

## **Review Article**

# **Current State of Animal Testing on Cosmetic Products in Indonesia, Malaysia and Singapore**

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## **ABSTRACT**

The rapidly expanding segment within the cosmetics and personal care industry represents a convergence of personal care and pharmaceutical sectors. Traditionally, animal testing has been utilized to ensure the safety and efficacy of cosmetic products for human use. However, in response to consumer demands, many prominent brands have transitioned to being cruelty-free, gaining widespread acceptance. The official members of the Association of Southeast Asian Nations (ASEAN), including Indonesia, Malaysia, and Singapore, have implemented the ASEAN Cosmetic Directive (ACD) as an agreement that aims to harmonize the regulations and standards for cosmetic products. However, the ACD does not provide specific legislation on animal testing. The directive defines cosmetics and specifies prohibited ingredients while allowing for permitted preservatives, UV filters, and colorants. This critical review focuses on the current state of animal testing for cosmetic products in Indonesia, Malaysia, and Singapore. The review was carried out with a reference to research works released between 2015 to 2022 by searching using an electronic database and involved referencing various articles. Its primary objective is to review the current state of animal testing on cosmetic products and the alternative methods used to ensure that cosmetic products are in regulatory compliance.

**Keywords:** Cosmetic products, animal testing, Indonesia, Malaysia, Singapore

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## 1.0 Introduction

The cosmetics and personal care industry has witnessed substantial growth over the years, with cosmetics being one of the fastest-growing industries. Animal testing has been a common practice employed to assess the safety and efficacy of cosmetic products (1,2). Rodents, rabbits, and other small animals have been subjected to skin and eye irritation tests, systemic toxicity evaluations, and other assessments for the potential risks associated with product use (1,3). According to Silvia Morel et.al. some ASEAN countries such as Malaysia, Indonesia and Singapore, animal testing for cosmetics is currently permitted. However, in 2016 the Indonesian Ministry of Health issued a regulation mandating the adoption of alternative testing methods and minimizing animal testing for cosmetic products (2). As a result, many cosmetics companies have chosen to discontinue using animal testing and consumers are actively supporting these companies by selecting products labelled as “cruelty-free” or “not tested on animals” (4,5,6).

### 1.1 Cosmetic Products in Indonesia

The Republic of Indonesia maintains stringent regulations governing the production and formulation of cosmetic products. The Indonesian agency for drug and food control is namely *Badan Pengawas Obat dan Makanan (BPOM)*, operating under the Ministry of Health, oversees the registration process for cosmetics and drugs. Manufacturers are required to adhere to comprehensive standards outlined in the cosmetic good manufacturing practice guidelines which it called in Indonesia as *Cara Pembuatan Kosmetika yang Baik (CPKB)* to ensure the products' quality aligns with their intended purposes (7). BPOM's definition of cosmetics encompasses

substances or preparations intended for application on various external parts of the human body, such as the epidermis, hair system, nails, lips, external genital organs, teeth, and the mucous membranes of the oral cavity. The primary purposes of these products include cleansing, perfuming, altering appearance, correcting body odors, and providing protection or maintaining their condition (8).

The cosmetics industry experiences annual growth of 10-15% due to an increase in disposable income and aggressive marketing efforts by cosmetics companies. Urban areas of Indonesia serve as the primary market for cosmetic products, while the rural population shows a stronger preference for personal care items. In Indonesia, it has been mandatory for cosmetics and medicines to acquire halal certification (2,9). This has made halal beauty products a huge potential market for a large Muslim population in Indonesia (10). Table 1 shows selected examples of commercial cosmetic products in Indonesia.

