Biodegradable or not? Developing a standardized international approach to assess the biodegradability of cosmetics formulations

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Introduction

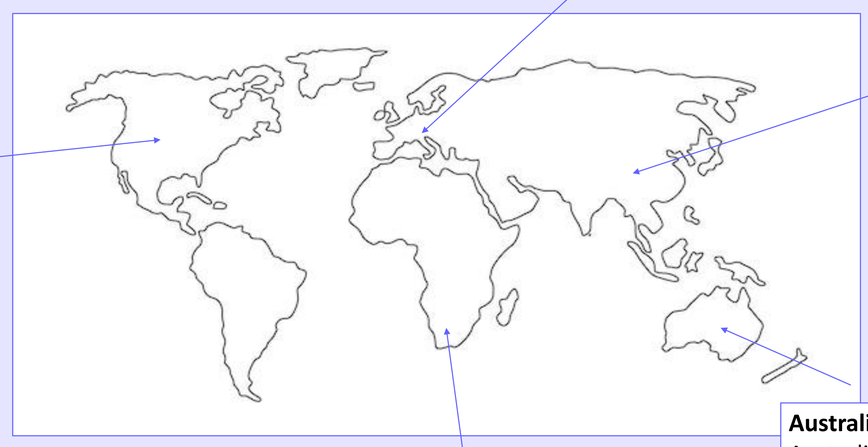
Consumer expectations and demands for biodegradable product formulations are increasing rapidly. Although biodegradability assessment of cosmetic formulations is included in various certification and labelling programs and environmental/sustainability scoring tools, so far, no clear guidance is available to address how to consistently assess the biodegradability of cosmetic formulations. Therefore, the global non-for-profit science organization International Collaboration on Cosmetics Safety (ICCS) is undertaking development of an internationally validated process setting out standardized approaches for evaluating the biodegradability of cosmetic ingredients including how to calculate the biodegradability of product formulations. To support the development of a standardized approach, a critical review of regulatory positions, existing criteria, and standards specifically for assessing the biodegradability of ingredients, formulations and chemical mixtures is being performed and is presented in this poster. The review includes cosmetics, personal care, and homecare formulas. Based on the results of the review, suggestions regarding international standard development will be mapped and a roadmap for gaining acceptance of a possible international standard will be highlighted.

The approaches used today are acceptable, however a guideline will ensure these approaches are used in a consistent way.

Regulatory Landscape

Globally, requirements for characterizing the biodegradability of ingredients have been adopted under REACH, TSCA, CLT, CEPA, etc. with Cosmetics and Personal Care Products being regulated under various statues and regulations as depicted

UK and EU
Registration, evaluation, authorisation and restriction of chemicals (REACH)
Cosmetic Product Regulation
EU Detergent Regulation
Eco-design for Sustainable Products Regulation



North America
Federal Food, Drugs and Cosmetics Act
Modernization of Cosmetics Regulation Act (2022)
Regulations related to Cosmetics from Title 21 of the Code of Federal Regulations (21 CFR)
Canadian Food and Drug Act (F&DA)
Cosmetics Regulations
Canadian Environmental Protection Act (CEPA)
Chemicals Management Plan

Asia
Asea Directive

South Africa
South African Health Products Regulatory Authority (SAHPRA)

Australia
Australian Industrial Chemicals Introduction Scheme
Therapeutic Goods Administration

Current Approaches towards Biodegradability

Ecolabels

- Voluntary labelling schemes to certify products with a reduced environmental impact and to help consumers to choose environmentally friendly products.
- Biodegradability criteria refer to ingredients
- Certain organic ingredients must be readily biodegradable or criteria for % weight of product that must be readily biodegradable.

Certifications

- Certification schemes deal with different environmental aspects and biodegradation is considered to varying degrees.
- All programs have in common that the ready biodegradability or persistence of individual ingredients must preferably be tested or assessed.
- OECD guidelines for ready and inherent biodegradability and/or simulation test are used.

Scoring Tools

- Various eco-design and scoring tools were developed by the cosmetic industry to assess the impact of cosmetic formulas on the environment and to identify the environmental hazard of ingredients.
- Information on ready/inherent biodegradability or persistence (degradation half-live) of ingredients are used by the tools.
- Each cosmetic ingredient is classified into risk categories, or the biodegradation of the formula is calculated based on the individual ingredient data.

Biodegradation Criteria and Guidelines

Guidelines

The OECD system for testing the biodegradation of chemicals is the most recognized system and included in chemicals legislation worldwide.

