



Cosmetics & Hygiene

# SGS Digicomply Solution

Science Inspired, Quality Driven.

# Market context for Cosmetics & Hygiene products

Major trends in consumer preference and shifts in society are driving regulatory changes and impacting the way we manage risks in the product value chain.



## Product customization

Product design to include consumer preferences & customized features

Consumers demand technology to be part of their buying experience (access to real-time data)



## Naturalness and 'clean label'

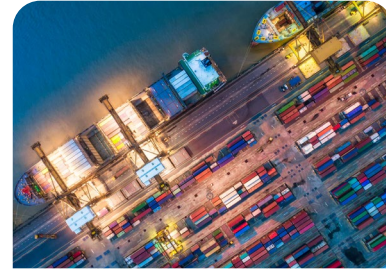
Consumers push to remove undesirable ingredients creating regulatory challenge to anticipate upcoming trends



## Sustainability & circularity

Consumers demand social responsibility from companies (ethical sourcing, organic ingredients, recyclable packaging, etc.)

Critical dependence on biodiversity for innovation & materials



## Supply chain resilience

Product cycle driven by fast changing consumer trends and forcing faster fulfillment

Supply chain disruptions requiring greater agility in supplier & raw material assurance



## Risk & trend monitoring

Constantly evolving policies & extremely fast changing trends (accelerated by social media) requiring risk & (perception) issue anticipation

# The challenge of product safety and compliance

To develop products meeting these evolving demands, professionals in the Cosmetic & Hygiene industry need to access complete, reliable, multilingual regulatory information and process it easily and efficiently to ensure product safety and compliance in every activity of the value chain.



# In a nutshell

SGS Digicomply is a collaborative platform with integrated support for your compliance management process from early-stage regulatory assessment, to guidance for market entry, and early warning insight for risk prevention.



# Search in a consolidated library of regulations

by MARKET, KEYWORD, STATUS and more



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## BY MARKET

## BY KEYWORD

Select Date **Market: China** **Smart Search: toothpaste** [Expand >>](#) [Reset](#)

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Annex 14 Test Method for Pseudomonas aeruginosa in Toothpaste

By National Institutes for Food and Drug Control on Nov 24, 2023 [Nov 24, 2023](#) [China](#) [Regulation](#)

...specification specifies the testing method for Pseudomonas aeruginosa in **toothpaste**....Annex 14 Test method for Pseudomonas aeruginosa in **toothpaste** Pseudomonas aeruginosa Test 1 Scope This...This specification is applicable to the detection of Pseudomonas aeruginosa in **toothpaste**. 2 Definition...

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## BY STATUS

In Force  Not In Force  Upcoming  Guidance

2 results found [EXPORT](#)

Title	Enforceable on	Published on	Markets
Announcement of New Measures related to Toothpaste in China - Order No. 71 of the State Administration for Market Regulation	Dec 01, 2023	Mar 23, 2023	<a href="#">China</a>
Order No. 71 of the SAMR - Measures for the Supervision and Administration of Toothpaste	Dec 01, 2023	Mar 15, 2023	<a href="#">China</a>

# Access to the post

BY LANGUAGE

English (Translation)

Chinese (Simplified) (Original)

## Notice of the Central Inspection and Quarantine Office on Public Solicitation of Opinions on "PH Determination of Toothpaste" and Other Issues

Enforceable on: Nov 24, 2023 | Published on: Nov 24, 2023 | Source: National Institutes for Food and...

<https://www.nifdc.org.cn/nifdc/b...>

Market: China | Topic: Methods and Manufacturing | Product Category: Cosmetic & Personal

AI Summary

The Central Inspection and Quarantine Office is seeking public opinions on various testing methods and requirements for cosmetics and toothpaste, including the "PH Measurement of Toothpaste" draft. Interested parties can provide feedback by filling out the provided feedback form and sending it via email before December 15, 2023. The draft and instructions for other testing methods are also included in the notice.

Ask a question about this post...



This feature is in BETA. Help us deliver best experience by providing feedback. You can also check out our best practices and tips.

Relevant units:

In order to further improve the technical standards for cosmetics and toothpaste, our institute has organized the drafting of 20 testing methods or related requirements (see Appendix 1-20) including the "PH Measurement of Toothpaste" (Draft for Comments), which is now open to the public for comments. To provide feedback, please fill out the "Feedback Form" (see Attachment 21) and send an email to hzpbwh@nifdc.org.cn before December 15, 2023.



