances allowed for use in cosmetics. The project was partly based on the recommendations of the SCCNFP, and also permitted relatively low maximum concentrations of acids: 7% based on free acid (for a single acid or a mixture of acids) and a pH of ⩾ 3.5. The Commission has also proposed the introduction of appropriate warnings.

The European Commission pointed out several times during working discussions that in some language versions of the Cosmetics Directive 76/769/EEC (Annex I) the category list specifically excluded chemical peeling agents. At the same time, the Commission stated that the list of categories of cosmetics is for informational purposes and is not exhaustive. In accordance with the Regulation 1223/2009/WE a new system of categories of cosmetics was introduced for notification purposes of framework formulas at Cosmetic Products Notification Portal CPNP. The system of cosmetic categories provides the category 1.13 - products for chemical peeling. The maximum sum of the concentrations of all chemically exfoliating substances in this formula is 10% (wt.), and for the centres for poison control exact concentrations of these substances should be given. However, it does not mean that the product can contain up to 10% of the exfoliating components. This only means that cosmetic peeling agents containing higher concentrations of exfoliating substances must be submitted with complete formulas (in a range of concentrations, or the exact concentrations of all components).

The case of chemical peeling agent classification came back on the agenda of the Commission in 2011. The Commission then presented a general statement on exfoliation products in the next update of the guide to borderline products .

Type of peeling agent	Depth of action of active substances	Examples of the types and concentrations of the active substances	Cosmetic/ dermatological indications	Classification
Very superficial	Part or all of the stratum corneum to the spinous layer (0.06 mm)	Alpha hydroxy acids (20-50%) Beta-hydroxy acids 10-20% TCA Retinoic acid	Surface wrinkles, superficial blemishes, lentigines, acne (noninflammatory lesions, post-acne lesions), solar hyperkeratosis	Cosmetic or non-cosmetic, depending on the components used and declaration of action. TCA and retinoic acid are prohibited for use in cosmetics.
Superficial	The entire epidermis to the basal layer (<0.45 mm)	Jessner's Solution Glycolic acid 70% TCA 20-30%		Non-cosmetic
Medium	Epidermis and surface layer of dermis to the upper part of the reticulate layer (<0.6 mm)	TCA 35-50% Jessner's Solution + TCA 35% Jessner's Solution + glycolic acid 70% TCA + solidified CO2 Phenol	Deeper wrinkles, blemishes, lentigines, shallow acne scars	Non-cosmetic
Deep	Epidermis and upper layer of the dermis to the middle part of the reticulate layer (>0.6 mm)	Phenol (Gordon-Baker formula)	Deep wrinkles and acne scars	Non-cosmetic

According to the Commission products which are designed to remove only the outer cell layers of the stratum corneum can be considered as cosmetic products, while deep peeling agents which cause the complete removal of the stratum corneum should not be considered as cosmetic products. Such products significantly alter the physiological functions of the skin, including barrier functions, and therefore do not meet the definition of a cosmetic product. To decide on the qualification of an exfoliation product both the manufacturer and the competent authorities shall take into account all the features of the product, including product communication (statements, directions for use, with the duration and frequency of a single application of the treatment) and the depth of the peeling with a single application of the product.

It is the most recent and the only official (though not legally binding) document containing the recommendations of the Commission for the certification of chemical peeling agents that are or are not cosmetics. As of today, no binding legal measures have been offered to regulate chemical peeling agents. However, the Commission's Guide presents a general statement, in which the classification of the product is based on action, and not a particular compound used, the concentration, pH, etc. Therefore, it is a more universal standpoint than the previously proposed regulation of the conditions of use of only two out of many substances with exfoliating properties.

Practice in the Polish market indicates that a similar approach is also used by the State Sanitary Inspectorate. Preparations leading to complete exfoliation of the stratum corneum (so-called controlled burns) are not considered cosmetic products.

Regardless of the absence of specific regulations for chemical peeling agents considered as cosmetics, the safety of a cosmetic product (at the stage of introduction of the product to the market) is determined mainly by safety assessments. Based on factors such as composition, toxicological evaluation of the components, and assessment of the dermatological properties of the product, a qualified person (known as the safety assessor) is to decide whether the product is safe for consumers in the declared conditions of use. The safety assessor considers the composition of the product, including the concentration of exfoliating substances, the pH of the preparation, as well as warnings and instructions for use. Thus, a product containing substances prohibited for use in cosmetics should be suspended at the stage of assessing safety - as posing a risk to human health.

However, it should be noted that the safety assessment covers only the recommended and reasonably foreseeable effects of a cosmetic product. This does not include the abuse and misuse of the product, especially if appropriate warnings are present (e.g. contraindications or recommended duration).

Therefore, improper use of the peeling agent by staff (e.g. beautician) may pose a direct risk to the consumer, and a peeling agent used not in accordance with the manufacturer's instructions is not a safe product.

Chemical peeling agents (non-cosmetics)

What then are chemical peeling agents that are not cosmetics? The answer is ambiguous, as there are no clear legal demarcations.

Such products can be medicinal preparations if they are used with an indication of the treatment of specific diseases or prevention of them. According to the definition in the Pharmaceutical Law (Journal of Laws from 2001 No. 126, item 1381, as amended) a medicinal product is a substance or mixture of substances presented as having properties for treating or preventing diseases of humans or animals, or administered to make a diagnosis, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.

For example, a peeling agent for the treatment of warts or acne can be a medicinal product, but then it is subjected to legislation on medicinal products - Pharmaceutical Law.

A chemical peeling agent can also be a medical product if the characteristics of the product meet the definition of a medical product included in the Act on Medical Products (Journal of Laws from 2010, No. 107, item 679), according to which a medical product is "an instrument, apparatus, appliance, piece of software, material or other article (...) intended by the manufacturer for use in humans in order to:

- diagnose, prevent, monitor, treat or alleviate disease,
- diagnose, monitor, treat, alleviate or compensate for the effects of an injury or handicap,
- examine, replace or modify the anatomy or a physiological process, whose primary intended action in or on the body of the human is not achieved as a result of the action of pharmacological, immunological or metabolic agents, but whose action can be supported by such agents.

According to this definition, a peeling agent which is described as designed for aesthetic correction or removal of scars can be classified as a medical product, but then it is subjected to the requirements of the Act on Medical Products.

It should be noted that the qualification of the product (to the particular group of products, and therefore also specific legal requirements) is very often dependent on the communication used, i.e. purpose of use, mode of action statements, and directions for use.

In commercially available (as treatments) chemical peeling agents, there are many substances prohibited for use in cosmetics (according to the provisions of Cosmetics Directive 76/768/EEC and the regulation of the Minister of Health, implementing it on the lists of substances prohibited for use in cosmetics (...):

- trichloroacetic acid (TCA) - prohibited for use in cosmetics, item 10 of Annex II of Directive 76/768/EEC
- salicylic acid (permitted at a maximum concentration of 2%, in exfoliating preparations up to 30%), retinoic acid (prohibited for use in cosmetics, item 375 of Annex II of Directive 76/768/EEC)
- Oxalic acid - allowed to be used in a concentration of 5%, but only in hair preparations - item 3 of Annex III to Directive 76/768/EEC
- phenol - prohibited for use in cosmetics, item 1175 of Annex II of Directive 76/768/EEC
- resorcinol (e.g. a component of Jessner's Solution) - allowed only for use in hair preparations in maximum concentrations of 0.5% in shampoos

and hair lotions, and 1.25% in oxidative hair dyes, item 22 of Annex III to Directive 76/768/EEC

- fluorouracil - prohibited for use in cosmetics, item 190 of Annex II of Directive 76/768/EEC
- kojic acid (has a brightening and non-peeling action, but is a component of some of the preparations for peeling) - its use in cosmetics is not regulated, but the Scientific Committee on Consumer Products decided in 2008 that kojic acid is safe for use in cosmetics in concentrations up to 1% and recommended such an application.

The descriptions of treatments that can be found on the internet very often lack a clear communication of what kind of preparation (cosmetic, drug or medical product) we are dealing with.

To which group, then, do products containing these substances belong? From a legal point of view, there are two possibilities: either they are illegal cosmetic products (cosmetics containing prohibited substances - in principle such products are automatically qualified as dangerous) or they are products subjected to other legislation, i.e. as medicinal or medical products. Both groups of preparations should definitely be used under the supervision of a specialist, such as a dermatologist.

A legal issue also arises here - the law does not clearly establish a catalogue of operations and types of treatments that can and cannot be performed by a beautician or cosmetologist who is not a doctor.

Cosmetic market in chemical peeling agents

The high efficiency of chemical peeling agents has made products and treatments with their use currently available in almost every beauty salon, and all major cosmetics companies carry in their portfolios a brand of professional cosmetics. Numerous studies that have been conducted confirmed the direct effect of these peeling agents: supporting the formation of a well-functioning skin barrier, acceleration of tissue regeneration, improvement of the skin's appearance by smoothing wrinkles, improvement of skin colour and the condition of problematic complexions - acne and others with abnormal keratinization processes.

