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CRUELTY-FREE APPROACHES FOR SAFETY EVALUATION OF COSMETICS: A REVIEW

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ABSTRACT

The safety of every cosmetic product is the highest priority of the cosmetic industry. It involves exhaustive testing of ingredients they contain. Cosmetic preparations were tested on animals for many years because they were considered as subjects due to their physiological similarity to humans. Animal testing is used to check whether the product is safe for human use or not. The biggest drawback of animal testing is that animals experience pain, suffering and ultimately die during this procedure. Various substitute methods to animal experimentation are proposed to overcome the drawbacks associated with animal testing. Many countries have banned animal testing including India. In India, Prevention of Cruelty to Animals Act 1960, was introduced and according to this act India banned cosmetic testing on animals in 2014. This review focuses on substitute methods for animal testing that include evaluation of cosmetic products using human cells and tissues (In-Vitro methods), advanced computer-modeling techniques (silico models) and studies with human volunteers. These cruelty-free models might be used to replace animal testing initiatives for safety evaluation of cosmetics and more precise results.

KEYWORDS: Animal Testing, Banned, Cosmetic Products, Cruelty-free, Safety Evaluation, Substitute Methods.

1. INTRODUCTION

Cosmetic is defined under section 3 of Drugs and Cosmetics Act, 1940 as, "any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise

applied to, the human body or any part for cleansing, beautifying, promoting attractiveness or altering the appearance. And it also includes any article intended for use as a component of cosmetic".[1] cosmetics are purely superficial means to improve your appearance. Cosmetics do not require prescription of any kind. People who apply cosmetics daily may not be aware of high levels of chemicals and toxins present in it. For Ex-Benzophenone is use in various cosmetic products such as nail polish, lip balms etc. It is a common ingredient in sunscreen products. benzophenone is a toxic, persistent and bioaccumulative carcinogen.[2][3] Various nanomaterials such as zinc oxide, titanium dioxide, silver found in nail polish, anti-aging creams, lotions and shampoos are more toxic than the larger particles of the same materials. Inhalation of these nanoparticles may cause oxidative stress and inflammation.[4] Phenoxyethanol acts as a stabilizer and preservative in various cosmetic products such as foundation, eye shadow, moisturizers, hair sprays, hand creams, nail polish etc. exposure to the phenoxyethanol may lead to allergic reactions and eczema.[5][6]

Therefore, it is very essential to test these chemicals for determination of safety, toxicity, efficacy and dosing. To ensure the safety of any cosmetic product, it is mandatory to perform various tests like skin irritation, contact urticarial, stinging, allergic sensitization, photo allergy and phototoxicity. These are adverse effects that may be caused due to cosmetics. Various methods are used to test the potential of the substance to induce irritation and sensitization. Draize test is performed for detection of primary irritation in which albino rabbits are clipped and the substance to be tested is applied. Other methods used for testing hair and bath preparations for eye irritation which performed on eye mucosa of albino rabbits. In case of skin irritation provocative patch test is performed on guinea pigs and rabbits.[7][8]

Animal testing is defined as "use of non-human animals in the experiments that seek to control the variables that affect the behavior or biological system under study." In India, Prevention of cruelty to animal Act 1960, was introduced and according to this "An Act to prevent the infliction of unnecessary pain or suffering on animals.[9][10] In 2014 India banned cosmetic testing on animals. The new rules has been added to existing Drugs and Cosmetics Act, 1945. As per new rules, it is prohibited to use animals for testing of cosmetic preparation. India has also banned import of such cosmetic products that tested on animals.[11][12]

2. THREE Rs STRATEGY : REDUCTION, REFINEMENT AND REPLACEMENT

To overcome some of the drawbacks associated with testing on animals, the strategy of 3Rs is being applied, which stands for Reduction, Refinement and Replacement[13]. Reduction of use of animals for safety evaluation of cosmetic preparations.[14] This 3Rs approach motivates the use of minimum number of animals for experiment i.e., 'Reduction', the use of animals must be planned and 'refined' so that the pain and stress experience by animals during experiment should be minimized and replacement of higher animals with alternative methodologies and microorganisms.[15] There are two types replacements such as relative and absolute. Animal use in experiments are not subjected to any pain and stress is known as relative replacement. In absolute replacement, there is an complete absence of animals in experiment.[16]

3. SUBSTITUTE METHODS

To avoid or minimize the use of animals in experiment, various methods have been suggested. The advantages of these substitute methods are cost effectiveness, less man power and efficiency. some of the substitute methods for animal testing for safety evaluation of cosmetic products are as follows –:

3.1 Computer Models

Specialized computer models and software programs are designed to replace the use of animals. Computer can help to understand various principles of biology. It is also use to predict the possible biological and toxic effect of a chemical without animal dissection. The Computer Aided Drug Design (CADD) software is used to identify the receptor binding site for a potential drug. This software also avoids the testing of unwanted chemicals that have no biological activity. [17] hence, the total number of animals use in the experiment is lowered.