- OECD biodegradation tests are applicable to predict the biodegradability of pure, organic chemicals or single compounds in mixtures and they are not adapted to conclude on the ready or inherent biodegradation of heterogenous mixtures.
- Biodegradation is tested in a stepwise approach for most regulatory requirements, testing starts with ready biodegradability and inherent biodegradability followed by simulation tests to simulate the degradation in a specific environmental compartment.

Readily Biodegradable

A positive result in a ready biodegradability test is regarded as proof for rapid and ultimate degradation in most environments.

- Ready biodegradability is a standard information requirement for organic substances under most chemicals' regulations worldwide.
- PBT Assessment: Positive results (biodegradation >60% after 28/60 days) allow the conclusion that a substance does not fulfil persistent criteria and further simulation testing is not required.

Inherent Biodegradability

Biodegradation in an inherent test under less stringent conditions is regarded as evidence of inherent, ultimate biodegradability.

- PBT Assessment: A positive result (meeting specific criteria) supports the evidence that a substance is not persistent.
- Substances reaching 60% degradation in an extended ready biodegradability test within 60 days are concluded as inherent biodegradable.

Simulation Tests

Provide information on the rate of degradation under more environmentally relevant conditions.

- Most sophisticated biodegradation study type, but tests are often very costly, and require a lot of analytical effort, time, and experience.
- Simulation tests are a standard information requirement under chemicals regulation for organic substances with higher registration tonnages (e.g. REACH > 100 t/y) if the substance is not readily biodegradable.
- Simulation studies are the preferred studies for PBT assessment as environmentally realistic degradation half-lives are determined.

Why is a new guideline needed?

- Consumers are looking for affirmation of the environmental performance of their products
- Various guidelines for testing individual substances exist.
- Cosmetic formulas are complex mixtures for which no biodegradation test guideline nor guidance to calculate the biodegradation exists.
- Biodegradation testing of cosmetic formulas is done although the guidelines don't allow formula/mixture testing.
- Biodegradation statements issued based on formula testing may therefore misinform the consumer.

Core Points to consider for a new ISO guideline

- Current established biodegradability tests methods are not intended for testing complete formulas and/or complex mixtures.
- The new guideline (approach) should consider the biodegradation of single ingredients of a cosmetic formula and will ensure that the approaches used today are used in a consistent way.
- The way to calculate the biodegradability of a cosmetic formula based on the biodegradation of the single ingredients must be addressed, e.g. IFRA calculates the biodegradability based on data on the individual ingredients by summing the percentage (by weight) of ingredients that are biodegradable.
- An approach to consider the biodegradability of heterogeneous ingredients like natural complex substances and UVCBs is necessary, as rarely test data for these substances exist.
- It will be evaluated how organic substances for which rarely data exist (e.g. polymers) should be considered in the calculations.
- It will be evaluated how different substance groups (e.g., water, organic, inorganic, heterogeneous mixtures) should be defined, addressed in the calculation of the overall biodegradation of the cosmetic formula, and communicated clearly to consumers
- % biodegradation refers to the % breakdown of organic ingredients

Standards Roadmap

Goal	• Develop a new standard for the evaluation of biodegradability of complete cosmetic formulas
Concept stage	• Contact key stakeholders • Develop idea and goals of a new standard • Begin drafting standard
Proposal stage	• Confirm the new subject area • Nominate project leader • Identify complications • Submit to ISO representative
Preparatory stage	• Election of working group by ISO technical committee • Finalise draft of standard
Committee stage	• Comments on draft from ISO members within technical committee (outside of working group)
Enquiry stage	• All ISO members can review, comment, and vote • If revisions are required, further drafts undergo the process
Approval stage	• Approval of final draft • (Step is skipped if no changes are made during the enquiry stage)
Publication stage	• Standard is published for public use

Key stakeholders and references

- International Fragrance Association (IFRA)
- Cosmetics Europe
- Cosmetic, Toiletry and Perfumery Association Limited (CTPA)
- Personal Care Products Council (PCPC)
- The cosmetic, Toiletry and Fragrance Association of Singapore (CTFAS)
- Cosmetics Alliance Canada
- Korea Cosmetic Association

- Saxe, J.K. Biodegradability Evaluation for Cosmetic Ingredients and Finished Products. Formulating, Packaging, and Marketing of Natural Cosmetic Products. 6 June 2011.
- IFRA white paper on selected criteria for supporting biodegradability statements pertaining to fragrance ingredients along the supply chain, 2023.
- Regulation (EC) N° 1223/2009 - Cosmetics products regulation
- OECD standards