### 1.2 Cosmetic Products in Malaysia

Malaysia's local market of cosmetic products offers more than 60,000 products available, including imports from The United States, Japan, Korea, China, and Indonesia (10). In Malaysia, a "cosmetic product" refers to any substance or preparation intended for external application on various parts of the human body, including the epidermis, hair system, nails, lips, external genital organs, teeth, and the mucous membranes of the oral cavity. These products are primarily formulated for purposes such as cleansing, perfuming, altering appearance, correcting body odors, and providing protection or maintaining good condition. Numerous examples of cosmetic products are available

**Table 1:** List of several commercial cosmetic products in Indonesia (11,12)

Brand	Manufacturer	Product	Active ingredients	Classification
<b>Viva Cosmetics</b>	PT Vitapharm	Acne Gel Triple Action	-Sulphur -Acid Salicylates -Triclosan	-Anti-acne
		Anti-Wrinkle Cream	-Walnut seed extract (oil)	-Anti-wrinkle
<b>Wardah</b>	Paragon Technology and Innovation (PT. PTI)	Acne	-Allantoin	-Anti-acne
		Cleansing gel	-Zinc Gluconate	
		Acne Treatment Gel	-Triclosan -Salicylic acid	-Anti-acne
<b>La Tulipe Cosmétique</b>	La Tulipe Cosmétique	Anti Aging Serum	-Panicum Miliaceum Seed Extract (Millet)	-Anti-wrinkle
		Acne Loose Powder	- Sulfur and salicylic acid (keratolytic agents)	-Anti-acne
		Acne Total Care Lotion	-4-terpineol -Salicylic acid -Sulphur -Camphor	-Anti-acne
<b>Pevonía Botanica</b>	PT. Universal Aesthetic Asia Pacific	Clarigel	-Saponaria	-Anti-Acne
		Exfoliating Cleanser	-Citric acid -Azulen -Grapefruit essential oil	

in Malaysia such as facial cleansers, moisturizers, nail care products, lipsticks, eye shadows, perfumes, body lotions, oral hygiene products, feminine hygiene wash, shampoos, and soaps (13). However, it's important to note that cosmetic products do not include methods of application such as oral consumption or injections for beauty purposes, like reducing facial wrinkles or moisturizing the skin (13).

In Malaysia, cosmetic products are governed by the Control of Drugs and Cosmetics Regulations, 1984, along with the Guidelines for Control of Cosmetic Products in the country. To be manufactured, imported, and sold within the nation, all cosmetic products must undergo notification and approval from the National Pharmaceutical Regulatory Agency (NPR), which operates under the Ministry of Health Malaysia (MOH) (14,15). The notification

process requires the responsible company to declare compliance with the stipulated regulations and requirements. Non-compliant product is subject to punitive action such as product recall from the market. Currently, 210 cosmetic manufacturers in Malaysia strictly adhere to the Good Manufacturing Practices (GMP) requirements, following the guidelines outlined in the ASEAN Guidelines for Cosmetics. (14,15). Additionally, cosmetic industries effectively use halal marketing techniques to cater to the Muslim consumer base. Nevertheless, it's important to understand that the certification of halal products relies on applications submitted by manufacturers or distributors, and it is not mandatory for cosmetics notification in Malaysia (16,17). Table 2 shows selected examples of commercial cosmetic products in Malaysia.

**Table 2:** List of commercial cosmetic products in Malaysia (13,18,19)

<b>Brand</b>	<b>Manufacturer</b>	<b>Product</b>	<b>Active Ingredients</b>	<b>Classification</b>
<b>Root remedies</b>	Rootremedies Sdn. Bhd	Sea Buckthorn Pure Oil	-Palmitoleic acid -Tocopherol -Carotenoids -Lycopene	-Antioxidants
		Tea Tree & Lemongrass Blemish Serum	-Argan oil -Black seed oil -Tea tree oil -Lemongrass oil -Lavender oil -Tocopherol oil	-Anti-acne
<b>The Mineraw</b>	The Mineraw Sdn Bhd	Toner	-Apple cider vinegar	-Anti-wrinkles
		Glow Serum: Face Oil	-Jojoba oil -Rosehip seed oil -Tea tree oil -Rose geranium oil -Vitamin E oil	-Anti-acne
<b>Kopara</b>	KOPARA Enterprise	Golden Jojoba Oil	-Jojoba oil -German chamomile essential oil	-Anti-acne
<b>Aro Sarawak</b>	Duuja Trading Sdn Bhd	Anti Ageing Serum	- Aloe Vera -Lemon Extract	-Anti-aging
<b>Kayman Beauty</b>	Kayman Beauty	CoalFace Cleanser	-Activated charcoal	-Anti-acne
<b>Cosmoderm</b>	Vanity Cosmeceutical Sdn Bhd	Tea Tree Oil	-Tea tree oil	-Anti-acne
		Day & Night Moisturiser	-Vitamin E	
<b>Simply Siti</b>	Simply SS Trading Sdn. Bhd	Clear Solution Acne Gel	-Tea tree oil -Papaya and Willow Bark extracts	-Anti-acne