RELATED POSTS



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Nov 24, 2023

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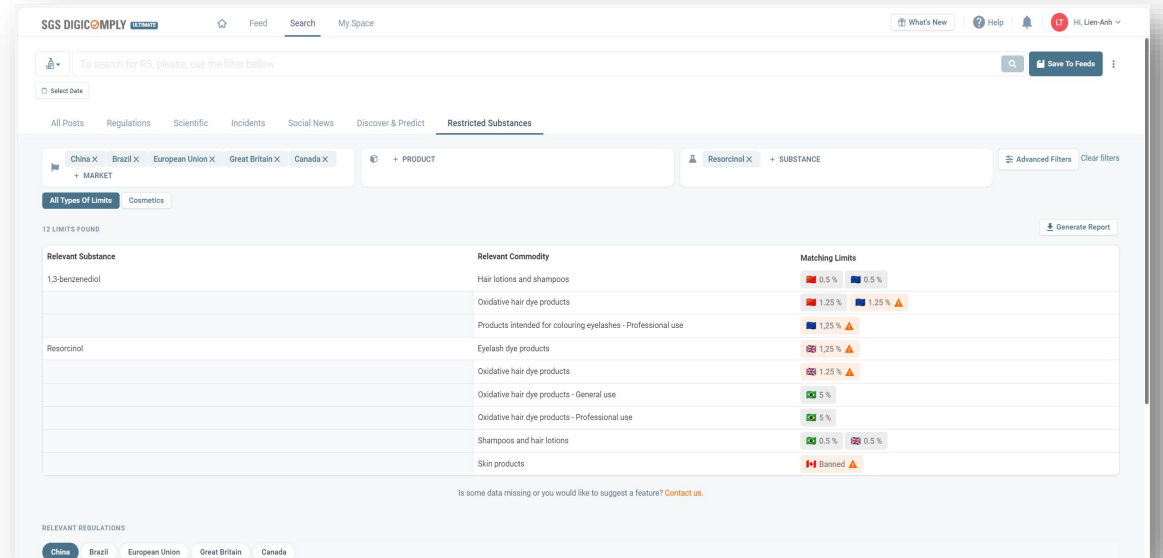
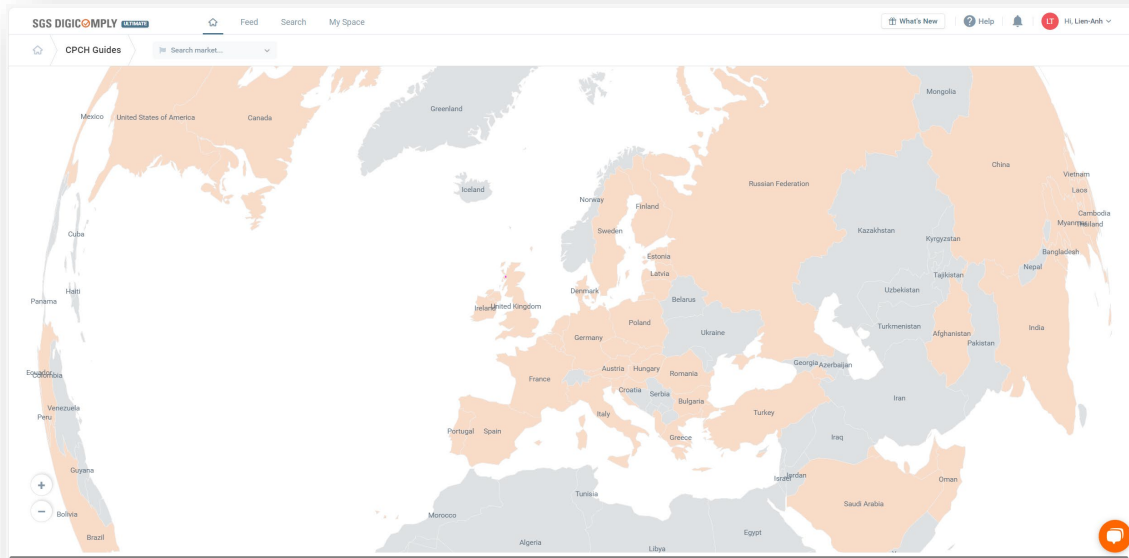
# Market entry guidance

The essential, digested, updated guidance for placing cosmetic and hygiene products on a new market