The first cosmetic chemical peeling agents based on alpha hydroxy acids (also known as fruit acids) appeared in the early 90s, and quickly gained popularity. To this day glycolic acid remains the most widely used acid, both in cosmetics and dermatology. In cosmetics its concentration ranges from 20% to 40%, and pH is usually not lower than 2.0. This acid has a low molecular weight, and hence a high penetration ability into the stratum corneum (the highest of all known hydroxy acids), but at the same time the highest irritation potential. Therefore, it is often used in combination with other alpha-hydroxy acids, such as lactic, citric, tartaric or malic acids. This allows the sustaining of the intended concentration of acids in the formula while reducing the irritating action of the product. In recent years great popularity has also been gained by polyhydroxy acids (PHA), which have a much gentler effect and are thus also suitable for sensitive skin. These include gluconolactone, gluconoheptanolactone and lactobionic acid, and the now widely used aromatic alpha hydroxy acid - mandelic acid. The latter shows properties similar to glycolic acid but it is a slightly stronger acid (pKa 3.41 vs. 3.83 for glycolic acid). Nevertheless, due to the size of a single molecule that is larger, it is harder for this acid to penetrate the skin, hence it acts much more slowly and more gently (practically non-irritating). It can be successfully used even with difficult complexions, such as sensitive or vascular complexions. Much less common are pyruvic acid, belonging to the group of keto acids, and salicylic acid, included in the beta hydroxy acids. Salicylic acid is

hardly ever used alone because of legal restrictions – the maximum concentration allowed is 2%, and this concentration does not exert a clear exfoliating action. It is, however, a valuable addition to the treatments of acne and rosacea complexions, due to its antibacterial properties. This is currently a very popular trend - combining common exfoliating components with ingredients with different properties, such as anti-inflammatory, antibacterial and, in particular, brightening properties. Among commercial cosmetic peeling agents we can easily find products based on alpha hydroxy acids with the addition of azelaic and kojic acids. Both of these acids affect melanogenesis, contributing to an increase of the effect of brightening blemishes.

The use of chemical peeling agents, even those belonging to a group of mild products, requires caution and a lot of experience. It is necessary to be acquainted with treatment contraindications, to take necessary protective measures if required (e.g. protecting the eye area and all pigmented moles from the effects of the preparation), and finally to properly diagnose the skin type and choose the right product and duration of treatment. This is why manufacturers do not direct this type of product to untrained people, but only to skilled cosmetologists. Consumers now have easy access to professional products through online stores, and those using these products on their own must be aware of the potential high risk, not only related to skin irritation. Furthermore, professionals performing treatments with preparations on the basis of highly concentrated hydroxy acids should avoid changes to the procedures recommended by the manufacturer. Too long and too frequent applications of alpha hydroxy acids, or combining these products with microdermabrasion treatments may prove dangerous for the consumer and cause permanent changes in the appearance of the skin. □

Summary

A cosmetic peeling agent is always going to be superficial when the mode of action is considered. Its composition must correspond to the constraints of cosmetics legislation, and the warnings on the package and the recommendations for use must ensure that the peeling agent applied according to them will be safe for the consumer.

Whereas, in the case of non-cosmetic peeling agents it should be noted that these products pose an explicit risk of side effects, especially when incorrectly applied, and should be used solely under medical supervision.

This material is a response to the article entitled Cosmetic peeling agents based on TCA - special task treatments, which appeared in No. 3/2012 of this journal.

[1] Manual on the Scope of Application of the Cosmetics Directive 76/768/EEC (Art. 1(1) Cosmetics Directive, Version 8.0, June 2011; 3.4. Borderline with Medical Devices; 3.4.1. Products which, according to their presentation, are intended to peel the skin, http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/manual_borderlines_ol_en.pdf

[2] from 11 July 2013 this directive is replaced by Regulation 1223/2009/WE, but at the time of preparation of this article annexes to the regulation have not yet been updated.

[3] SCCP/1182/08, Opinion on Kojic Acid, 2008, http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_148.pdf

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Depigmentation substances
in cosmetic products

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Melanin is a pigment which plays a crucial role in protecting human skin against UV radiation. About 10% of the cells located in the deep layer of the epidermis produce this pigment. It is produced in melanocytes in a process called melanogenesis.

The key enzyme regulating the production of melanin is tyrosine, which belongs to copper polyphenol oxidoreductases. This agent catalyzes two stages of pigment synthesis: hydroxylation of tyrosine to produce 3,4-dihydroxyphenylalanine (L-DOPA), and oxidation of o-diphenol to produce o-dopaquinone (L-DOPA-quinone). Oxidation of the latter compound generates a highly reactive intermediate product which can spontaneously polymerize to form a melanin pigment, composed of a mixture of pheomelanin and eumelanin.

$$\text{Tyrosine} \xrightarrow{\text{Tyrosinase}} \text{DOPA} \xrightarrow{\text{Tyrosinase}} \text{DOPA-quinone} \longrightarrow \text{Melanin pigment}$$

Certain factors, such as aging, excessive exposure to UV radiation, endocrine disruptions, inflammation, or use of drugs or cosmetics that cause sunlight sensitivity may impair this process. Melanin overproduction and its accumulation leads to skin dysfunctions of various types, such as freckles, melasma, lentigines and post-inflammatory hyperpigmentation. They are most often found in the epidermis, but can also occur in the dermis. There are also mixed forms thereof. The majority of the observed changes are formed under the influence of sunlight, hence the problems with excessive pigmentation usually become more intense in the summer, particularly in elderly persons.

Skin discoloration is a serious problem for many people, especially if it affects the face and hands. Since the incidence of skin pigmentation is constantly escalating, there is also a growing interest in agents that can counteract the condition. Therefore, it is not surprising that intensive studies are being conducted to resolve this problem.

Discolorations can be removed using peeling agents, cryotherapy or laser therapy. An alternative approach includes the local application of cosmetic products which contain properly selected chemical raw materials.

The compounds used in this type of skin dysfunction typically act as competitive and non-competitive tyrosinase inhibitors. These include chemicals chelating the copper ion associated with this enzyme. They prevent the conversion of tyrosine to L-DOPA and L-DOPA-quinone by reducing its catalytic activity, and thus effectively limit the total melanin synthesis pathway.

Ingredients which have been extensively used in skin bleaching preparations for a long time include hydroquinone and arbutin, as well as kojic and azelaic acids.

For a long time hydroquinone was one of the most frequently used ingredients in this type of cosmetic. This chemical belongs to natural compounds usually found in a free state or in the form of -glucoside – arbutin, and is derived from various plants and foods, including coffee, tea, beer and wine.

Over a long time it has been considered as one of the most potent inhibitors of melanogenesis, reducing its formation by up to 90%, as indicated by ***in vivo*** and ***in vitro*** studies. For this reason, it has been widely used for the treatment of melanosis and other pigmentation disorders. This phenolic compound has also been commonly utilized in cosmetics.

For a long time hydroquinone was regarded as a relatively safe compound, which may cause merely a skin irritation or contact dermatitis as a result of exposure. However, increasing evidence has revealed that its use is associated with many adverse side effects, including cytotoxicity with respect to melanocytes. Importantly, the detrimental effects of hydroquinone are not limited to pigment cells, although the doses inhibiting the metabolism are significantly higher for non-melanocytic cells than for the melanocytes. For this reason, hydroquinone has been recognized as a cytotoxic compound with a relatively high specifity to melanocytes.

The rare but severe side effects of hydroquinone include the development of virtually irreversible exogenous ochronosis (Latin: ochronosis), which is skin discoloration formed at the application site. This effect is uncommon in standard conditions but may occur when the compound is administered in high concentrations or following prolonged administration of small amounts of this substance.

According to the topical information, hydroquinone, particularly at higher concentrations, may also cause adverse effects with respect to the human body, even though the outcomes of the systemic application of this compound have not been fully explained.

Since large body of evidence question the safety of hydrochinon, the utilization of this substance to produce cosmetics for skin care is practically prohibited in the European Union, while in the United States it is closely monitored by the Food and Drug Administration (FDA). However, the derivatives of this compound, especially arbutin, are commonly used in preparations for skin lightening. This naturally occurring substance is identified as beta-glycoside of hydroquinone. The richest plant sources include the leaves of Bergenia crassifolia and Bergenia cordifolia, European pear Pirus communis, Arctostaphylos uva ursi and Vaccinium vitis idea.

Cosmetic formulations may contain arbutin, a chemical which releases free hydroquinone as a product of its decomposition, or plant extracts containing arbutin. However, a pure compound is considered more efficient.

Recently, deoxyarbutin, a novel derivative of hydroquinone, appeared on the cosmetics market. The comparative studies of the activity of this compound against hydroquinone and arbutin confirmed that all these compounds exhibit similar efficacy.

However, unlike the two previously used chemicals, deoxyarbutin does not demonstrate increased cytotoxicity under the influence of UV-A radiation. Furthermore, it was identified as one of the inhibitory factors of tyrosinase expression. Recent studies have confirmed that it can be a safe and efficient ingredient of skin lightening formulations.

Another compound which can be used in formulations of this type is p-hydroxybenzyl alcohol (4HBA). This chemical is characterized by a pronounced capacity to inhibit the synthesis of melanin at levels comparable to hydroquinone, with low cytotoxicity and lack of effects on gene expression.

Another agent that for a long time has been used in bleaching formulations is kojic acid, a metabolite produced by several species of fungi, such as Aspergillus, Acetobacter and Penicillium. Current research has revealed that this substance acts as a competitive and reversible inhibitor of both plant and animal polyphenol oxidases, including tyrosinase, a key element of the synthesis of melanin. Kojic acid interferes with oxygen uptake, a process essential for enzymatic browning, and thus significantly reduces the formation of different types of hyperpigmentations. Because of its properties it is widely used in dermatological medications and cosmetics. Administration of this compound in concentrations of 2-4% provides a slow and reversible inhibition of competitive tyrosinase. It is a commonly used component of leave-in preparations for facial care. Products containing this component may not only lighten the pigmented spots but also moisturize the skin and cause a visible smoothing effect.

It is worth noting that this substance is also used as a food additive to prevent enzymatic browning. Because of the ability to block various oxidases it is widely used in some countries, such as Japan, as an additive to vegetables, crabs and shrimps. It keeps the food fresh and prevents changes in colour. Kojic acid is also used as an effective antioxidant for fats and oils.

Another ingredient often used in whitening products is azelaic acid, a natural dicarboxylic compound found, for example, in cereal grains. In the body it is formed by lipoperoxidation of both free and ester-linked polyunsaturated fatty acids, including linoleic and linolenic acids, which constitute a structural component of cell membrane phospholipids. Numerous studies on the activity of azelaic acid provide evidence that this compound is characterized by a multidirectional activity which can be utilized in the treatment of a number of skin dysfunctions, including acne and inflammation.