### 1.3 Cosmetic Products in Singapore

Cosmetics in Singapore are subject to regulation under the Health Products (Cosmetics Product- ASEAN Cosmetic Directive) Regulations, a Subsidiary Legislation of the Health Products Act. The Health Sciences Authority (HSA) is responsible for overseeing safety concerns related to cosmetic products. HSA divides cosmetics into two categories: low-risk

cosmetics and high-risk cosmetics. The classification is defined only to determine the notification fees. The fee for high-risk cosmetics is higher than low-risk cosmetics (16,20).

- Higher Risk: Cosmetic Products deemed to be of higher risk are cosmetic products to be applied around the eyes, on the lips, hair dyes containing phenylenediamines and oral and dental care products.

• Lower Risk: Cosmetic Products deemed to be of lower risk are all other cosmetic products not listed above such as skin whitening products and moisturizers (21).

Scientists in Singapore successfully created human skin in a petri dish on year 2019, presenting a groundbreaking advancement that could potentially replace animal testing in cosmetics. The possessing

similar chemical and biological properties to real human skin, marks a significant stride towards cruelty-free and vegan product development, appealing to ethically conscious consumers (22). Table 3 shows several commercial cosmetic products in Singapore.

**Table 3:** List of several commercial cosmetic products in Singapore (23)

<b>Brand</b>	<b>Manufacturer</b>	<b>Product</b>	<b>Active Ingredients</b>	<b>Classification</b>
<b>Pera</b>	Pera Skin Care	Deep Nourishing Multi-Nutrient Serum Oil	-Jojoba Oil -Rose hip oil -Red tocol artie cranberry seed oil -Sea buckthorn berry seed oil	-Anti-pigmentation
<b>Allies of skin</b>	Allies of skin	Peptides & Antioxidants Firming Daily Treatment	-Teprenone	-Antioxidant
		35% Vitamin C Collagen Rebuilding Serum	-25% Ethylated L-Ascorbic Acid -10% Tetrahexyldecyl Ascorbate -Superoxide dismutase -Glutathione	-Anti-aging - Antioxidants -Anti-pigmentation
		Mandelic Pigmentation Corrector Night Serum	-11% Mandelic + Lactic + Salicylic Acid -Hyaluronic Acid - Niacinamide -Organic Rosehip +Tamanu Oil -1% Superoxide Dismutase -Rumex Occidentalis Extract -Bakuchiol -Palmitoyl Tripeptide-5 -Nonapeptide-1 -Acetyl Tetrapeptide-40	-Anti-pigmentation -Anti-aging
<b>Alcheme Skincare</b>	Alcheme Skincare Pte Ltd	Personalised Serum	-Glycerin, -Camellia japonica seed oil -C13-15 alkane -Polyglyceryl-6 distearate -Centella asiatica extract -Evodia rutaecarpa fruit extract	-Anti-pigmentation

## 2.0 Methods

This review paper was carried out with a reference to research works released between 2015 to 2022 by searching using an electronic database and involved referencing various articles. There is no restriction to use any databases such as PubMed, Scopus, NCBI, ScienceDirect and Google Scholar as the critical review references. Keywords or medical subject heading (MeSH) terms used in the search strategy were “animal testing”, “alternative method”, “cosmetic product”, “Malaysia”, “Indonesia”, “Singapore”, “hewan percobaan” and “kosmeseutika. The reference list of the identified articles will be manually studied to retrieve other related articles. All aspects of the text will be examined related to animal testing and public awareness regarding animal testing on cosmetic products.

