Biodegradable or Not? Developing a Standardized International Approach to Assess the Biodegradability of Cosmetics Formulations

Silke Fiebig[1], Juliet Hodges[2], Amelie Ott[3], Ryan Heisler[3], Karina J Reynolds[4], Andrea Carrao[5], Guillaume Cottin[6], Jennifer Dorts[7], Judith Kaumanns[8], Monica Lam[8], Fanny Minetto[10], Beta Montemayor[11], Jennifer K. Saxe[12], Harald Streicher[13], Cyril Sweetlove[6], Nadine Wedler[15]
1) Vitis Regulatory GmbH, 2) Unilever, 3) ICCS, 4) WSP UK Ltd, 5) Kao USA, 6) L'Oreal France, 7) IFRA, 8) Wella Germany GmbH, 9) Procter & Gamble United States, 10) Chanel, 11) Cosmetics Alliance Canda, 12) Kenvue, 13) Beiersdorf Germany, 14) Kao Germany GmbH

Introduction

Consumer expectations and demands for biodegradable product formulations are increasing rapidly. Although biodegradability assessment of cosmetic formulations is included in various certification and labeling programs and environmental/sustainability scoring tools, so far, no clear guidance is available to address how to assess the biodegradability of cosmetic formulations consistently.

Therefore, the global not-for-profit science organization, International Collaboration on Cosmetics Safety, is seeking 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 that they are used consistently.

Current Approaches towards Biodegradability

Ecolabels

- Voluntary labeling schemes to certify products with a reduced environmental impact and help consumers choose environmentally friendly products.
- Biodegradability criteria refer to ingredients
- Certain organic ingredients must be readily biodegradable, or there must be criteria for the percentage of the product's weight 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 individual ingredients' ready biodegradability or persistence must preferably be tested or assessed.
- OECD guidelines for ready and inherent biodegradability and/or simulation tests are used.

Scoring Tools

- The cosmetic industry developed various eco-design and scoring tools to assess cosmetic formulas' environmental impact and identify ingredients' environmental hazards.
- 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.

Regulatory Landscape



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



UK and EU

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



Australia

- Australian Industrial Chemicals Introduction Scheme
- Therapeutic Goods Administration

Biodegradation Criteria and Guidelines

Guidelines—The OECD system for testing chemical biodegradation is the most recognized system and is *included in chemicals legislation worldwide*.

- OECD biodegradation tests are applicable to predict the biodegradability of pure, organic chemicals or single compounds in mixtures. They are not adapted to conclude on the ready or inherent biodegradation of heterogeneous mixtures.
- Biodegradation is tested stepwise 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 — *Apositiveresultinareadybiodegradabilitytestisregardedasproofforrapidandultimatedegradationinmostenvironments.*

- 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 fulfill 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.*

- 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 fulfill persistent criteria, and further simulation testing is not required.

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 chemical regulation for organic substances with higher registration tonnages (e.g., REACH > 100 t/y) if the substance is not readily biodegradable.
- Simulation studies are preferred for PBT assessment as environmentally realistic degradation half-lives are determined.

Roadmap Towards an ISO Standard

Goal	Concept stage	Proposal stage	Preparatory stage	Committee stage	Enquiry stage	Approval stage	Publication stage
Develop a new standard for the evaluation of biodegradability of complete cosmetic formulas	• Contact key stakeholders • Develop idea and goals of a new standard • Begin drafting standard	• Confirm the new subject area • Nominate project leader • Identify complications • Submit to ISO representative	• Election of workgroup by ISO technical committee • Finalize draft of standard	• Comments on draft from ISO members within a technical committee; External	• All ISO members can review, comment, and vote • If revisions are required, further drafts undergo the proces		

Key Stakeholders

- 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

References

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