## 1 MARKET ENTRY GUIDES



## 2 RESTRICTED SUBSTANCES



**Continuous updates!**



**Friendly-user digital platform!**

# Market entry guidance

## 1 MARKET ENTRY GUIDES (1/4)



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← **Korea Cosmetics Regulatory Guide (CRG)** Released ★  
Modified on Sep 18, 2023 by Fred PRO Lorber

Approvers ✓ Fred PRO Lorber Approved

### Korea Cosmetics Regulatory Guide (CRG)

**DIGICOMPLY**

Market: South Korea (Republic of Korea)

**Dossier Info**

Updates: 3

**Properties**

Dossier Type: Cosmetics Regulatory Guide (CRG)

Author:  June Lee  Fred PRO Lorber

Published on: 📅 Sep 18, 2023



# Market entry guidance

## 1 MARKET ENTRY GUIDES (2/4)



### Competent Authorities

Ministry of Food and Drug Safety (MFDS)

### LEGISLATIONS

#### General Law

Overview	References
Cosmetic products (general cosmetics, functional cosmetic or quasi-drugs) placed on the Korean market must comply with the overarching Cosmetics Act.	<a href="#">COSMETIC ACT (consolidated version)</a>
Cosmetic Enforcement Rules and Enforcement Decree of Cosmetics Act complete the Cosmetic Act	<a href="#">Consolidated Enforcement Rules of the Cosmetics Act</a> <a href="#">Consolidated Enforcement Decree of the Cosmetics Act - Penalties</a>
Different Ministry of Food and Drug Safety (MFDS) Notifications also regulate cosmetics. MFDS Notifications related to ingredients, labelling and safety standards are listed in below related sections	<a href="#">Ministry of Food and Drug Safety Announcement No. 2020-53 - Cosmetic safety information management regulation revision</a> <a href="#">Consolidated Regulation on cosmetic safety standards</a>
Food and Drug Safety (MFDS) Notifications on functional cosmetics	<a href="#">Partial revision notice on functional cosmetics review (Ministry of Food and Drug Safety Notice 2021-55)</a>
Food and Drug Safety (MFDS) Notifications on infants and children's cosmetics	<a href="#">Regulations for the preparation and storage of cosmetic safety data for infants and young children (Notification 2020-66)</a>
Food and Drug Safety (MFDS) Notifications on organic cosmetics	<a href="#">Some amendments to regulations on standards for organic cosmetics</a>
Ban of microbeads in cosmetics	<a href="#">Ministry of Environment Notice No. 2020-117 - Safety Standards for Chemical Substances - Prohibited and restricted substances</a>



# Market entry guidance

## 1 MARKET ENTRY GUIDES (3/4)

### Definition

"Cosmetics" means any item intended to be used by means of spreading, rubbing, spraying on or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness or brightening the appearance, or maintaining or improving the health of skin and hair, which have light effects on the human body

The Cosmetics Act defines three categories of cosmetics:

- General cosmetics: skin and hair care products
- Functional cosmetics : Whitening products, Anti-wrinkle products, Sunscreens, Hair Dyeing, hair-decolorant products, bleach agent, Epilating agent, Alleviating hair loss agent, Acne (pimple) products (Rinse-off products only), Alleviating atopic skin dryness products and Cosmetics to help thin red lines caused by stretch marks
- Quasi-drugs: Sanitary napkins, Anti-hair fall products, Hair dye (Permanent hair dye), Toothpaste, Mouth Refreshers, Hand sanitizer, and Antiperspirant Antiseptic

### Ingredients

#### Overview

The MFDS has notified 'prohibited ingredients' on the basis of negative list system, so all ingredients except prohibited ingredients could be used under the Cosmetics Responsible Person's responsibility for their safety.

For the preservatives, UV-filters, and colorants only the ingredients notified by MFDS can be used.

In addition, the MFDS establishes safety management standards for cosmetic products through risk assessment

#### References

[MFDS Notice No. 2022-27 - Partial revision and announcement of regulations on cosmetic safety standards, etc.](#)

[Types, Standards and Test Methods of Cosmetic - Color Additives](#)

### Labelling

#### Overview

Cosmetic product labels must conform to the specific requirements for labelling in the Cosmetics Act, and in the Cosmetics Notification from the Korean government.

A cosmetic manufacturer, responsible person shall not make any false or misleading labeling or advertisements and shall be able to substantiate claims they displayed and/or advertised

#### References

[Regulations on cosmetics labeling and advertisement verification last amended by MFDS No. 2020-80](#)



# Market entry guidance

## 1 MARKET ENTRY GUIDES (4/4)

### Other Requirements

Animal testing on cosmetics and ingredients is banned in South Korea under the law of the Cosmetics Act.