## 3.0 Animal testing and cosmetics regulation in Indonesia, Malaysia and Singapore

### 3.1. Animal testing in research

Approximately 115 million animals are employed in research experiments worldwide in a year (24). The precise tally of animals utilized exclusively for regulatory testing is uncertain and presents challenges in assessment due to incomplete data collection and reporting across many countries, with some offering only limited insights (24). There was a study in the United Kingdom, comparing animal testing in medical research versus cosmetics. The findings indicate a greater societal acceptance of animal testing for medical research as opposed to cosmetic applications, owing to ethical concerns regarding the inhumanity and injustice associated with utilizing animal life solely for aesthetic enhancements in humans (25). According to data compiled by the European

Commission (EC) in 2013, based on information from 27 European Union (EU) member states for the year 2011, approximately 9% of all animal experiments were executed for the explicit purpose of regulatory toxicology. This classification encompasses assessments directed at ensuring the safety of diverse substances including pesticides, biocides, industrial chemicals, food additives, and pharmaceuticals, with pharmaceutical testing standing out as the primary focus (24). From previous reports, rodents and rabbits account for 80% of the total number of animals used in animal testing for various studies in the EU. Mice are the most widely used species with 61% of total use, followed by 14% of rats. The second most used group of animals was the cold-blooded animals, which accounted for nearly 12.5%. The third-largest group of animals used was birds with 5.9 % of the total use (24,26). In 2013, the United Kingdom and all the member states of the European Union banned the use of animal testing for cosmetic products (25).

### 3.2. Animal testing in cosmetic products

In cosmetics research and development, the process of animal testing commonly involves the utilization of animal subjects to evaluate new cosmetic products and their constituent ingredients. This procedure encompasses the application or administration of these substances to different parts of test animals, often via forced ingestion or injection (27). The objective is to assess various factors such as systemic toxicity which refers to potential harm to human health, skin and eye irritation, ultraviolet light-induced toxicity, and the potential for gene mutations. In recent years, substantial endeavours have been made to develop alternative methodologies that ensure the safety of cosmetics without relying on laboratory animals. These alternative approaches encompass innovative

techniques with the goal of decreasing the number of animals used per test, refining methodologies to reduce the discomfort of animals, and substituting animals with non-living materials. The 'Three Rs' framework provides a systematic strategy for minimizing animal use while upholding the scientific quality of research, ultimately striving for a complete transition from animal models to non-animal alternatives (25) (28),(29). However, in 2013, the United Kingdom and all the member states of the European Union banned the use of animal testing for cosmetics products (25,30).

As in Indonesia, Malaysia and Singapore, there is no prohibition on animal testing for cosmetic products as long they follow the regulations (2). Within the ASEAN countries, they referred to the guidelines in the ASEAN Cosmetic Directive (ACD), a document that draws direct inspiration from Regulation 1223/2009/EC (2,16,20,31). As per the guidelines outlined in the ACD, a cosmetic product brought into the market must not present any risk to human health when used under regular or reasonably anticipated conditions of use. The entity accountable for introducing the product to the market is required to confirm the completion of a safety assessment (16). Outlined in Section 2 of Annex I, part 5, it is required that the evaluation of human health safety related to the final product, its constituents, their chemical composition, and the extent of exposure of a cosmetic product must be affirmed starting from the initial stage of raw material selection and extending to the marketing of the product. (16,26). In-depth information about the ACD is easily accessible on the official ASEAN website and is provided in the English language. As per the guidelines established by the ACD, it is the responsibility of the manufacturer or designated individual to notify the competent authority of each member state about the respective product (2).

### 3.3. Cosmetic regulation in Indonesia, Malaysia and Singapore

Regulatory agencies overseeing cosmetics policies and regulations in Indonesia, Malaysia, and Singapore are the Indonesian Agency for Drug and Food Control (BPOM), National Pharmaceutical Regulatory Agency (NPRA), and Health Sciences Authority (HSA), respectively. (2,16,32,20).

In Indonesia, the BPOM has its procedures for evaluating cosmetic products before it is notified for market entry and post-market evaluation, which involves monitoring and ensuring ongoing compliance of products already on the market. The analysis of cosmetic products is governed by four essential method categories as outlined in Table 4. These obligatory tests are essential for assessing potential contaminations in cosmetic products and are anticipated to fulfil the criteria of the cosmetic products which comply with the regulation as well as safe for the user. (2,28).