This compound is also regarded as an effective bleaching agent. It has been used in skin lightening products since the early 1980s. The depigmenting effectiveness of azelaic acid results from the fact that this substance inhibits the activity of the mitochondrial oxydoreductase and DNA synthesis within the activated melanocytes. It also acts as a tyrosinase inhibitor, thereby inhibiting melanogenesis and the formation of a natural pigment, melanin.

The clinical studies provide evidence that the prolonged application of this substance in concentrations ranging from 15% to 20% lasting for several months produce positive results in the treatment of lentigines (Latin: lentigo) or chloasma (Latin: chloasma). This compound is also effective in removing postinflammatory hyperpigmentation of the skin. It should be noted that azelaic acid shows no phytotoxic or phototoxic

The bleaching formulations also utilize substances known as melanin inhibitors, which are converted to form a colourless product, such as dithia-octanediol, via a competitive reaction with DOPA-quinone.

activity. It is considered to be a well-tolerated compound, and therefore it can be used for a long time in high concentrations. The possible side effects following application occur rarely and include transient, rapidly disappearing erythema or skin irritation.

The azelaic acid derivatives including complexes with glycine, which have a higher solubility than the native compound, and are used as brightening and sebum normalizing agents.

The bleaching formulations also utilize substances known as melanin inhibitors, which are converted to form a colourless product, such as dithia-octanediol, via a competitive reaction with DOPA-quinone.

Furthermore, this group of cosmetics also exploits substances that distort the process of melanogenesis by reducing DOPA-quinone to DOPA. The effective representative of this group of compounds is L-ascorbic acid, or vitamin C. Other substances that maintain stability in emulsion preparations and exert pronounced skin lightening effects include magnesium ascorbyl phosphate, so-called MAP. This compound, used at a concentration of 10%, effectively prevents the formation of melanin. Clinical studies confirm a significant skin lightening effect in patients with melasma or solar dyschromia.

An alternative product for previously used preparations is resveratrol, a compound which has recently appeared on the cosmetics market. This component was isolated for the first time in 1940 from the roots of Veratrum grandiflorum. It has also been detected in many other plants, such as the fruit rind of mulberry (Morus L.) and black currants (Ribes nigrum L.), as well as hop cones (Humulus lupulus). It is also present in various species of blueberries (Vaccinum) and unripe peanuts (Arachis hypogea). However, one of the richest sources of trans-resveratrol is a Japanese knotweed (Polygonum cuspidatum, Fallopia japonica) originating from China and currently also widely distributed in Poland. In 1976 the presence of this compound was found in a common grape vine (Vitis vinifera, Vitaceae). Trans resveratrol and its derivatives are present mainly in fruit rinds.

This compound belongs to the polyphenol phytoalexins, which are characterized by a powerful antioxidant activity, as well as a range of pharmacological effects, such as the inhibition of the activity of various enzymes, including tyrosinase. It belongs to the group of competitive inhibitors. Importantly, this compound is considered as generally safe, practically without any side effects.

The hydroxyl derivatives, especially oxyresveratrol, have proved to be equally effective. This compound is characterized by the ability of biotransformation of tyrosinase to its oxidized form, which causes partial inactivation and consequently inhibition of the synthesis of the natural pigment melanin. Although some studies point out that this substance cannot be used as the sole active ingredient of bleaching preparations since its melanogenesis inhibiting activity is too low, it can be combined in formulations with other depigmentation compounds.

Another group of tyrosine inhibitors encompass flavonoids isolated from the peel of citrus fruits, an industrial by-product of the production of juices. They are represented by the flavones nobiletin, naringin and neohesperidine.

In addition to the aforementioned plant elements other components can also be used in bleaching preparations. Materials used over time include the extracts of Achillea L., Chamomilla recutita L., Reseda L.,

Paeonia, Petroselinum crispum, Morus L.,Camelia (green tea), Coffea L.(coffee), Carthamus tinctorius L., and Tamarindus Indica. The extract of the birch (Betula), containing betulin - an effective tyrosinase inhibitor, is also a valuable material.

Novel materials derived from fruits such as Pyracantha fortuneana, roots of Sophora japonica, Euphorbia lathyris L., Datura metel L. and Tricholoma matsutake are also used in these formulations.

In conclusion it is worth noting that the assortment of substances which effectively reduce the process of melanogenesis, especially plant extracts, is systematically enlarging. Particularly special interest is directed to plants originating from the East, including species used in traditional Chinese medicine.

□

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Beauty care products

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Proper cleansing and moisturizing are the most important processes that mutually interact to ensure the healthy condition of our skin.

The appearance of our skin, as well as its proper function, depend primarily on proper cleaning. This ensures normal functioning of the skin and prepares it for further beauty treatments, including adequate moisturizing after using nourishing substances. Beauty care products are important in basic skin care, especially when clinical or subclinical skin changes appear, including skin barrier protection disorder, often caused by transepidermal water loss (TEWL). This may result from poor or even improper moisturizing of the skin, manifested as hyperkeratosis, which is characterized by excessive drying, exfoliation, roughness, cracking, and accompanying itching. The health of the skin is also influenced by conditions that affect its deeper layers (e.g., atopic dermatitis, diabetes or hypothyroidism) and drugs damaging the epidermal barrier. These include cleansing and astringent substances, as well as some locally-acting drugs. Very often, these substances are necessary, and their withdrawal or reduction is virtually impossible. Therefore, it is important to ensure proper care and moisturizing of the skin.

The choice of a suitable moisturizer is very often determined by the principle „simple is best", especially when in pharmacies and shops many products advertise special additives that make the skin healthy and attractive, but do not always immediately restore the intended effect, which is improving the protective function of the skin barrier.

Maintaining proper skin condition and water content in the skin depend on many factors. Water balance of the skin, its good appearance and moisturizing is generally conditioned by the intact epidermal barrier. The epidermal barrier is composed of two functional components, namely the cellular protein matrix and the intracellular lipid matrix, made up of two layers. The proper function and maintenance of the two components provide the skin's integrity and a sort of exclusive protection ensured by correct water balance. The ideal level of water content in the stratum corneum of the skin is from 20% to 35%.

When the water content is normal, exfoliation occurs as a result of enzymatic degradation of desmosomes. This allows for the separation and disposal of corneocytes lying closest to the skin's surface.

It was found that small, hygroscopic ingredients defined as „natural moisturizing factor" NMF are responsible for the maintenance of hydration within corneocytes.

The chemical composition of natural moisturizing factors within corneocytes is shown in Table 1.

Intracellular lipids are another element that eases unfavourable skin changes.

Abnormal permeability of the epidermal barrier can be inhibited by the release of extracellular lipids into the interstitial tissue of the stratum corneum. Many studies have shown that topically administrated lipids locate between corneocytes and soothe skin irritations caused by the external environment, thus restoring proper skin hydration, Figure 1.

An increase in skin hydration using the example of liposome is shown in Figure 1.

The chemical composition of natural moisturizing factors inside corneocytes	
Concentration >5%	**Concentration <5%**
• free amino acids • pyrrolidone carboxylic acid (PCA) • glucosamine • sugars • urea • chlorides • sodium	• ammonia • uric acid • lactate • creatine • calcium • magnesium • phosphates • citrates • formate

Table 1. The chemical composition of natural moisturizing factors inside corneocytes

The conducted studies (Figure 1) indicate an increase in skin hydration of the face after 30 days' exposure to liposome. In addition, active substances contained in liposomes enhance the moisturizing effect and improve the condition of the skin.

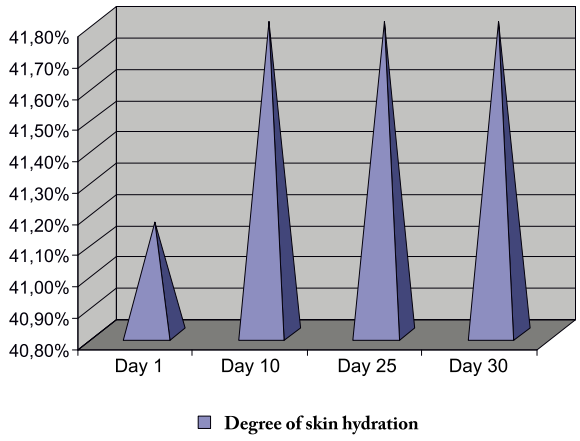

Figure 1. The measurement of skin hydration after the application of liposome

Using moisturizers in practice requires noticeable effectiveness and acceptance. A good moisturizer should contain occlusive, wetting and softening ingredients. The major advantages of occlusive ingredients, which are listed in Table 2, include delayed evaporation and water loss due to the formation of a hydrophobic layer on the surface of the dermis. Moisturizers attract water from the dermis and move it to the outer layer of the epidermis. Softening ingredients, often highly regarded for being able to „fill the cracks", contribute to the clinical efficacy by improving the smooth soft texture on the skin's surface. Occlusive ingredients are often effective, and are most useful when applied to slightly wet skin. These include petrolatum, lanolin, mineral oils and silicone derivatives.

Several components are added to moisturizers which, due to their highly moisturizing properties, attract water from the dermis to the epidermis.

Figure 2 presents basic ingredients of moisturizers commonly used in moisturizing formulations, and their effects.

Softeners are often „fatty" substances, which include a number of chemical compounds having different structures. They make the skin smooth and healthy. Examples of softeners are presented in Table 3. As shown in the accompanying figure, based on their properties softeners can be divided into protective, emollient, drying and astringent.