- Physical and chemical testing
- Stability Testing
- Toxicology Testing
- Microbiology Testing

### PLACING ON THE MARKET

The Cosmetic Act defines the Marketing Authorization Holder System which regulates the cosmetic products registration, importing and marketing in South Korea Markets.

Cosmetics manufacturers shall register with the MFDS as a cosmetics manufacturer (With the regional office that has jurisdiction over where the manufacturing facility is located).

The Cosmetics Responsible Person shall register with MFDS Marketing Authorization Holder (With the regional office that has jurisdiction over where the manufacturing facility is located)

In case of import, the Marketing Authorization Holder shall be registered, and must submit an "Entry Notice of Imported Products Report" before every customs clearance

Locally manufactured or imported functional cosmetics shall be approved by the MFDS through evaluation.

The MFDS conducts regular and ad-hoc on-site inspection of cosmetic manufacturers and responsible person, tests distributed products, monitors labeling and advertisements, and monitors risk information from overseas.

# Market entry guidance

## 2 RESTRICTED SUBSTANCES



**RESTRICTION DETAILS**

Substance  
[1,1'-\(1,4-piperazinediy\)bis\[1-\[2-\[4-\(diethylamino\)-2-hydroxybenzoyl\]phenyl\]-methanone - Nano](#)

Restriction value  
**10 %**  
Only nanomaterials having the following characteristics are allowed:  
- Purity ≥ 97 %  
- Median particle size D50 (50 % of the number below this diameter): > 50 nm of number size distribution.  
Not to be used in applications that may lead to exposure of the end user's lungs by inhalation

Product  
[All products](#)

Market  
European Union

Category  
Cosmetics

Restriction type  
Restriction

Regulatory type  
Regulation

Status  
● In force

Date of Application  
01 December, 2022

Notes  
In case of combined use of Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine and Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine (nano), the sum shall not exceed 10 %.

Commission Regulation (EU) 2022/2195 of 10 November 2022 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of Butylated Hydroxytoluene, Acid Yellow 3, Homosalate and HAA299 in cosmetic products and correcting that Regulation as regards the use of Resorcinol in cosmetic products (Text with EEA relevance)

**SEARCH**

China X European Union X + MARKET

+ PRODUCT

Methylparaben X Paraben X

1,1'-(1,4-piperazinediy)bis[1-[2-[4-(diethylamino)-2-hydroxybenzoyl]phenyl]-methanone - Nano X

+ SUBSTANCE

All Types Of Limits **Cosmetics** Food Additives Pesticides

12 LIMITS FOUND

Relevant Substance	Relevant Commodity
1,1'-(1,4-piperazinediy)bis[1-[2-[4-(diethylamino)-2-hydroxybenzoyl]phenyl]-methanone - Nano	All products
	Cosmetics
Benzyl 4-hydroxybenzoate (INCI: benzylparaben)	All products
Isobutyl 4-hydroxybenzoate (INCI: Isobutylparaben); Sodium salt or Salts of Isobutylparaben	All products
Isopropyl 4-hydroxybenzoate (INCI: isopropylparaben) sodium salt or salts of isopropylparaben	All products

**IDENTIFY**

Matching Limits

- 10 %
- 10 %
- Banned
- Banned
- Banned
- Banned
- Banned
- Banned

**DEEP-DIVE**

Notification 74 - Updated Annex 2 of STSC 2015 -List of banned ingredients in cosmetics  
By National Medical Products Administration on May, 28 2021 May 28, 2021 Regulation

# Regulatory watch

With so much information available in so many places – keep track (in real-time) of regulatory updates and prepare for emerging risks



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Search name: PFAS US & EU

Data categories: All Posts, Regulations, Scientific, Incidents, Social News, Restricted Substances

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Draft H2906 PFAS IN COSMETICS

By Minnesota House of Representatives on Jan 01, 2025 | United States of America | News

...BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA: Section 1. [116.943] PFAS IN COSMETICS....on Health Finance and Policy as Amended 1.1 A bill for an act relating to environment; prohibiting PFAS...required for distribution or dispensing; and (2) "pe substances" or "PFAS..."

Consolidated text: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establish

By EUR-Lex on Dec 01, 2023 | Dec 01, 2023 | European Union | Regulation

02006R1907 – EN – 01.12.2023 – 060.001 This text is meant purely as a documentation tool and has no legal effect.