In Malaysia, before any company can proceed with manufacturing, importing, possessing, or marketing their products locally, the Cosmetic Notification Holder (CNH), the company itself, or the responsible individual must officially notify the Director of Pharmaceutical Services through the National Pharmaceutical Regulatory Agency (NPRA). This procedure is obligatory to ensure regulatory compliance in terms of safety, quality and substantial claim benefit. They can submit the notification through the NPRA official website. Malaysia also produces halal cosmetics and any cosmetic product aiming to showcase the halal logo must obtain official halal certification and endorsement from the Department of Islamic Development Malaysia (JAKIM) or a recognized Islamic institution under the purview of JAKIM (2).

**Table 4:** Selected scope of testing, type of testing and the purpose of test compulsory for testing cosmetics in Indonesia (33,34)

<b>Scope of testing</b>	<b>Example of test</b>	<b>Purpose of test</b>
<b>Microbial contamination testing</b>	Determination of Yeast Mold Figures	To determine the number of mold and yeast in cosmetics by counting the colonies in the media to be selective after aerobic incubation
	Total Plate Number Test	To determine the number of aerobic mesophyll bacteria that have the ability to live in cosmetics products
<b>Heavy metal testing</b>	Analysis Method for Determination of Heavy Metal Content (Arsenic, Cadmium, Lead, and Mercury)	To determine levels of metal contamination weight (arsenic, cadmium, lead and mercury) in cosmetics
	Identification of Retinoic Acid in Cosmetics by Thin Layer Chromatography TLC and High-Performance Liquid Chromatography HPLC	To identify deep retinoic acid cosmetics.
	Identification of Retinoic Acid in Cosmetics by TLC and HPLC	To identify deep retinoic acid cosmetics.
<b>Prohibited ingredients used in cosmetic testing</b>	The identification of Dyes Prohibited in Cosmetics by TLC and HPLC	To identify the dyes prohibited in cosmetics
	Identification and Determination of Hydroquinone Levels in Cosmetics by TLC and HPLC	To identify and determine hydroquinone levels in cosmetics.
	Identification of Corticosteroid Compounds in Cosmetics by TLC and HPLC	To identify and determine corticosteroid levels in cosmetics
<b>Preservative Levels Testing</b>	TLC and HPLC	To identify preservatives: 2-phenoxyethanol, methyl 4-hydroxybenzoate, ethyl 4-hydroxybenzoate, propyl 4-hydroxybenzoate and butyl 4-hydroxybenzoate in cosmetics.
<b>Scope of testing</b>	<b>Example of test</b>	<b>Purpose of test</b>
<b>Microbial contamination testing</b>	Determination of Yeast Mold Figures	To determine the number of mold and yeast in cosmetics by counting the colonies in the media to be selective after aerobic incubation



	Total Plate Number Test	To determine the number of aerobic mesophyll bacteria that have the ability to live in cosmetics products
<b>Heavy metal testing</b>	Analysis Method for Determination of Heavy Metal Content (Arsenic, Cadmium, Lead, and Mercury)	To determine levels of metal contamination weight (arsenic, cadmium, lead and mercury) in cosmetics
	Identification of Retinoic Acid in Cosmetics by Thin Layer Chromatography TLC and High-Performance Liquid Chromatography HPLC	To identify deep retinoic acid cosmetics.
	Identification of Retinoic Acid in Cosmetics by TLC and HPLC	To identify deep retinoic acid cosmetics.
<b>Prohibited ingredients used in cosmetic testing</b>	The identification of Dyes Prohibited in Cosmetics by TLC and HPLC	To identify the dyes prohibited in cosmetics
	Identification and Determination of Hydroquinone Levels in Cosmetics by TLC and HPLC	To identify and determine hydroquinone levels in cosmetics.
	Identification of Corticosteroid Compounds in Cosmetics by TLC and HPLC	To identify and determine corticosteroid levels in cosmetics
<b>Preservative Levels Testing</b>	TLC and HPLC	To identify preservatives: 2-phenoxyethanol, methyl 4-hydroxybenzoate, ethyl 4-hydroxybenzoate, propyl 4-hydroxybenzoate and butyl 4-hydroxybenzoate in cosmetics.