Structure Activity Relationship (SARs) computer programs determines the biological activity of a chemical which based on presence of chemical moieties that attached to the parent compound. Another important tool is Quantitative Activity Relationship (QARs) which gives the mathematical relationship between the physicochemical molecule of the drug and its biological activity.[18] Computer Assisted Learning program (CAL) is an learning program without involvement of real experimental tools. Therefore, the cost of these new computer technologies is much less than laboratory experiments.[19]

3.2 Cells And Tissue Cultures

Another important substitute for animal experiments are use of cells and tissue cultures**.** These cells and tissues from liver, kidney, brain and skin are removed for experiments. It is kept outside the body and allowed to grow in a suitable medium for few days or several months or even for few years. Cellular components like membrane fragments, cellular enzymes are also used. Various types of cultures like cell, tissue, callus or gan cultures are also used for this purposes. Some of the advantages of this method are easy to follow, less expensive and less time consuming.[20][21] Many cosmetic preparations are tested for their toxicity, efficacy and irritancy. To test the irritancy of chemicals present in cosmetics previously, Draize test was used. In Draize test, every time new animal was used and it was very painful. Therefore, a substitute method was proposed by Ke Ping Xu , which uses Bovine Corneal organ cultures.[22]

Human skin equivalent tests can be used to replace animal testing for corrosive and irritative studies. Epiderm, Episkin and skinethic RHE model are derived from human skin cells which have been cultured to produce a model of human skin.[23] A skin patch test is used to measure development of rashes, abnormal tissue growth, inflammation, swelling on human volunteers.[24]

3.3 Substitute Organisms

Many restrictions have posed over use of higher animals such as rats, monkeys and guinea pigs for experimentation. Therefore, the use of substitute animals have been proposed. Different organisms can be used to substitute animals for testing different cosmetics. Lower vertebrates, invertebrates and microorganisms are used as substitute for higher animals.

- **Lower vertebrates –** Lower vertebrates can be used as substitute animals because of their genetic relatedness to higher animals including mammals.

ex- Zebra Fish – it is a small freshwater fish. During early development stage, it has transparent body which helps easy visualization of internal organs. Zebra Fish can be an attractive substitute because of its small size, short life cycle, low cost of laboratory experiment, less working space and manpower requires.[25]

- **Invertebrates –** The most widely used substitute organisms for higher animals are invertebrates. Numerous benefits associated with invertebrates are small size, simple anatomy and brief life cycle.

ex- Drosophila Melanogaster[26], Caenorhabditis elegans. C[27]

- **Microorganisms** – ex -– Saccharomyces cerevisiae – it is a brewing yeast which is most popular and ideal eukaryotic microorganism which is used as a substitute for biological studies.[28]

4. BENEFITS OF SUBSTITUTE METHODS

- The substitute methods to animal testing have many advantages like saving countless animal lives, more efficient and reliable.
- These substitute methods are more cost-effective and expedient than animal testing. ex – synthetic skin (corrositex) can provide chemical corrosivity determination within 3 minutes to 4 hours. while animal testing takes 2-4 weeks, animal testing used to determine the effectiveness of sunscreen products it takes months to do while substitute method was reported do in days.
- The use of human tissue in toxicity testing is more accurate than animal testing.
- Cruelty free products are more environmentally friendly. Some organizations such as Ethical Science Education coalition, human society of united states have established alternative loan for the students who need to borrow non-animal software to satisfy their course requirement. so that students will not have to bear a financial burden of purchasing the product.
- Substitute scientific tests are also more reliable than animal testing. ex- Epiderm is an In Vitro test which was found to be more accurate in identifying chemical skin irritant than traditional animal testing.[14]

5. CONCLUSION

There is an increased concerned for animals used in testing of cosmetic products over recent years**.** India has banned animal testing in 2014 and initiated towards cruelty free products. These move will protect the animal from unnecessary pain and suffering. Many countries are also trying to bring new regulations related to animal testing for safety evaluation of cosmetic products and ingredients. There are many ways that can be used to decrease the used of animals for cosmetic testing in labs. Another way to eliminate animal testing is consumer pressure. If the cosmetic companies see that the consumers give more preference to the products that are not tested on animals, they will target the cruelty free product. However, eliminating animal testing requires serious action. Many cosmetic companies are supporting substitute methods, reduced animals testing and even more companies favour a complete ban on use of animals for experimentation. Animal testing is very expensive, unpredictable and

slow process while alternative methods are much better, time saving and reduced expenses. The effective implementation of 3Rs strategy during use of animals in laboratories is also very important.

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