Parliament adopts revamped rules to reduce, reuse and recycle packaging

By European Parliament on Nov 22, 2023 | European Union

...Renew, BE) said: "Recent events in Europe, and particularly in Belgium, concerning water pollution by PFAS..."

# Regulatory watch

## Newsfeed and AI - Copilot



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**PFAS US & EU** Share your workload Invite your colleagues and utilise our collaborative features. Invite Colleague

**What's new**

**AI co-pilot summarizes your unread posts**

The Environmental Protection Agency (EPA) is proposing revisions to its Safer Choice Standard to improve efficiency and effectiveness. The proposed changes involve updates to packaging requirements, on-site audits for product ingredient verification, restrictions on heavy metals in packaging materials, and the prohibition of sensitizers in certified pet care products. Stakeholder input is being sought on all aspects of the proposed revisions, including the addition of criteria for evaluating odor elimination chemicals and clarifying language on additive components in nonwoven substrates. The proposal also introduces the Safer Choice Cleaning Service Certification, which requires the use of a Safer Choice-qualified third-party profiler.

Meanwhile, the European Parliament has adopted new rules on packaging to tackle the issue of waste and promote reuse and recycling. The rules include targets for reducing plastic packaging, banning lightweight plastic carrier bags, and restricting certain single-use packaging formats. The use of "forever chemicals" and Bisphenol A in food contact packaging will also be prohibited. The aim is to encourage consumers to opt for reuse and refill options, as well as improve the collection and recycling of packaging waste. The Parliament will now engage in negotiations with EU governments to finalize the law.

Ask a question about unread articles in your feed...

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**Parliament adopts revamped rules to reduce, reuse and recycle packaging**  
2 days | Mark as read

**Proposed Revisions to EPA's Safer Choice Standard**  
11 days | Mark as read

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AI-Copilot

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- WTO - Cosmetics & Deterge...
- CPCH REVIEW CPCH
- EU 1223/2009
- Canada Env law
- WTO duplicates
- US MOCRA
- GSO Standards
- Cosmetics China
- PFAS US & EU**

+ CREATE NEW FOLDER

# Expert connect

In case of doubt or special requests – our team of SGS Experts is only a click away through SGS Digicomply collaborative platform



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## Advisory Requests

Local experts on hand! Our experienced regulatory team can easily help you with common tasks. Choose one of the services by our expert regulations team.

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### Label review

Review of a label artwork considering generic and product-specific regulatory requirements. The service is provided with local experts for a large number of markets.

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### Ingredient Review

On basis of a recipe or a product composition we verify if the ingredients and additives used during the preparation of a final product are in compliance with specific market regulatory requirements.

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### Submit a Query

Do you have question around specific legislation topic? e.g. questions about regulatory requirements, assessment of analytical results

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**CONNECT DIRECTLY**

- Our Experts answer your queries promptly (with ticket tracking)
- **SGS Regulatory & Consultancy Services** include –
  - Label review and product labelling
  - Ingredient review
  - Product safety assessments

# Benefits of SGS Digicomply

A powerful compliance platform combining AI technology with SGS expertise to provide digested and continuously updated regulatory information for the cosmetics and hygiene industry



## SPECIALIZED

Built by a team of SGS Experts

Highly skilled staff to help clients ensure product compliance



## SIMPLE

Worldwide updated regulations at your fingertips

From multilingual sources and available in English



## PRACTICAL

Workspace, filing cabinet, exchange forum on one single platform

Access, review, annotate and share any document



## ORGANIZED

Organize and store your regulatory knowledge

Create your own product and market dossiers, alerts, newsfeeds



## PRIVATE

Customize with your own private library (documents, data, internal policies)



# Why SGS

We bring the credibility of SGS capabilities and expertise to serve our clients' products and end-consumers



## Analytical, *in vitro* & microbiological

- Physical & chemical
- Microbiological
- Stability
- *In vitro* tests
- Ecotoxicology & biodegradability



## Clinical & Consumer Panels

- Clinical studies
- CRO services
- Consumer panels
- Home-use studies



## Performance Testing

- Physical & instrumental performance
- Packaging performance



## Regulatory & Consultancy

- Product labeling & ingredient review
- Product safety assessment
- Online compliance & regulatory watch  
**SGS Digicomply**



## Audit & Certification

- Product certification & verification
- Customized supplier audit
- Other ISO & management standards