Occlusive ingredients

hydrocarbon oils/waxes
- yellow petrolatum
- mineral oil
- paraffin
- squalene
- silicone derivatives
  – dimethicone
  – cyclomethicone

Fatty alcohols
- cetyl alcohol
- stearyl alcohol
- lanolin alcohol

Fatty acids
- stearic acid
- lanolin acid

Wax esters
- lanolin
- beeswax
- stearyl stearate

Plant waxes
- carnauba
- candelilla

Phospholipids
- lecithin

Sterols
- cholesterol

Polyhydrogen alcohols
- propylene glycol

Table 2. Occlusive ingredients

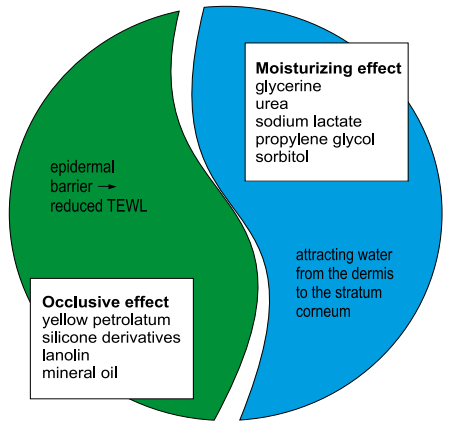

Figure 2. The basic components of beauty care products

The main advantages of beauty care products include maintaining skin integrity and satisfactory appearance by sustaining proper water content, preventing TEWL and starting repair of the skin barrier in the case of damage. Moisturizing, occlusive and softening ingredients are the major components of beauty care cosmetic prescriptions. The proper choice and balance in cosmetic prescription bring the desired effect, manifested as the clinical efficiency and cosmetic attractiveness of these substances. It is important to appropriately adjust ingredients to „skin type" since different skin variants, including dry, normal, oily and mixed require different care depending on needs and desired outcomes. □

Softening ingredients

Protective softeners
- diisopropyl dilinoleate
- isopropyl isostearate

Emollient softeners
- castor oil
- propylene glycol
- octyl stearate
- glyceryl stearate
- jojoba oil

Astringent softeners
- dimethicone
- cyclomethicone
- isopropyl myristate
- octyl octanoate

Drying softeners
- isopropyl palmitate
- decyl oleate
- isostearyl alcohol

Table 3. Softening ingredients

KAPITAŁ LUDZKI
NARODOWA STRATEGIA SPÓJNOŚCI

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Parabens – facts and myths

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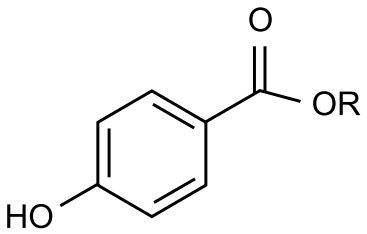
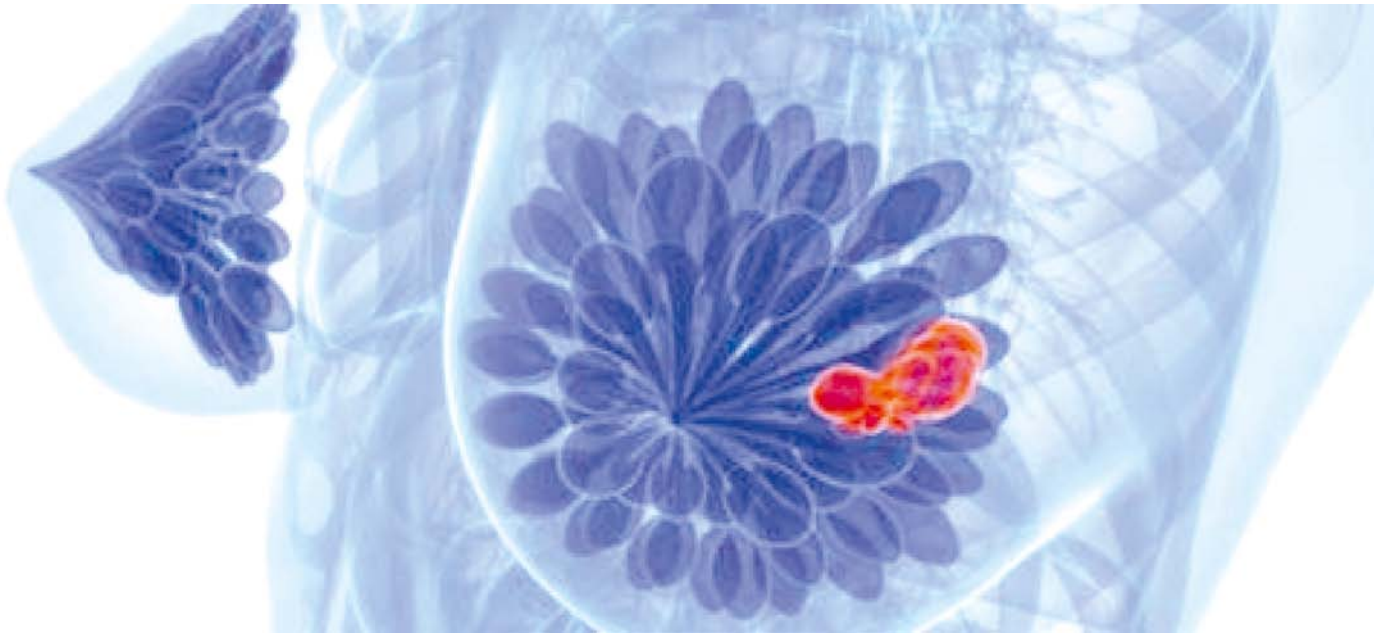
Parabens (syn. nipagins, aseptins) are esters of p-hydroxybenzoic acid which are used as preservatives. However, are they safe for your health? On this subject scientists, manufacturers and consumer organizations have been arguing for years. Also, the Internet and various media often provide information which is critical of them. It is very important that no group of preservatives is subjected to various tests and the evaluation of risk as often as parabens. So you can go ahead and take a chance that these compounds are among the best-tested preservatives used in cosmetic products.



We have been using parabens since the 1940's in the cosmetics, pharmaceuticals and food industries (cakes, spices, fruit juices, frozen foods, jams, preserves). They are the most popular preservatives in different categories of cosmetic products (they are present in more than 13,000 products), such as moisturizing creams, make-up removing preparations, hair care products, cosmetics for before and after shaving, and less in soaps. The popularity of parabens as a means to increase the sustainability of cosmetics is also apparent from the fact that they do not change the colour, texture or odour of products. We often use parabens as methyl esters (M paraben), ethyl ester (A paraben), propyl ester (P paraben). In addition, there are some analogues: butylparaben, isopropylparaben, isobutyloparaben. Parabens are barely soluble in water, especially at room temperature, but are readily soluble in propylene glycol. They demonstrate compliance with anionic and cationic compounds in the range of pH 3-8. They are most effective against fungi, and also show activity against Gram-positive, and weak activity against Gram-negative bacteria. The antimicrobial activity of parabens increase with the length of the alkyl chain. Methyl and ethyl derivatives exhibit moderate antimicrobial activity. The propyl analogue is effective against gram-positive bacteria and fungi, and has a moderate activity against Gram-negative bacteria and yeast. However, parabens are not too effective when the product contains compounds which are good for microorganism growth, so we often use parabens in products which are not good for microbial growth. Despite good antifungal properties they may be less effective for mold contamination. Therefore, we use a mixture of parabens with other preservatives which exhibit a synergistic effect. According to the U.S. Agency for Food and Drug Administration (Food and Drug Administration - ww.fda.gov) the average daily exposure to parabens for a person who weighs 60 kg is 76 mg, 1 mg from food, 50 mg from cosmetics and personal care, and 25 mg from drugs. Although they are not toxic at these dosages there has for several years been continuing discussion on the possible estrogenic effects on the human body. Parabens are often described as „endocrine disrupting", and can cause the development of breast cancer. Another effect of these substances is that they imitate estrogen and can decrease men's fertility.

American scientists have discovered the presence of parabens in the urine of 90% of the general population, Danish researchers have detected parabens in the urine of nearly 100% of men that were tested, while Spanish scientists discovered them in the urine of 100% of tested pregnant women, and children. In 2011, Norwegian researchers confirmed the presence of parabens in the blood of 60% of the general population, which is probably a strong association with the use of cosmetics. In addition, there are also data on their presence in human breast milk and semen. Studies carried out in 1998 showed that the strongest butylparaben-characterized estrogenic activity of all the parabens is about 10000 – 100000 less active than estradiol or an estrogen present in the

human body, which confirmed the safety of these compounds. In 2003 and in other years a team led by Dr. Philipp Darbre of the University of Reading in England, studied samples derived from breast tumours taken from 20 patients. Parabens were detected in all the samples, with an average concentration of 20.6 nanograms per gram of tissue. At the same time, these compounds were detected in their original form (in the form of esters), which means that they penetrate into the skin without going through the digestive system. This caused speculations about the cause-and-effect relationship with respect to cosmetics containing parabens for use in the armpit area, and was supported by the fact that the majority of tumours are located in the upper quadrant of the breast, and therefore closest to the armpit. Dr. Darbre's team did not show this relationship. Experiments published in the Journal of Steroid Biochemistry and Molecular Biology showed that to obtain the estrogenic effect of parabens which could pose a risk the dose would have to be 25,000 times higher than that used for the preservation of products. Similarly, the estrogenic effect caused by a dose of parabens is negligible in comparison with other natural estrogens and phytoestrogens. This means that consumers are exposed to a much higher dose of estrogen from a vast number of sources other than cosmetics. In the most recent publication of the group Dr. Darbre (2012) analyzed the presence of five different parabens in the breast tissue of 40 women with primary breast cancer. In each patient at least one ester of parabens was present. However, seven of the 40 patients analyzed had never applied cosmetics under the arm, such as antiperspirants, which contained parabens. This means that the source of these compounds must be other cosmetics or foodstuffs. According to the opinion of the SCCS (The Scientific Committee on Consumer Safety) on the 2005 Darbre study it contained a number of methodological errors. In addition, the most common paraben in tumour tissue was methylparaben, which has the weakest estrogenic activity, which excludes more epidemiological studies which link the use of underarm cosmetics in the area of breast cancer. Most cosmetics (> 98%) used in the armpit area do not contain parabens, and hormones are the most important factor in the pathogenesis of breast cancer. Their presence in and around the armpits, according to many, is because of the lymph glands. Clinical studies clearly showed that there is a flow of lymph from the breast toward the armpit, and then in the direction of other organs and tissues, so the reverse process of substance penetration from the armpit to the breast tissue is not possible. It should also be noted that parabens are very rarely used in preparations around the armpits. Cosmetics such as these, due to the low pH (antiperspirants) or alcohol (deodorants), rarely contain parabens, and in some cases do not require any preservative system.



