

EN
ANNEX

The Annex to Regulation (EC) No 440/2008 is amended as follows:

- (1) Part 0 is amended as follows:
 - (a) In Table 1 the entry ‘Dustiness (for nanoforms of a substance)’ is replaced by the following:

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| ‘Dustiness (for nanoforms of a substance)’ | EN 17199-1:2019 – Workplace exposure - Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles | |
| | EN 17199-2:2019 Workplace exposure – Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles – Part 2: Rotating drum method | |
| | EN 17199-3:2019 Workplace exposure – Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles – Part 3: Continuous drop method | |
| | EN 17199-4:2019 Workplace exposure – Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles – Part 4: Small rotating drum method | |
| | EN 17199-5:2019 Workplace exposure – Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles – Part 5: Vortex shaker method | |
| | EN 15051-1: Workplace exposure - Measurement of the dustiness of bulk materials - Part 1: Requirements and choice of test methods | |
| | EN 15051-2: Workplace exposure - Measurement of the dustiness of bulk materials - Part 2: Rotating drum method | |
| | EN 15051-3: Workplace exposure - Measurement of the dustiness of bulk materials - Part 3: Continuous drop method’; | |

(b) Table 2 is amended as follows:

(i) in the entry ‘Serious eye damage/eye irritation’ the ‘In vitro’ section is replaced by the following:

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| ‘Serious eye damage/eye irritation | <i>In vitro:</i> | |
| | 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) | (B.47.) |
| | 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) | (B.48.) |
| | OECD Test Guideline 460: Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants (2023) | (B.61.) |
| | OECD Test Guideline 491: Short Time Exposure <i>In Vitro</i> Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2023) | (B.68.) |
| | 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 (2024) | (B.69.) |
| | OECD Test Guideline 492B: Reconstructed Human Cornea-like Epithelium (RHCE) Test Method for Eye Hazard Identification (2024) | |
| | OECD Test Guideline 494: Vitrigel-Eye Irritancy Test Method for Identifying Chemicals Not Requiring Classification and Labelling for Eye Irritation or Serious Eye Damage (2021) | |
| | OECD Test Guideline 496: <i>In vitro</i> Macromolecular Test Method for Identifying Chemicals Inducing Serious Eye Damage and Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2024) | |
| OECD Test Guideline 467: Defined Approaches for Serious Eye Damage and Eye Irritation (2024)’; | | |

(ii) in the entry ‘Skin sensitisation’, the ‘In vitro’ section is replaced by the following:

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| Skin sensitisation | <i>In vitro:</i> |
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| | OECD Test Guideline 442C: <i>In Chemico</i> Skin Sensitisation: Assays addressing the Adverse Outcome Pathway Key event on covalent binding to proteins (2024) | (B.59.) |
| | OECD Test Guideline 442D: <i>In Vitro</i> Skin Sensitisation: Assays Addressing the Adverse Outcome Pathway Key Event on Keratinocyte Activation (2024) | (B.60.) |
| | OECD Test Guideline 442E: <i>In Vitro</i> Skin Sensitisation: <i>In Vitro</i> Skin Sensitisation Assays Addressing the Key Event on Activation of Dendritic Cells on the Adverse Outcome Pathway for Skin Sensitisation (2024) | (B.71.) |
| | OECD Test Guideline 497: Defined Approaches on Skin Sensitisation (2023)'; | |

- (iii) in the entry 'Skin sensitisation', in the 'In vivo' section the row corresponding to the OECD Test Guideline 442B is replaced by the following:

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| | 'OECD Test Guideline 442B: Skin Sensitisation – Local Lymph Node Assay: BrdU-ELISA or –FCM (2024) | (B.51.)'; |
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- (iv) in the entry 'Acute toxicity', in the 'Inhalation' section the row corresponding to the OECD Test Guideline 403 is replaced by the following:

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| | 'OECD Test Guideline 403: Acute Inhalation Toxicity (2024) | (B.2.)'; |
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- (v) in the entry 'Endocrine disrupting properties', the row corresponding to the OECD Test Guideline 493 is replaced by the following:

| | | |
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| | OECD Test Guideline 493: Performance-Based Test Guideline for Human Recombinant Estrogen Receptor (hrER) <i>In Vitro</i> Assays to Detect Chemicals with ER Binding Affinity (2024) | (B.70.)'; |
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- (c) Table 3 is amended as follows:

- (vi) in the entry 'Fate and behaviour in the environment', the following row is inserted:

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| | 'OECD Test Guideline 321: <i>Hyalella azteca</i> Bioconcentration Test (HYBIT) (2024)' | |
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(vii) in the entry 'Endocrine disrupting properties', the following rows are inserted:

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| | 'OECD Test Guideline 252: Rapid Estrogen Activity <i>In Vivo</i> (REACTIV) assay (2024) | ' |
| | OECD Test Guideline 253: Short-term juvenile hormone (JH) activity screening assay in <i>Daphnia magna</i> (2024) | |

- (2) in part B, the text below the heading of the Chapter B.2. is replaced by the following: 'The full description of this test method has been deleted. The equivalent international test method appears in Part 0, Table 2'.
- (3) in part B, the text below the heading of the Chapter B.70. is replaced by the following: 'The full description of this test method has been deleted. The equivalent international test method appears in Part 0, Table 2'.