Review Article

Review on Safety Assessment of Cosmetic Product

K. Priyanka[1], T. Sowdameni[1]*, Mujeebuddin CS[2]

1. Intern at Clinosol Research Private Limited, 48-7-53, Rama Talkies Rd, Vegetable Market Rd, near SBI, Srinagar, Rama Talkies, Dwaraka Nagar, Visakhapatnam, Andhra Pradesh 530016, India.

2. Founder and CEO of Clinosol Research Private Limited, 48-7-53, Rama Talkies Rd, Vegetable Market Rd, near SBI, Srinagar, Rama Talkies, Dwaraka Nagar, Visakhapatnam, Andhra Pradesh 530016, India.

***Corresponding author's E-mail:** sowdamenithothadi@gmail.com

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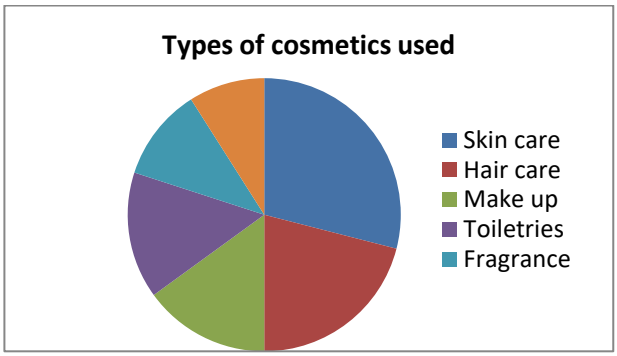
ABSTRACT

Cosmetics are products to enhance the appearance of the face, aroma and texture of the body. Many cosmetics are designed for applying to the body and face. According to the United States, the Food and Drug Administration regulates cosmetics defined as intended to be applied to the human body foe cleansing, beautifying, promoting, attractiveness or altering the body function or structure. This review encompasses a brief description of the process of safety of a cosmetic product. There is no systemic absorption of cosmetics by penetration through skin, but some products are intended to apply on the mucous membrane or skin surrounding mucous membrane which may results in systemic absorption on continuous use. So, there will be no systemic absorption of cosmetics by penetration through skin. Allergy, irritation, comedogenicity, genotoxicity is seen in some cases. Hence safety evaluation of a cosmetic product is the most prominent step before the release of the product into the market. This article explains about different organization that is responsible for the safety of the product and different tests deployed for the safety of cosmetic product.

Keywords: Safety of cosmetic product, safety assessment of cosmetic.

INTRODUCTION

The Federal Food Drug and cosmetic Act drug which are intended to use as cure, mitigation, treatment or prevention of disease which are intended to affect the structure and function of human body or other animals. Cosmetics are applied externally and they are classified based on then area of the application.[1, 2]



There is no need for the pre-market approval of FDA for the cosmetic product or for these ingredients in United States. FDA only regulates the prevention of usage of these ingredients that are already proved harmful for the human use. Example: Color additives. The agency has strictly advised the cosmetic manufacture to deploy suitable method for establishing the safety, purity, and authenticity of their products.

According to cosmetics, Director of European Union and they have to establish the safety requirement under the relevant safety requirement under the regulation then only they can market a cosmetic product.[2-3]

"Cosmetovigilance'' is developing and systemic monitoring of the safety in cosmetics regarding human health. The main aim is to detect adverse effects of cosmetic product and to prevent them by taking appropriate measures. Monitoring of cosmetic products primarily address the safety of products which may be used by vast populations of active consumers. The identification and analysis OD adverse event related to cosmetic product is a process that is currently still, to a large extent, industry driven.[4,5]

ICCR and basic steps in safety of cosmetics

The International Co-Operative on Cosmetic Regulations is an international group of cosmetics regulatory authorities of Brazil, Canada, the European Union, Japan, US. ICCR works voluntarily, it meets on annual basis to discuss common issues on cosmetics.[6]

ICCR define safety assessment: The cosmetic ingredients which have been used in the safety assessment are not in uniform procedure, but it should be performed on case by case basis using the best science. In particular checklist approaches and decisions based on hazard alone are considered inappropriate and non -adequate to thoroughly assess safety. Safety assessments must be utilize the most up-to-date approaches available with taking into account current legal/regulatory requirement.

