

Member Associations
Members of IFRA Committees
cc RIFM
Members of the JAG
Downstream Users Associations

7 October 2024

Information Letter 1192

Subject: EU REACH test methods Regulation (EC) No 440/2008 revised

Related ILs: 1153

Dear Colleagues,

On 23 September 2024, Commission Regulation (EU) 2024/2492 amending the EU REACH Test Methods Regulation (EC) No 440/2008 was published in the EU's Official Journal and will enter into force on the twentieth day following that of its publication.

Seven methods have been added and 14 methods updated following the new OECD guidelines.

The seven tests added are: one new test method for basic physicochemical properties, one new and two updated test methods for the determination of effects on human health, relating to in vitro tests for immunotoxicity and skin sensitisation and three updated test methods for the assessment of ecotoxicity:

- Physicochemical properties
 - ✓ OECD Test Guideline 126: Determination of the Hydrophobicity Index of Nanomaterials Through an Affinity Measurement (2023),
- In vitro test for immunotoxicity and skin sensitisation,
 - ✓ OECD Test Guideline 444A: In Vitro Immunotoxicity: IL-2 Luc Assay (2023),
 - ✓ OECD Test Guideline 442C: In Chemico Skin Sensitisation: Assays addressing the Adverse Outcome Pathway key event on covalent binding to proteins (2023),
 - ✓ OECD Test Guideline 442E: In Vitro Skin Sensitisation: In Vitro Skin Sensitisation assays addressing the Key Event on activation of dendritic cells on the Adverse Outcome Pathway for Skin Sensitisation (2023),
- Assessment of ecotoxicity
 - ✓ OECD Test Guideline No. 240: Medaka Extended One Generation Reproduction Test (MEOGRT) (2023),
 - ✓ OECD Test Guideline 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment (2023),
 - ✓ OECD Test Guideline 219: Sediment-Water Chironomid Toxicity Using Spiked Water (2023).

OECD has issued in 2023 new corrected versions of test methods, which have been included in Regulation (EC) No 440/2008 and outdated versions are deleted. These are:

- OECD Test Guideline 125: Nanomaterial Particle Size and Size Distribution of Nanomaterials (2023)
- OECD Test Guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis (2023)
- OECD Test Guideline 405: Acute Eye Irritation/Corrosion (2023)
- OECD Test Guideline 437: Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2023)
- OECD Test Guideline 438: Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2023)
- OECD Test Guideline 456: H295R Steroidogenesis Assay (2023)
- OECD Test Guideline 458: Stably Transfected Human Androgen Receptor Transcriptional Activation Assay for Detection of Androgenic Agonist and Antagonist Activity of Chemicals (2023)
- OECD, Test Guideline 460: Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants (2023)
- OECD Test Guideline 487: In Vitro Mammalian Cell Micronucleus Test (2023)
- OECD Test Guideline 491: Short Time Exposure In Vitro Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2023)
- OECD Test Guideline 492: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage (2023)
- OECD Test Guideline 496: In vitro Macromolecular Test Method for Identifying Chemicals Inducing Serious Eye Damage and Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2023)
- OECD Test Guideline 497: Defined Approaches on Skin Sensitisation (2023)
- OECD Test Guideline 498: In vitro Phototoxicity - Reconstructed Human Epidermis Phototoxicity test method (2023)

Finally, in order to achieve better alignment with related legislation, in particular with the EU CLP Regulation (EC) No 1272/2008, the listing of the test methods for physicochemical properties in Part 0, Table 1 of the Annex to Regulation (EC) No 440/2008 has been restructured and relevant test methods added.

If you have any further questions, please contact Cristina Arregui (carregui@ifrafragrance.org) at IFRA.

Best regards,
IFRA

Attachments:

Att 01: Commission Regulation (EU) 2024/2492

Relevant links:

Official Journal of the EU: <https://eur-lex.europa.eu/eli/reg/2024/2492/oj>