

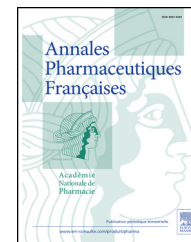


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GENERAL REVIEW

Perspectives and strategies of alternative methods used in the risk assessment of personal care products

Perspectives et stratégies des méthodes alternatives utilisées lors de l'évaluation du risque des produits cosmétiques

P. Quantin, A. Thélu, S. Catoire, H. Ficheux*

Département de toxicologie, Thor Personal Care, 147, rue Irène-Joliot-Curie, 60208 Compiègne cedex, France

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Summary Risk assessment for personal care products requires the use of alternative methods since animal testing is now totally banned. Some of these methods are effective and have been validated by the "European Union Reference Laboratory for alternatives to animal testing"; but there is still a need for development and implementation of methods for specific endpoints. In this review, we have focused on dermal risk assessment because it is the prime route of absorption and main target organ for personal care products. Within this field, various areas must be assessed: irritation, sensitisation and toxicokinetic. Personal care product behaviour after use by the consumer and potential effects on the environment are also discussed. The purpose of this review is to show evolution and the prospects of alternative methods for safety dermal assessment. Assessment strategies must be adapted to the different chemical classes of substances studied but also to the way in which they are used. Finally, experimental and theoretical technical parameters that may impact on measured effects have been identified and discussed.

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* Corresponding author.

E-mail addresses: paul.quantin@thorpc.fr (P. Quantin), amelie.thelu@thorpc.fr (A. Thélu), sophie.catoire@thorpc.fr (S. Catoire), herve.ficheux@thorpc.fr (H. Ficheux).

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MOTS CLÉS

Évaluation du risque ;
Toxicologie ;
Peau ;
Cosmétiques ;
Méthodes
alternatives

Résumé L'évaluation du risque en cosmétique nécessite l'utilisation de méthodes alternatives depuis que l'expérimentation sur les animaux a été totalement interdite. Certaines de ces méthodes sont efficaces et validées par l'« European Union Reference Laboratory for alternatives to animal testing » ; cependant, il existe toujours un besoin d'améliorer ces méthodes et d'en développer de nouvelles pour l'étude de certains effets toxiques. Dans cette revue générale, nous nous sommes concentrés sur l'évaluation du risque au niveau cutané car il s'agit de la voie d'absorption et de la cible principale des molécules utilisées en cosmétique. Dans ce cadre, différents aspects doivent être évalués : irritation, sensibilisation et toxicocinétique. Le devenir des produits cosmétiques après leur utilisation par le consommateur ainsi que des potentiels effets sur l'environnement sont également abordés. Le but de cette revue est de montrer l'évolution et les perspectives des méthodes alternatives utilisables pour l'évaluation du risque dans le domaine cosmétique. Les stratégies doivent être adaptées aux catégories chimiques des substances étudiées et à leur mode d'utilisation. Enfin, différents paramètres techniques, expérimentaux et théoriques, qui font varier les réponses mesurées sur les différents modèles ont été identifiés et analysés.

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Introduction

Risk assessment is commonly used in various industries such as pharmaceutical, chemical, personal care, food, agricultural. The first step is to identify hazard and the second to study the probability that hazard becomes a risk to the population studied. Exposure is the third component to be considered in the equation. Manufacturers must ensure that their products meet current regulations and cause no health hazards when used under normal and reasonable conditions. Personal care regulation is established at a European level and safety of use is evaluated according to specific guidelines from the Organisation for Economic Co-operation and Development (OECD), which controls substances, their chemical structures and their toxicological and exposure profiles. Numerous data and studies are required to identify hazards [1] in order to establish toxicological profiles: acute toxicity, corrosion and irritation, sensitisation, repeated toxicity, reproductive toxicity, carcinogenotoxicity, photo-induced toxicity and toxicokinetics studies.

In addition to human toxicity assessment, ecotoxicity is becoming an increasingly concern and is therefore more and more investigated.

The evolution of European regulations results in a reduction in the number of animals used in research to ensure the safety of chemical molecules to which humans are exposed. According to regulation No. 1223/2009 of the European Commission, experimentation on animals is prohibited for personal care products. Since September 2004, a testing ban on animals has been applied for finished personal care products, whereas the testing ban on ingredients or combinations has been effective since March 2009. For specific effects on health (repetitive dose toxicity, reproductive toxicity and toxicokinetics), the testing ban has been in force since March 2013.

Alternative approaches (in vitro, in silico and in chemico methods) have been proposed for risk assessment in cosmetology [2]. Some of these methods are effective and have been validated by EURL-ECVAM (European Union Reference Laboratory for Alternatives to Animal Testing) as tests for irritation, corrosion and phototoxicity. Concerning sensitisation, two methods have just been validated, and two others are in the last stage of validation and will be available very soon. However, doubts have been expressed by the European Scientific Committee on the possibility of replacing all animal testing by reliable alternative methods which guarantee a high level of safety for consumers. This is particularly the case for repeated dose toxicity, reproductive toxicity and toxicokinetics tests.

Therefore, when dealing with the risk assessment of personal care products, there are two main items to be addressed.

Which tools/methods/models are ready to be used today for personal care risk assessment?

A state of the art is proposed with the description and outlook of alternative methods available or soon to be validated by European agreements to predict local dermal toxicity of topical applied substances such as percutaneous absorption, irritation, corrosion, phototoxicity and sensitisation.

What needs to be improved in the near future and how can this be integrated into the global risk assessment strategy?

Toxicological parameters and associated alternative methods, which need strong improvements and integration in global risk assessment strategies before they can be used in labs are discussed. Dermal toxicokinetic assessment,

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