Companies in Singapore dealing with cosmetic products must ensure the safety of the products to humans and follow the guidelines provided. Within the existing regulatory framework, the companies' representative (as indicated in section 5) is obligated to notify the Health Sciences Authority (HSA) prior to distributing and/or selling the cosmetic product. This individual is responsible for ensuring that the cosmetic product's label adheres to regulatory mandates, maintaining supply records, and promptly reporting any product faults or adverse effects stemming from their products to the HSA. As per the regulations, there are

certain ingredients prohibited in the formulation of cosmetic products, while others are permitted with specific limitations and the list of ingredients similar to the European Union (EU) guideline (16).

Despite the ACD is to harmonize the regulations and standards for cosmetic products, there are variations in product notification, labelling and ingredient requirements according to ASEAN countries' laws based on conditions such as religious perspective or cultural sensitivity.

### 3.4. Consumer awareness on cruelty-free cosmetic products

Cruelty-free cosmetic products refer to cosmetics or personal care products that are not tested with animals during the development process (35,36,37). The ethical considerations regarding animal well-being among consumers enhance the awareness of using cruelty-free cosmetic products (25,38). Furthermore, changes in cosmetics regulation that lead to the prohibition of animals or the reduction of the number of tests require cosmetics companies to adopt alternative approaches, such as cell-based (*in vitro*) methods (including stem cell technologies, tissue engineering, and organs-on-chips), next-generation sequencing and 'omics technologies (including genomics, epigenomics, and proteomics), and computational (*in silico*) modelling techniques (2,25,38,39,40). Several factors have contributed to the growth of consumer awareness on cruelty-free cosmetics such as social media and online information, campaigns by organizations supporting animal welfare, the release of reports on animal testing practices, and the promotion of alternatives to animal testing (36,37). Consumers are becoming more environmentally conscious and are seeking out products that align with their values (41).

Nowadays, numerous cosmetic products advocate for cruelty-free practices (42). Most of the brand in Southeast Asia has taken a firm stance in favor of non-animal testing, aligning with the principles of halal cosmetics as indicated on their product labels. The concept of halal cosmetics has gained significant prominence in Indonesia, and it has become mandatory to incorporate halal labelling in accordance with the new Regulation 31/2019 (Halal Law) (28,43). All cosmetics should have an official certification for Good Manufacturing Practice (GMP) which conducts thorough

testing to ensure the safety and efficacy of their beauty product range (44). Importantly, it's worth noting that methods involving rat skin or animal sacrifices are considered exceedingly unlikely within the context of halal testing for cosmetic products (2,7,22,43,45,46, 47, 48,49).

## 4.0 Conclusion

In conclusion, the adoption of harmonized requirements in Indonesia, Malaysia, and Singapore, as outlined in the ACD underscores the commitment of these nations to ensuring the safety and quality of cosmetic products within their borders. The emphasis on pre-market notification and post-market monitoring highlights a proactive approach to regulatory compliance. However, a notable gap in the ACD is the absence of a prohibition on animal testing, raising ethical and scientific considerations.

The notion of compliance notification serves as a pivotal mechanism for companies to affirm the safety and quality of their cosmetics, requiring a thorough safety assessment of ingredients and finished products. While the ACD does not mandate new animal testing for established ingredients, it acknowledges potential challenges, particularly concerning new substances derived from local botanical sources lacking a safety profile.

In the face of evolving scientific methodologies offering alternatives to animal testing, the question arises: Is animal testing still a necessity? The focus on scientific relevance over social aspects, such as animal protection and rights, prompts a critical examination of the ethical considerations surrounding cosmetic testing. As alternative methods advance, there is an opportunity for the cosmetics industry to embrace more humane and scientifically robust approaches, thereby aligning with global trends toward ethical and sustainable practices.

In navigating the complex landscape of cosmetic regulations, stakeholders should actively engage in discussions that transcend regulatory compliance alone. Addressing the ethical dimensions of animal testing in tandem with advancements in alternative methods is crucial for fostering a cosmetics industry that prioritizes both consumer safety and ethical responsibility.

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### Conflict of Interest

Authors declare no conflict of interest in the present work.

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