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Permanent Make Up-PMU Colorants and Regulations

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Abstract

Decorative tattoos is a popular way of expression in young people. Permanent Make Up (PMU), is gaining ground every day for facial characteristics correction. Colorants used for PMU applications do not always follow the regulations of the European legislation and may contain harmful ingredients for the health. European countries are trying to create a common regulation followed by each country member to protect public health.

KEYWORDS

permanent make-up, PMU, colorants, regulations

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1. INTRODUCTION

The tattoo procedure dates to the Neolithic years. It exists in every historical period of human existence and “marks” in a unique way the archaeological findings of today. Nowadays decorative tattoos are a way of expressing of everyday art with the characteristics of the last decades which has formed into a popular procedure in the young and older population [1].

Permanent make up (PMU), at the beginning of its appearance in the tattoo market, was used for facial characteristics correction, such as eyebrow shape, eyelids shape, and lip shape. As years passed it was developed in a more “medical” use - Medical Permanent make up. It can be used over the head for creating hair follicles pigmentation, on the breast for areola reconstruction after mastectomy, medical procedures like scar covering and color corrections after various skin problems [2].

At the same time tattoo and PMU colorants, come from a wide spectrum of color industry use,

with untrustworthy substances and no obligative legislative framework for the manufacturers to write on the ink bottles all the ingredients. This can lead to side effects which in the PMU case can cause a bad result over the face area [3].

The present article is an overview of the PMU colorants as they exist in the market today and the European regulations as they have formed until now for the tattoo inks and permanent make up colorants.

2. PERMANENT MAKE UP (PMU) COLORANTS

Permanent make up (PMU) procedure is almost the same as tattoo application. Small droplets of specific permanent make up ink are implanted into the superficial layer of the dermis. In decorative tattooing, the procedure differs in the depth of pigment deposition which occurs deeper within the dermis [2,4].

After the first days of healing, the color is eliminating. When the area is healed, the remaining pigment particles are stored in dermal macrophages and fibroblasts. The machines used, the needles and the nature of the colorants can influence the quality and stability of the results. The permanent makes up applications may fade after several months to several years. This can happen because of various reasons. One of the major reasons are the colorants used in permanent make up application which are different from tattoo inks [5].

3. REGULATIONS

The last fifteen years that tattoo and permanent make up procedure has gain popularity and many people obtain their first tattoo in ages under 18 years old. Because of this fact, a lot of research has been done over the PMU and tattoo inks. US Food and Drug Administration (FDA) registered over 250 reports of adverse reactions associated with remanent make up the last twenty years [6].

Most inks being used for tattoos are manufactured in European union (estimated at 70– 80%). Tattoo inks from the US, are usually used from licensed professional artists, while Asian products are mainly used from non-professionals because of the low cost of the products.

Permanent make-up colorants are mainly manufactured in Europe (estimated at 70–80%), and only a few products are imported from America and Asia [7,8].

The European Union in order to protect people who undertake tattoos and permanent make up, create regulation ResAP(2008)1 for the requirements

and criteria for the safety of tattoos and permanent make-up. This regulation was the first for the safety manufacture of tattoo inks [9].

European Union countries have adopted national regulations on tattoo inks (Netherlands, Germany, France, Spain, Sweden, Switzerland, and Norway). Very few have national regulations as Denmark and Austria. In many countries, there is no control at all which is a very big problem [7].

There is a scientific knowledge gap about the process of tattooing and what happens when inks enter the body. For this reason, cosmetic regulations are used to create prohibited ingredient lists. Furthermore, ingredients which have been forbidden for use in cosmetic products can be used in tattoo inks. All other ingredients that are not regulated in cosmetics can be used. Some colorants that are allowed in cosmetics but have been identified as dangerous for tattoos have been added to the prohibited list [7-9].

Manufacturers in Europe have reformulated their inks and avoid ingredients that are banned for use in tattooing according to ResAP(2008)1. In 2015, the European Commission asked ECHA (European Chemicals Agency) to assess the health risks of chemicals in tattoo inks and permanent make-up and to examine the need for a restriction on their use. ECHA did this assessment together with Norwegian, Italian, German and Danish authorities [10,11].

The restriction proposal was submitted in October 2017 to the Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) for their evaluation. A wide consultation on the proposal ran from December 2017 to June 2018. Subsequently, there was a consultation on the SEAC draft final opinion from December 2018 to February 2019 [12].

The investigation covered chemicals known to be used in tattoo inks and permanent make-up that may be hazardous to our health. Special attention was given to chemicals that are carcinogenic, mutagenic and toxic to reproduction (CMRs); sensitizers, irritants and corrosive to the skin; substances that are corrosive or damaging to the eye; metals; and other substances.

Following the Council of Europe's guidelines on requirements and criteria for the safety of tattoos and permanent make-up, many companies established a system of raw material management, defining and controlling the quality of raw materials used in their products.

4. EUROPEAN RESTRICTIONS

To protect European citizens, thousands of hazardous chemicals found in tattoo inks and permanent

make-up are restricted in the EU under the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation from January 2022 [13].

The restriction is about chemicals that cause cancer or genetic mutations and chemicals that are toxic to reproduction. Skin sensitizers and irritants are also in the restrictions. The aim is not to ban tattooing but to make the colors used in tattoos and permanent make-up safer. From the colorants that were investigated, only two were not as safe as others. These colorants were Pigment Blue 15:3 and Pigment Green 7. There was given a twelve-month time to the manufactures to identify and switch to suitable safer alternatives.

The biggest problems in the past were the microbiological contamination of inks and the presence of carcinogenic aromatic amines and carcinogenic polycyclic aromatic hydrocarbons (PAHs). Today inks manufactured in countries with national regulations are much safer. The microbiological quality is good, and the contamination of inks is now a minor problem. Inks are delivered sterile and are formulated to remain in microbiologically stable conditions after opening. Most European manufacturers have replaced these pigments. Resolutions and regulations have significantly improved ink quality about carcinogenic aromatic amines but there are still products with not allowed ingredients.

5. CONCLUSION

Permanent Make Up colorants are under the same regulations and restrictions as the tattoo inks. European market has followed the rules and restrictions for the pigments in order to protect the health and safety of tattooed persons. Today many manufactures follow the European Union restrictions. In the future most of the tattoo inks will have better quality and will be safer for human health.

Most inks being used for tattoos are manufactured in European union. Tattoo inks from the US, are usually used from licensed professional artists, while Asian products are mainly used from non-professionals. Permanent make-up colorants are mainly manufactured in Europe and only a few products are imported from America and Asia.

European Union in order to protect citizens, restricted thousands of hazardous chemicals found in tattoo inks and permanent make-up. The restriction harmonises the measures on hazardous chemicals used in tattoo inks and permanent make-up at EU level.

The use of more than 4000 hazardous chemicals in tattoo inks and permanent make-up will be

limited. The restriction introduces maximum concentration limits either for individual or groups of substances used in tattoo inks or permanent make-up. Examples of chemicals are certain azo-dyes, carcinogenic aromatic amines, polycyclic aromatic hydrocarbons (PAHs) and heavy metals. Before, there was no specific EU-wide legislation in place although some European member countries had similar national legislation.

The new rules apply in the EU/EEA as of January 2022, and for Pigment Blue 15:3 and Pigment Green 7. The restriction also requires that mixtures meant for tattooing and permanent make-up have this use mentioned on their labels. The label also needs to include a list of ingredients and relevant safety statements.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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