At the moment most of the scientific community agree that it is not possible that parabens have any hormonal impact in man. However, studies carried out so far, and their analysis, show that parabens poorly penetrate the epidermal barrier. In addition, after entering the bloodstream they are metabolized and do not accumulate in the tissues. Therefore, an estrogenic effect on the human body is not likely, and therefore parabens do not interfere with hormones. A number of factors contribute to the development of breast cancer, so one cannot blame just one chemical. Parabens are only part of a larger whole.

Another problem about parabens concerns compounds that can might cause skin irritation. In the case of normal skin not showing a tendency to irritation, parabens should not irritate. However, with sensitive skin it very often causes itching, redness and hives, and therefore use on this type of skin is discouraged. They can also increase the tendency to develop acne rosacea, or irritation such as perioral dermatosis. Allergies are caused more often by the use of medicinal preparations applied to the skin than cosmetics. Patients with a known hypersensitivity to parabens in dermatological formulations can tolerate cosmetic products containing the same preservative, which has been described as the „parabens paradox". This is due to the fact that cosmetics are applied to healthy skin, and drugs are applied to damaged skin, which is much more sensitive to all allergens and other harmful environmental factors. The fact is that parabens are quite potent allergens, but you should differentiate between 2 cases. Substances which are dangerous harm the population. However, allergens are harmful only to those who are allergic to the compound. Following the arguments of

Substance	Maximum acceptable concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
Metyloparaben	0.4% (as acid) for individual concentrations of methyl-, ethylparaben and their salts 0.8% (as acid) for the sum of individual concentrations of 4-hydroxybenzoic acid, methyl, ethyl, butyl- and propylparaben and their salts	---	---
Etyloparaben			
Butyloparaben	0.14% (as acid) for the sum of individual concentrations of butyl- and propylparaben 0.8% (as acid) for the total sum of concentrations of 4-hydroxybenzoic acid, methyl, ethyl, butyl- and propylparaben and their salts	Not to be used in leave-on products for the nappy area intended to be used on children under three years of age	For leave-on products which may be used on the nappy area of children: "Not to be used on the nappy area of children under three years of age"
Propyloparaben			
Isopropylparaben, Isobutylparaben, Pentylparaben, Fenylparaben, Benzylparaben and their salts	Prohibition of use		

Tab. 1. Limits, restrictions and requirements on parabens

opponents of parabens, we should prohibit the use of virtually all substances because it is difficult to find a component which the majority of people would not be allergic to. It should also be noted at this point that allergies to parabens are not found very frequently, and even plant extracts used in a wide range of natural cosmetics also cause allergies in certain groups of subjects. An independent organization, CIR (Cosmetic Ingredient Review), which reviews cosmetics stores and analyzes the safety of components on the basis of more than 265 studies in the Journal of Toxicology, registered no negative effects, and confirmed the safety of parabens. In addition, in 2009 the Nordic Association of Cosmetic Chemistry (SCANCOS), published the results of a new study on parabens, whose aim was to confirm the negative impact of parabens on the human body. The study confirmed that parabens are immediately metabolized in the body, and therefore are not able to cause negative reactions.

In EU countries the maximum acceptable concentration of parabens can not be more than 0.4% (methyl, ethyl, propyl) for individual concentrations or 0.8% for their mixture expressed as benzoic acid.

The most recent SCCS reports on parabens (SCCP/1348/10) were prepared in March and October 2011, taking into the account overall risk assessment based on the level of evidence. Acceptable and safe levels of methyl and ethylparaben remain unchanged (0.4% for individual concentrations and 0.8% for the mixture of parabens). In its report the Committee notes that the most important issue related to safety is the effect of propyl and butylparaben on the hormonal system. In this case, the Committee adopted more restrictive assumptions to determine the safe level, which is the basis of risk assessment for the component of the cosmetic. The Committee considered that butyl paraben and propyl paraben are safe, but at a lower concentration than before - 0.19% for both the use of these substances alone or in a mixture. A report published in 2011 also confirmed the safety of parabens in cosmetics for children, except for products for the nappy area of children under 6 months. In Denmark, the use of propyl and butylparaben is prohibited in cosmetic products for children under 3 years of age. Denmark is a pioneer in the field of consumer protection against endocrine disruptors, and has now become the first country in Europe to prohibit the use of parabens in products for children. According to a recent suggestion SCCS Commission, the maximum allowable concentration, restrictions and requirements parabens, are presented in Table 1.

As a consequence, some cosmetics manufacturers have decided to withdraw the use of parabens. This is due to marketing considerations, especially the atmosphere of „danger" created by the media, rather than on the safety of parabens for consumer health.

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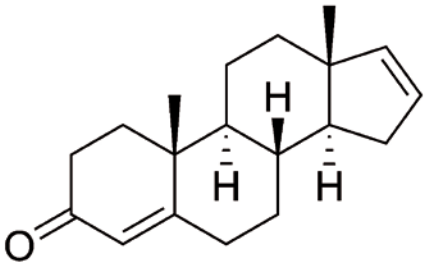
They facilitate establishing contacts. Increase self-confidence. Emphasize our femininity or masculinity and strengthen physical attractiveness. They enhance the perception of our selves, improve the mood and relax. Numerous scientific studies confirm the influence of pheromones on human behavior and make them very popular among consumers. But what actually are pheromones?

Pheromones are natural, semiochemical compounds produced by animals, which act as chemical stimulants transferring information and causing certain physiological or behavioral response in other individuals of the same species. The existence of communication through pheromones is known in almost all social animals. These compounds affect numerous territorial, social, sexual, defense and many others behaviors.

In humans, apocrine glands are the main source of pheromones, but its production can also be related to the skin's sebaceous glands, the source of pheromones in mammals. The activity of these pheromone producing glands starts with hormonal changes in puberty. Apocrine glands, which are associated with a hair follicle, are abundant in regions where hair develops during puberty, for example in the armpit, and are primarily responsible for producing our body odor. It is believed that the specific development of hair in these regions is to facilitate the dispersion of substances such as pheromones in sexually mature humans.

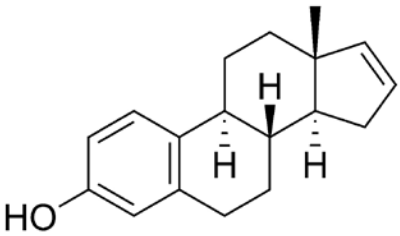
Pheromones are odorless and consciously undetectable to the human nose, but our sense of smell can perceive secreted pheromones without being aware of it. In most mammals, these molecules are detected by a special organ, the vomeronasal organ (VNO), that signals the hypothalamus to trigger this behavioral or physiological response. The brain receives a signal and triggers reactions which, as a result, cause in the recipient an attraction and longing for the person who has released them.

From chemical point of view, pheromones are usually steroid molecules derived from sex hormones. In humans, the substance that currently is mostly postulated as male pheromone is androstadienone, however androstenone and androstenol are also mentioned. It is a substance produced mainly in men, where its presence has been described in sweat, skin, saliva, semen, blood



and male axillary hair. Comparatively, it is detected in very small amounts in women, for instance in the case of sweat, where the concentration in men can be 20 times higher. The female equivalent of androstadienol is estratetraenol, ought to have an impact on the sexual behavior of men. Also the so-called copulins are considered as compounds that emphasize femininity. Copulins are a mixture of volatile, short-chain (C2-C5) carboxylic acids, like acetic acid, propanoic acid, butanoic acid and their derivatives. There is also a group of social pheromones, that affect both sexes and in public relationships benefit both women and men. A representative of this group is androstenol.

Confirmed effect of pheromones on social relations, physical attractiveness, perception of individuals and other public aspects of male-female relationships induced the commercial popularity of pheromones. Products commonly and commercially called pheromones are usually a blend of different compounds, composed according to the target group. Pheromones are commercially available in various forms. One of the most popular are alcoholic, glycolic or glycerinic solutions of a mixture of pheromones, dedicated for direct application on the skin. The total content of pheromones in such products ranges from 0.03% to 0.07%, with a price reaching even 100 € per vial. Pheromones are



also used as a component of massage oils, perfumes, creams, wet wipes and other cosmetic products, however their final concentration in these type of products generally does not exceed 0.01%.

An alternative to synthetic pheromones, especially attractive for those manufacturers, who want to enter the world of sensual cosmetics, are active ingredients stimulating natural synthesis of human pheromones. ***In vitro*** studies on cellular model of human sebocytes proved, that a special combination of black tea theaflavins and forskolin from makandi increased the production of male pheromone androstadienone. The quantity of this pheromone in the cells treated with active ingredient was almost three times higher compared to the control. The effect of the active resulted from the synergistic action of its two botanical components. Forskolin, influencing the activity of 3β-HSD enzyme, which participates in the synthesis of pheromones, increased the production of androstadienone, while the polyphenols derived from black tea, which inhibit the activity of 5 -reductase, prevented from further metabolism of the pheromone, facilitating its accumulation in cells.