The basic step in the safety assessment process is

- Determination of various ingredients that comprise a product, followed by the ingredient characterization through relevant physico-chemical data, purity and profile of impurities and chemicals structure identification.
- Based on the literature reviews, the relevant toxicological information of all the ingredients is assessed. Data on closely related structural analogues and structural activity modelling data may also be considered for assessment.
- Stability of the ingredients, their microbiological states and the overall composition of the product is also studied.
- Based on exposure data of the two products the safety margin and exposure margin are calculated using the relevant dose.[7,8]
- After composition of the safety assessment the data is given in the form of Cosmetic Product Safety Report (CPSR). CPSR is a main part of the Product Information File (PIF) which establishes that cosmetic product is safe to use.

The two main parts in Cosmetic Product Safety Report are PART – and PART-B

PART-A: Gives all the necessary data, which is required to perform product safety assessment. The main section under this are.

1. Quality and quantity of the cosmetic product.
2. Physical/chemical characteristics and stability of cosmetic product.
3. Microbiological status of the product.
4. Impurities traces, information about the packing materials.
5. Normal and reasonably foreseeable use.
6. Exposure to the cosmetic product.
7. Toxicological profile of the substances.
8. Exposure of the substances

PART-B: Gives the conclusion of the safety assessment. The main sections under Part-B are.

1. Warning and operating instructions that must be displayed on the label.
2. Scientific reasoning.

In US and EU the Product Information File (PIF) is mandatory, in India, there is Dossier on Cosmetic Product', which can be referred as PIF. The concept of PIF is not mandatory in India, but the manufacture must be able to prove the safety upon request from authorities.

Cosmetic Product Dossier consists of

1. Technical description of the product i.e., the data to be presented on the label and package.
2. Ingredients list or the formulation of the product.
3. Detailed information on every raw material or ingredients use including additives and contaminants.
4. Details on compliance with Good Manufacturing Practices.
5. Product safety assessment.[8, 9]

Safety assessment of cosmetic products

Most of the females use cosmetic products on regular basis. Though interval contact of any ingredients are often not leads to vital systemic absorption by entering into the skin, systemic susceptibility of cosmetic ingredients can be rarely excluded, because some of the products had been used greatly on oral cavity (face, lips, eyes and mucous) example: kajal, mascara, eye shades, lip stick etc. These may leads to some toxicity like, heavy metal exposure, before releasing into market so the cosmetics and their ingredients must be evaluated for their safety because of extensive use and relatively uncontrolled human exposure ton cosmetics.[10]

The safety assessment for cosmetics product is conducted mainly at two levels.

Level 1: The very first level is at industry

Level 2: It is done after production, it make's sure that safety of production which is produced and which are ready for release into market.

Specific guidance for cosmetic manufactures

1. Documentation: At industry level the document should be in such a manner that, it must secure every condition or aspect of manufacturing process and also organization process that pretend errors or analysis or loss of information. Good documentation helps one to tract or trace problems that may acquire during production and takes appropriate therapeutic actions.
2. Records: Records should be conserved in detail for certain procedure, any justification instructions, protocols, reports, methods, precautions, and other measures which is required by GMP. Records serve as a proof for example: with the help of the materials are verified to assay batch production control records were taken on to check whether the batches are consistent are not, similarly evaluation of laboratory controls of raw and in -process materials and also finished products etc.
3. Building and facilities: These are mainly used for manufacturing and must be of adequate size, design, and also construction, must be maintained in clean and orderly manner.

4. Equipment: The equipment which has been used in processing, holding, transferring, and packaging should have suitable design; size should be adequate for intended use.
5. Internal Audit: To know about adherence or compliance laid down procedure, audit must to be conducted regularly. Persons who conduct the audit should not have any direct contact to the data being audited. After completion of audits the observation and dose and should be shared with the management and follow -ups are done to make sure that the observation has been followed.[8-11]

Safety assessment of cosmetic ingredients

The assessment mainly takes place at industrial level. Some of the ingredients already have safety profile but for new ingredients the safety profile should or must be established before using any information.