Cosmetic active ingredients stimulating the synthesis of pheromones can be considered as a new wave in the development of this part of the market, but also innovative and intriguing raw materials, improving the marketing attractiveness of „classic" cosmetics. Continuously and rapidly growing segment of products dedicated for men, who are especially keen of technological innovations and original solutions, is particularly interesting field of application. However, a positive receipt of such kind of actives by the cosmetic ingredient market suggests, that in the near future we can also expect actives dedicated for women, stimulating the synthesis of female pheromones. Active ingredients aimed at increasing the synthesis of pheromones are an ideal ingredient for all hungry for success in social interactions.

□

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Processing of plastics in the process of manufacturing packaging for make up cosmetics

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The process of manufacturing packaging for make up cosmetics relies on the use of the two most common plastic processing methods: injection molding and extrusion. The goal of this article is to describe topics closely related to the everyday operation of a packaging production company.

Injection using screw injectors is a relatively new albeit rapidly developing technology; the first screw injectors were used about 1960. Today, it is the basic and the most common manufacturing process. Injection molding is a complex cycle-based process. In most cases, thermoplastic materials are used for injection. Injection molding technology has many advantages, including the ability to obtain the final product without additional processing, the ability to produce elements of complex structures, a wide range of molding weights (from 0.01 g up to 70 kg), high quality, and repeatability. The disadvantages of the technology include high equipment costs and the need for highly skilled employees that can use the equipment in a proper manner.

The injection molder consists of functional assemblies, including a plastification and injection assembly, a mold closing/opening assembly, a drive assembly, a control and adjustment assembly, and the body.

The plastification and injection assembly, also known as the injection unit, is responsible for the preparation of the material and its injection into the mold. There are many types of injection units, including piston units and preliminary

plastification units. The most popular types of injection molders are screw injectors. The assembly consists of a hopper and a plastification zone. The plastic material is plasticized using heating zones.

The plastic material is injected under pressure into the mold, i.e. to the mold closing/opening assembly. The mold is affixed to fixing plates, one of the plates being a mobile plate. The plate movement and closure strength are exerted by the drive assembly. The mold is moved along columns or, in the case of column-free injection molding machines, along guide rails within the body. The molding is formed and partially cooled within the mold. Ready-made elements are removed from the mold after opening.

As suggested by the name itself, the control and adjustment assembly is used by the operator to predefine the settings of the injection process. Depending on the type of machine, the control and adjustment assembly may consist of an electrical system, a touch panel, a control cabinet and, in the case of older machines, a cam set. Injection molding machines are capable of saving predefined settings, helping to maintain the repeatability of products.

The machines are operated by a drive assembly. Today, electric drive assemblies are used more and more frequently, allowing a reduction in energy consumption by as much as 25%, as evidenced by the results of numerous studies conducted by academic researchers in Poland. Each drive assembly is comprised of a number of subassemblies supplied by pumps.

The last functional assembly is the body protecting the working parts and securing the machine in its place. The size and shape of the body depends on needs, as well as on the location and numbers of plastification and injection and mold closing/opening assemblies.

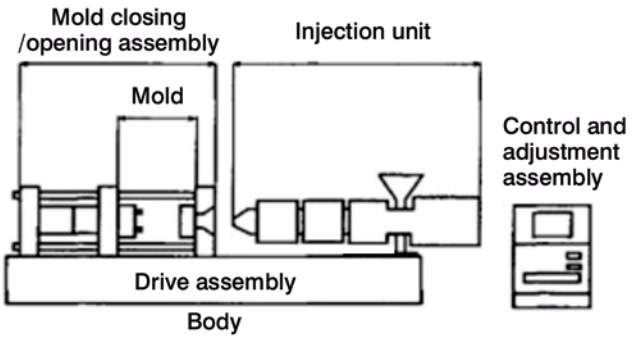

Fig. 1. Schematic diagram of an injection molding machine [10]

Injection is a complex process. Firstly, the hopper is filled with material, which has to be appropriately prepared beforehand. In many cases, the material is dried using special dryers. This is to eliminate moisture that might be present in the material. Drying allows the avoidance of molding defects, manifesting as silvery glitter on the surface.

After the hopper has been filled, the material is transferred onto a screw conveyor. The rotating conveyor transports the material down the cylinder. In transport, the material passes through three zones, i.e. the feed zone, the compression zone, and the dosage zone. In these zones the material is plasticized and degassed. Material regurgitation is prevented by appropriate geometry of the screw conveyor and a special valve installed at the end of the conveyor. The material is injected through a nozzle into the mold cavity, where the molding solidifies. After the molding is removed the entire process is repeated.

In contrast to injection molding, extrusion is a continuous process aimed at shaping products. As with injection molding machines the plastic material is transported along a cylinder and then pressure-forced through an extrusion head. The production process often makes use of extrusion bottle blowers. The bottle forming process is slightly more elaborate. After profile extrusion the material is returned into the mold, where it is blown to the size of the molding cavity using compressed air.

Plastic materials are large-molecular compounds, also known as polymers, i.e. compounds of complex molecular structure. From the chemical standpoint, polymers may be divided into particles comprised of subassemblies, i.e. macromolecules and micromolecules. Macromolecules are defined as chain structures connected by numerous covalent bonds. Macromolecules are composed of basic components called mers. Mers form groups of similar atom bonding. Macromolecular structures may be classified as one-, two-, or three-dimensional. One-dimensional macromolecules are characterized by one distinguished spatial direction. Examples of such macromolecules include polyamides or polyesters. Likewise, two-dimensional macromolecules are characterized by two, and three-dimensional macromolecules are characterized by three stretching dimensions. All these structures are characterized by configurational isomerism. As they consist of a large number of identical elements, polymers form various topological structures. These structures pertain to connections between units. Example topological structures include linear, branched and cross-linked macromolecules. The number of branches depends on the polymerization process, namely on the pressure applied during the process. One-dimensional structures are comprised of both linear and branched chains. This, however, is not the case for two-dimensional structures.

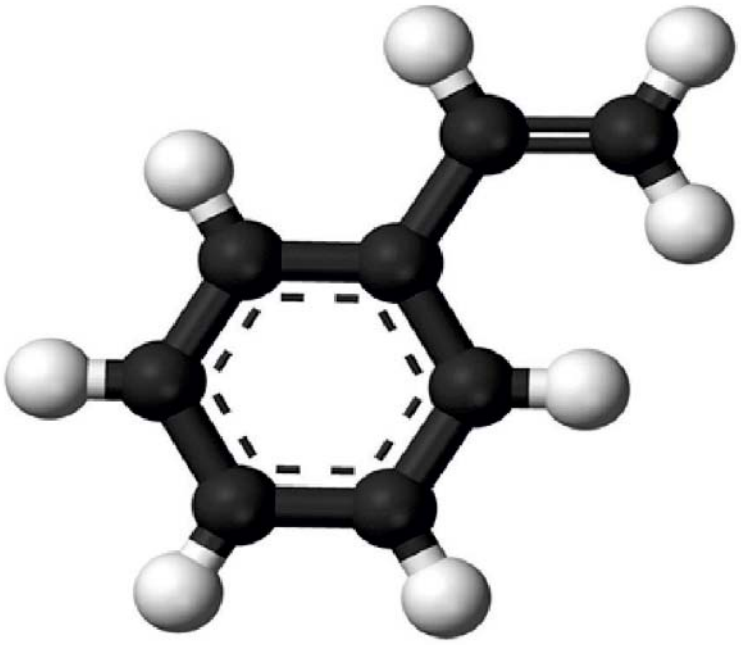

Fig. 2. An example chain of monomers [9]

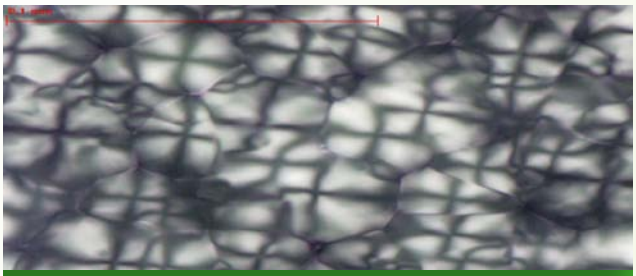

Fig. 3. Radial spherulites of polypropylene (PP) at x400 magnification [6]

When describing the inner structure of polymers, it is also worth mentioning their supramolecular structure. The classification includes three groups of plastics: amorphous, partially crystalline, and mesomorphic, also known as liquid-crystalline. They differ in the spatial arrangement of their polymer molecules. Molecules are arranged in partially ordered structures, or form amorphous structures.

In the amorphous structure, the molecules remain unarranged. The structure resembles spaghetti, and is a vitreous state structure. The rise in temperature leads to microtranslations of entire chains or chain fragments, resulting in reversible deformations. Thus, the polymer undergoes a transition from a vitreous state to a high-plasticity state. The transition is responsible for the development of elasticity. Amorphous polymers are capable of attaining a viscoelastic state. Tension forces within the polymer structure are responsible for creeping and relaxation.

In contrast to the amorphous structure, molecules in partially crystalline structures are partly ordered. This crystalline structure can be attained only by polymers with stereoregular molecules. Stereoregularity facilitates changes in the conformation of meres and entire segments. These changes lead to the formation of crystallite unit cells. Crystallites formed within polymers are known as lamella; the structure of the lamella is based mostly on regularly bent chains or chain fragments. Crystallites may also have the structure of stretched macromolecules aligned in parallel to one another. In such cases, they are called fibriles. Fibriles form band-like aggregates around a common center. In the case of lamella, such aggregates are called spherulites.

The degree of crystallinity describes the amount of crystalline phase within the polymer, affecting its thermal, mechanical and optical properties, as well as the types or temperatures of phase transitions. The crystallization process is caused by transition from the amorphous to the crystalline structure.

The most popular plastics may be classified to either of the two groups described above. Examples of amorphous plastics include Poly(styrene-co-acrylonitrile), acrylonitrile-butadiene-styrene, poly(methyl acrylate), polystyrene, polycarbonate or polyvinyl chloride. Examples of partially crystalline plastics include: isotactic polypropylene, polyamide, polyethylene, poly(ethylene terephthalate), poly(butylene terephthalate) and some polyuretanes.

Knowledge of supramolecular classification is useful in everyday production processes. It is particularly important for selecting appropriate materials.

The bottles mentioned above are extruded from a thermoplastic polyester resin of the PET family (PETG). It is a copolyester that, thanks to the addition of glycol, is particularly well suited for the production of transparent packaging. The main advantages of this plastic include reflective properties, gloss and transparency. The material is well suited to the addition of colorants, so that virtually every color may be obtained. Ready PETG packaging is a good substrate for prints, facilitating enhancement of the visual appearance of details. Caps and assembly parts are made of more commonly used plastics. These include polypropylene (PP), polyethylene (PE), polystyrene (PS), Poly(styrene-co-acrylonitrile) (SAN), and acrylonitrile-butadiene-styrene (ABS). These plastics are selected on the basis of their properties that affect the quality of the final product.

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Systematic development

– how an IT system can show a company the way for development and assist it in implementing changes

Stanisław Juźwicki
Consultant, specialist of Business Intelligence solutions, I&B Consulting

What are Business Intelligence tools and how do they work?

Business Intelligence tools are one of the key functions fulfilled by business solution. Their task is to analyze data coming from all over the company's IT system, including, above all, ERP software, but also from the fiscal system, CRM solutions and specialized custom-made applications, designed specifically for a particular company and supporting it in a strictly defined area. These tools, when properly configured, also use data downloaded from the Web. Currently, these type of applications have reached such a degree of sophistication that they can be integrated into virtually any software and download data in a variety of formats (text files, xls, images, graphs, etc.) from different locations, for example, from websites, including online software, databases distributed in various systems used in the company, as well as files spread out on its employees' computers.

Business Intelligence software allows you to translate chaotic data into knowledge. In using archival and current data coming from the company's IT system, these tools allow you to prepare reports, comparisons and simulations that specifically look at the selected business areas of the company, analyze the effects of particular processes and make decisions based on specific and hard data.

Daily decisions – small steps of major significance

By knowing more about particular activities and their effects, you can improve the efficiency of daily processes taking place in the company, which are the foundation of its activities. On the basis of currently analyzed data, Business Intelligence applications are a great help in identifying areas and products where you might want to invest, as well as identifying the scopes of the company's activities where changes are required. Briefly, they allow a company to make the most of its potential, both at the level of daily operational decisions and key issues of strategic importance. There are many examples of using Business Intelligence tools.

Will it pay off?

Balancing sales data of particular products, generated by using the application, clearly shows which of them are most popular and which are less popular. If you compare this data with information on their prices, you can see how they affect demand and determine their optimum level, or decide to close the production of a given product.

The application also suggests which cosmetics are most profitable for the company to manufacture. By using the system to analyze the cost of production, margin and supply, one can determine the proportions in which to produce a given product in order to maximize the use of the company's resources (machine park, personnel) and obtain the highest possible profit.

In the case of factories producing to realize the orders of external entities, the possibility of estimating costs of particular orders is extremely helpful, as well as predicting the realization date of a specific lot. By using current and archival data, tools for business analysis allow you to carry out simulations, which can assess the profitability of the order.

The recipe for success

When developing new products, Business Intelligence applications dictate which recipe and which sales strategy is the most profitable – whether it is better to use cheaper substrates and sell cosmetics at a lower price, but in larger quantities, or whether the optimal solution is the production of selected, more expensive components and selling products in smaller quantities, but with higher margins.

The recipe and sales strategy are significant, but the time in which a new product reaches the market is also important. Business analysis tools help in determining the right moment. On the basis of data on the dynamics of sales from previous years - they show the period of greatest interest in a given product category, as well as enable to estimate how long production will take. This feature is additionally useful in planning the production of seasonal products - e.g. sunbathing creams and lotions.

Introducing a new product onto the market always involves risk. Many manufacturers have painfully experienced this by releasing a cosmetic which was completely ignored by customers. Business Intelligence tools allow you to specify a safe amount of a new product, which should reach the stores – large enough to make the product noticeable, but small enough to not to cause large losses in the event of failure.

Furthermore, these applications make it easier to develop the strategy for disseminating a new product and updating it on the basis of consumer interest (sales figures) in accordance with the principle: the greater the supply, the faster you should provide stores with the largest quantity of the cosmetic. Great popularity of new products may involve the need to change production plans. It is worth to make the most of novelty's attraction and increase the interest of clients aroused by a strong marketing campaign accompanying the market premier of the product, as well as consider increasing the production of the best-seller at the expense of reducing the production of other cosmetics.

What if...

Business Intelligence tools configured with a module of supply and production are an invaluable asset in a situation when it is impossible to act in accordance with the plan e.g. in the event of failure of one of the machines, or the absence of a substrate. Then, by analyzing the stock available - the application suggests what other products can be manufactured, in order not to stop the production line and minimize any downtime and losses associated with it.

Everything is under control

Business analysis applications are also invaluable in controlling the company's expenses. In times of a weakened economy it is worth knowing exactly what money is allocated for, in order to make financial cuts, if necessary, in an area which will least affect company performance.

Business Intelligence tools can also be used to optimize everyday work that does not constitute the company's key business activity, but is essential to its functioning - e.g. developing delivery routes to particular recipients and loading delivery vehicles. The order system configured with a road map e.g. Google maps enables you to set up the optimal route in terms of fuel costs and delivery time. In addition, the use of these tools can help plan loading so that the goods that should be delivered first are placed closer to the door, and those that have to go the longest route - are packed further, which also improves the logistics process and additional savings.

Intelligent marketing

Customers rarely like advertising spam, while among commercial chains, chemists are leaders in drowning customers with „super offers" and newspapers informing about new products. As a result, instead of attracting customers - they discourage them to visit the store, because most of the information simply does not interest them. Costly mailing or shipping catalogues, promotional coupons or newspapers appears to be throwing money down the drain. However, thanks to Business Intelligence tools you can significantly raise efficiency and lower the costs of these kinds of activities. It is enough to accurately provide an offer that is adequately targeted at the needs of specific customers. Commercial chains which have a system that supports a loyalty program (regular customer cards) with the ability to track purchases made by customers, thanks to business analysis applications, are able to determine what type and what brand of specific products customers buy the most often. On this basis, they can profile the offer targeted at them. What's more, the system is also able to track the effectiveness of campaigns carried out like this - by comparing the data on the number of recipients of the offer and the sale of the products covered by it.

100%, 200% or 80% of the plan?

With business analysis applications, managers will have an easier time in planning expenses, as well as production and sales plans. By having specific data and directions on demand dynamics, the management is able to predict the company's real potential and develop plans at the optimal level - sufficiently ambitious and at the same time possible to carry out. On the other hand, Business Intelligence applications, using updated data on a regular basis, facilitate controlling the level of performing established plans. You can compare data of previous achievements with an earlier established plan at any time in order to determine whether it is on the right track to be realized or if efforts must be increased.

Changes for the better?

If the company's board decides to make changes - the validity of decisions and efficiency of transformations can be monitored and compare with archival data from before the reforms. This way, you can correlate e.g. information on production efficiency with increasing employment in the production hall or changes in the manufacturing technology. If the modification process is in progress, by following its results it can be adjusted regularly in order to obtain the best effects – in this case observe how indicators changes in employing extra employees or an alternative technology.

Business Intelligence software is necessary not only in the assessment of the effects of changes introduced in the company, but also help in anticipating their effects. In the event of planned restructuring, the system is able to generate a few scenarios of its consequences and compare them with each other in terms of an unlimited number of criteria. Thus, critical decisions are burdened with lower risk and it is easier to assess the probability of their occurrence. These types of functions in the system are especially useful when there are high stakes, e.g. if the decision concerns expanding onto a new market or closing one of the plants.

Strategy of the brand or... towards the brand

In the case of companies which have in their portfolio a number of different brands or product lines, Business Intelligence tools help you manage both individual entities and the entire company. Thanks to this, in the event of problems with one of the brands, one can take a closer look at the condition of the entire company and decide whether it pays off to keep it, e.g. due to strategic or image reasons, by balancing the losses it caused with the successes of other lines, or whether it should be closed altogether or sold. By comparing its results with other brands, conclusions may be drawn, in which areas is it mostly „limping" and identify the causes of its failures in order to make the appropriate changes and revive it or not commit similar mistakes in other product lines.

Business analysis applications can also be used when one is considering purchasing a brand from another manufacturer, if of course we have the relevant data, e.g. financial data for the company, or information on the sales level from the sales chain through which the brand is distributed. This type of analysis can also be useful in the case of cosmetics importers. On the basis of sales data and analysis of the competitive environment, and other information from different sources, they can decide whether introducing a brand onto a specific market has chance of success.

Business analysis – guarantee of good decisions

Business Intelligence tools support the producers, importers and distributors of cosmetics in decisions at the operational, tactical and strategic level. They facilitate everyday choices, as well as provide guidance when making key decisions involving high costs and of long-term consequences. In a clear form of tables, graph or animations generated by just a few clicks of the mouse, they change terabytes of data into specific, valuable knowledge that allows to gain advantage over the competition. They are a modern „crystal ball" for predicting the future of the company... except that to decrypt the predictions one does not need supernatural powers. □

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Current trends in modern hair care

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Since the ancient Egyptians began using creams in their hair to moisturise it, overcoming the drying effects of the hot, desert climate, hair products have become part of everyday life1. From simple shampoos to complex styling products the hair care market remains buoyant and provides many of us with a cheap way of altering our look. The type of products we use are often dictated by which cuts are in fashion, product being used to emphasise certain features of the hair and maintain its shape or applied prior to styling to protect from the high temperatures often involved.