Cosmetic Ingredient Review (CIR): This type includes a non-profile program which assess the safety of ingredients mainly in personal care of production. This remains as the only scientific program in the whole world which is committed to systemic, independent review of cosmetic ingredients. The main purpose is to review the ingredients in over-the-counter personal care products which works in accordance to the procedures that laid down by USFDA.[8-12] there are different tests used in the safety assessment of ingredients-

1. Physico-chemical characterization
2. Toxicological studies

Physico-Chemical characterization:-

- Chemical identity
- Physical form and molecular weight
- Purity and composition of isomers
- Stability and homogeneity
- Functions and its uses

Toxicological studies

- Toxic kinetics
- Acute toxicity
- Local toxicity example: - Corrosion, irritation and skin semitization.
- Systemic toxicity like dermal absorption mutagenicity or genotoxicity, carcinogenesis etc.[13]

Safety assessment of a finished cosmetic product

Recent study, found that on an average nearly nine adults uses cosmetic products daily but women uses 15 products or may be more. It was also found that some of the products like cosmetics, toiletries and other skin-care products show hospital referrals with allergic contact dermitries. It is estimated that 1-3 % of the population are allergic to cosmetics. In India the allergic dermatitis observed nearly 3:3:1. Who uses the various cosmetics and shows common adverse event that had been using hair dyes and lipsticks in 35% of population.

Based on area of application and like the exposure of skin to the products. Safety evaluation of cosmetics products is generally performed. As there is a large variety of cosmetic products used, the exposure can be described as:-

- Toiletries (Soaps) or skin cleansing agents.
- There is possibility of ingestion to some extent by the products which are generally used on lips and mouth.
- Due to thin epithelial lining there may be some unwanted reaction because they can come in contact with both conjunctive and mucosa in which products are applied around eyes and genital region.[14]

Test procedures in both In-vivo and In-vitro: Different tests are conducted in both animal (In-vivo) and also in human models (In-vitro).

- Patch and photo-patch Test
- Repeated Open Application Test (ROAT)
- Chemical Analysis
- Di-methyl gloxime Test
- Test of irritancy and sensitivity
- Draize eye irritancy Test
- Tests for mutagenicity/ genotoxicity

Patch and photo-patch Test

This test is usually performed to determine the reaction of particular cosmetic i.e to identify it is irritant or allergic. The standard test series which are conducted also identifies the agent causing allergy which is generally not identified by blood test or skin pricking test. In this type of series of test local allergic seen are observed for reaction. The chemicals used are example: nickel, rubber, leather, formaldehyde etc. [15]

ROAT/Provocative use test

This test is performed to screen allergy to cosmetics which contain fragrances and also determine the clinical significance of fragile positive patch test. The chemical which is usually suspected is administered/ applied twice, on daily basis up to two weeks on 5cm2 area of flexor surface of forearm. Based on appearance of rest the safety of cosmetics is considered for example: appearing of rash one week then it is not considered as safe similarly if rash doesn't appears after one week then the test is negative and it is safe.[16]

Chemical Analysis

This test is sometimes done to identify the unknown allergies. It also requires determining the presence of unexpected allergens in product.

Test for irritancy and sensitivity

It is generally determined or measured by using two tests-

A) Soap chamber test or use test

B) Repeat insult patch test

In-Vitro memorization cell chromosome absorption test

This test is mainly performed to identify agents which cause structural chromosome delusion in cultured mammalian cells. Cell culture are defined to that substance with and without metabolic activities after exposure of time, the cell cultures are evaluated with coshicine, harvested, (after 3-6) laborated and metaphase cells are observed microscopically for the existence of chromosome aberration by using metaphase-arresting substance are studied and dissolved on suspended in suitable solvent or vesicle before starting of the test and liquids which may be added directly.

CONCLUSION

The cosmetics and personal care products have become an essential tool in beautification and personal health of human race. For the usage of different purpose, different products have been introduced into the market, worldwide. There are no specific safety regulations to start the safety of cosmetic products in many countries, and the safety is optional and mostly controlled by the manufacture because of their regular and prolonged use of the cosmetic which are not generally associated with common serious health hazards to humans, the main aim is safety of the products. Thought they do not possess any serious health effects on daily and regular use but the effects on the prolong use is unknown. Before introducing to the markets cosmetic products safety should be the main principle to avoid any health risk and should be treated with special attention during manufacturing, formulation and safety assessment. The ingredients which are incorporated and whose safety is unclear or ingredients like UV absorbance, dyes, and penetration should be limited due to avoid risk factors. After releasing of products into the market, products analysis must be done repeatedly to ensure the safety of products.

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