Hair trends for the end of 2012 and the start of 2013 include the ponytail, with the ponytail positioned centrally and mid-height for a preppy look or sectioned for more a more sophisticated and glamorous look. The hair is swept off the face allowing the complexion to be seen so the trend for naturally beautiful skin with an even, radiant appearance fits perfectly with this look. Centre partings will be super straight although long locks can also be tamed by putting them in a side-parted "up-do", particularly during the day with the hair being let down in the evening. Straight hair may be cut into a super sleek bob style, or, if kept long, the side parting will be back in fashion and has already been seen on the runways of the catwalks. Up-dos will be made more exciting with the addition of delicate and fancy accessories and clips will be used to make small buns in the hair. Styles have been understated recently but in 2013 there will be a return to glamour, volume can be boosted in straight hair by adding waves but most important of all the hair should have a silk like finish and be super sleek, shouting to all onlookers how naturally healthy it is and by inference how healthy the owner is2.

In the following article I will dip my toe into the ocean that is the global haircare market giving an overview of some of the more recent launches, trends and scientific literature and providing an insight into what the future may look like for this important member of the personal care family.

Shampoos and Conditioners

Unsurprisingly shampoo remains the largest sector in haircare and with the trend for sleek and shiny hair looming large this will not change in the foreseeable future. From humble beginnings shampoos now come with a wealth of claims and added extras. In times past the shampoo also contained conditioning agents (who can remember when we had to take 2 bottles into the shower) to make them two in one products with a large number of three in one products now on the market (shampoo, conditioner and body wash). These can be particularly suitable for the kids market where mildness will also be key alongside the important "no tears" claim. The products will be formulated with mild, sulfate free surfactant systems suitable for young skin which is easily irritated.

Although cleansing is obviously a primary function of a shampoo product recently it has been noted that some of the claims on shampoos and conditioners mimic those found in the skincare market, hydration and damage repair being very popular. Also, similar to skincare, where the mantra was once "cleanse, tone and moisturise", we can see the emergence of "regime" type products particularly when looking at repair, for example Tresemme's recent "Split Remedy" concept composed of professional quality split mend shampoo, separate conditioner and a mend and protect leave in treatment, resulting in an 80% reduction in split ends after three uses. In the more premium sector of the market Phylia de M boasts a range consisting of three products, Clean, Condition and Connect which promise to give thicker and healthier hair, again designed to be used as a regime.

As wet weather and the resultant high air humidity seems to be a perpetual problem in many countries the launch of the Umberto Giannini Frizzi range, specifically designed to tame unruly hair, will be welcomed by many. Frizz has long been the enemy of neat, styled and particularly long hair and the highlights of this range include "Frizz Off" blow dry cream (moisturising and repairing), Transformation Fluid Silicone Serum and "Make My Day" smoothing conditioner.

Again mirroring the skincare market, hair products have been developed specifically for the mature market. As we age our hair characteristically becomes drier, more brittle and thinner and this is observed in both males and females. Ranges such as Dove Pro-age and L'Oreal Elvive Age Defying contain products which can counter these effects and have been available on the market for a while. More recently Proctor and Gamble have launched the Pantene Expert Collection which will combat the signs of hair aging and repair badly damaged and over processed hair3. P&G conducted one of the largest, longitudinal hair studies ever undertaken, involving over 500 volunteers with an age range spanning from 2 to 88 years and following them for 8 years to assess how their hair changed4. The study concluded that significant levels of grey hair occur after age 45 years, the rate of greying increases most dramatically after age 50+ years, hair gets rougher with age, the diameter of hair changes significantly with age, over a third of women over the age of 30 years reported a decrease in hair volume and thickness over the 8 year study and finally the tensile strength of hair decreases above age 50 years (related to the decrease in hair diameter). A further study by Robbins et al also concluded that hair shaft diameter and the density of hair decreases with age,becoming more noticeable in the mid-40's5.

L'Oreal have being looking into grey hair and its prevalence in global populations to test the 50/50/50 rule (at age 50 years at least 50% of the population has at least 50% grey hair) using a panel of over four thousand volunteers. Their research noted that between the ages of 45 and 65 years 74% of the population are affected by grey hair, with men having significantly more grey hair then women. The study concluded that at age 50 years the percentage of people showing 50% coverage of grey hair was in the region 6 – 23% so well below what had been previously reported6.

Recent research by Saki et al has identified three markers in the cortex of the hair shaft which become reduced as we age, leading to the conclusion that these molecules could be targets for cosmetic products to treat and so anti-aging shampoos may become more prevalent in the market place in the future, preventing aging rather than treating it7.

Styling

The styling market is both format and fashion driven with an almost bewildering array of products available even in the simplest of supermarket displays. Formats vary from the traditional hair sprays (Elnett, now over 50 years old, is a timeless classic in this sector8), through mousses, creams

and pastes, puttys, waxes and gels to the more recent powder stylers which are simply shaken on to the hair. Schwarzkopf's Osis Dust-it product was the launch which broke powder stylers into the market place with many others, including the designers, quickly following. Powder stylers, usually presented in a pepper-pot style pack, tend to be comprised of a silica material blended with a polymer in the powder form which gives the actual styling properties, (formulations with varying degrees of hold are available from the Cornelius TQR if required9) and their popularity may be in part due to the rise in the use of dry shampoos which have also become more complex and may now incorporate styling materials and even pearlescent pigments to make them stand out from the crowd (according to Batiste there are over 2.5 million users of their dry shampoo in the UK alone and they have recently added Paisley and Graffiti variants to their range10).

As stylers have become more sophisticated and formulations more advanced consumers have become more demanding in what they expect from products. In previous decades product would be visible on the hair, holding the hair in very unnatural poses and giving a large amount of mirror-like specular reflection to the hair which, whilst shiny, did not mimic naturally healthy and glossy hair. Now consumers want all day styling effects with low tack, low flake, high levels of humidity resistance, increased volume and a natural, silk like shine rather than a glass like finish.

Mens styling products, such as the recently launched and widely lauded Lynx range, now claim "strong hold with irresistible touch" highlighting the fact that product should not be "crunchy" as was so often the case in the past. Luckily for formulators new styling polymers has been an area of much activity for ingredient suppliers with new products enabling todays ever tougher formulation demands to be met.

Natural products are viewed as an area of high growth in the haircare sector with many brands and products available, a recent example being Tara Smith's vegan hair range launched at Marks and Spencers. It is important in this sector to be able to communicate effectively with your consumers, a problem highlighted by Unilever recently who have invested heavily in this area. Natural products may be viewed as not being as efficacious or cost effective as their more mainstream counterparts so the consumer needs to be educated to understand the benefits of natural products11. With a wide range of naturally derived ingredients available to formulators, including materials such as the Soil Association, EcoCert or NaTrue approved, it is no surprise natural and organics are being viewed as a rising star in this category and as major companies launch more products in this sector we can be sure that consumers will gain a better understanding of the benefit and therefore have a greater choice of product than ever before.

View to the Future

It appears a large amount of research is being conducted into both the changes occurring in hair as we age as well as the molecular basis for this which would indicate that anti-aging claims will no doubt cross- over more than ever from skincare to haircare in the next few years, a phenomenon which has been predicted by many for a long time now. In light of the P&G study into aging hair mentioned earlier in this article4 it is probably no surprise that towards the end of 2011 a further paper, also by P&G, was published detailing how a cosmetic product can be used to treat thinning hair. The test product contained a blend of caffeine, niacinamide, panthenol, dimethicone and an acrylate polymer with results showing an increase in hair shaft diameter and an increase in the hairs tensile strength after application12.

Obviously as we age the hair becomes grey due to pigmentary changes in the hair shaft and, as previously detailed, this appears to be an area of interest for L'Oreal, who have published research detailing age related changes in eumelanin levels in three ethnic groups13. Johnson and Johnson have also investigated grey hair concluding that grey hair is perceived as being wilder, drier and less manageable14.

More recently the use of gold has been investigated for dying hair. Human hair was exposed to alkaline solutions of HAuCl4 which initiated the production of gold nanoparticles (AuNP's) within the hair fibre cortex in a regular pattern of whorls. The hair turned yellow and after further exposure a dark brown colouration was observed15. Water quality and hardness has also been the subject of research, an important factor for any formulator developing hair care products as the performance of hair products can be affected by hardness levels which vary widely even within the same country. It appears harder water favours a reduction in combing force levels and also allows for longer style retention16.

Photoprotection of hair appears to have been investigated extensively in the early 1990's but interest in this area, in terms of published papers, appears to be on the wane, perhaps as the dangers of the sun have become more widely understood leading consumers to seek the shade or wear a hat to avoid over exposure.

Finally, many publications have looked at methods for assessing the effects of cosmetic products on hair, including breakage force, shine measurements, combing force etc17. Rapid and objective screening methods for hair product performance are much in demand for assessing new formulations so it is encouraging to see this is still generating interest.

Conclusions

The haircare market is being driven by a consumer demand for ever more innovative products with multifunctional performance to match. Claims on products are becoming more complex and increasing levels of functionality are important, especially as the use of heated styling tools, such as irons and curling tongs, has rocketed over the past few years. A recent survey of teenagers showed that straight hair was by far the preferred way of wearing hair and that the purchase of styling and protection/repair products was becoming common place in this age group driven in part by the fact that hair products still remain relatively inexpensive18. It looks like anti-aging will be one of the key claims for the future in what is becoming an increasingly exciting and fast moving sector.

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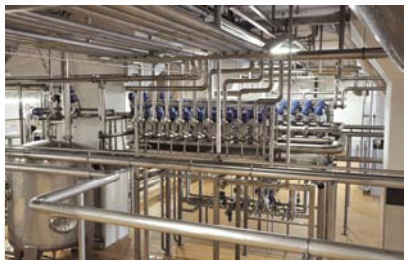

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