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COMPET 317  
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## PRŮVODNÍ POZNÁMKA

|                |                                                                                                                                                                      |
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| Odesílatel:    | Martine DEPREZOVÁ, ředitelka, za generální tajemnici Evropské komise                                                                                                 |
| Datum přijetí: | 12. března 2024                                                                                                                                                      |
| Příjemce:      | Thérèse BLANCHETOVÁ, generální tajemnice Rady Evropské unie                                                                                                          |
| Předmět:       | PŘÍLOHA<br>nařízení Komise (EU) .../...<br>ze dne XXX,<br>kterým se mění nařízení (ES) č. 440/2008, pokud jde o přizpůsobení<br>zkušebních metod technickému pokroku |

Delegace naleznou v příloze dokument D095103/02 ANNEX.

Příloha: D095103/02 ANNEX

**CS**  
**PŘÍLOHA**

Příloha nařízení (ES) č. 440/2008 se mění takto:

- 1) Část 0 se mění takto:
- a) tabulka 1 se nahrazuje tímto:

| <b>„TABULKA 1: ZKUŠEBNÍ METODY PRO STANOVENÍ FYZIKÁLNĚ-CHEMICKÝCH VLASTNOSTÍ LÁTKY</b> |                                                                                                                                                             |                                                                                                                                                                                                                                                              |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Základní fyzikálně-chemické vlastnosti</b>                                          |                                                                                                                                                             |                                                                                                                                                                                                                                                              |
| <b>Sledovaná vlastnost</b>                                                             | <b>Zkušební metoda</b>                                                                                                                                      | <b>Příslušná kapitola v části A této přílohy obsahující úplný popis zkušební metody (čísla v závorkách znamenají, že úplný popis zkušební metody byl z části A odstraněn; prázdná buňka: v části A této přílohy není žádná odpovídající zkušební metoda)</b> |
| Bod tání / bod tuhnutí                                                                 | OECD Test Guideline 102: Melting Point/Melting Range (1995)                                                                                                 | A.1                                                                                                                                                                                                                                                          |
|                                                                                        | ASTM D4359-90: Standard Test Method for Determining whether a Material Is a Liquid or a Solid                                                               |                                                                                                                                                                                                                                                              |
|                                                                                        | Test for determining fluidity according to section 2.3.4 of Annex A of the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) |                                                                                                                                                                                                                                                              |
| Bod varu                                                                               | OECD Test Guideline 103: Boiling point (1995)                                                                                                               | A.2                                                                                                                                                                                                                                                          |
|                                                                                        | Test methods according to Table 2.6.4 of Annex I, Part 2 of Regulation (EC) No 1272/2008                                                                    |                                                                                                                                                                                                                                                              |
| Hořlavost                                                                              | EN 15188:2020 – Determination of the spontaneous ignition behaviour of dust accumulations                                                                   |                                                                                                                                                                                                                                                              |

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| Dolní a horní mezní hodnota výbušnosti | Test methods according to section 2.2.4.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008 (ISO 10156 and EN 1839)                                                        |       |
| Bod vzplanutí                          | Test methods according to table 2.6.3 of Annex I, Part 2 of Regulation (EC) No 1272/2008                                                                                     |       |
| Teplota samovznícení (kapaliny, plyny) | ISO/IEC 80079-20-1:2017 – Explosive atmospheres - Part 20-1: Material characteristics for gas and vapour classification - Test methods and data                              |       |
| Teplota rozkladu                       | Calorimetric test methods according to section 20.3.3.3 of Part II of the UN Manual of Tests and Criteria                                                                    |       |
|                                        | Test Series H, part II, section 28, of the UN Manual of Tests and Criteria for the self-accelerating decomposition temperature (SADT) (with reference to a specific package) |       |
| pH                                     | OECD Test Guideline 122: Determination of pH, Acidity and Alkalinity (2013)                                                                                                  |       |
| Kinematická viskozita                  | OECD Test Guideline 114: Viscosity of Liquids (2012)                                                                                                                         |       |
| Rozpustnost ve vodě                    | OECD Test Guideline 105: Water Solubility (1995)                                                                                                                             | A.6   |
| Rozdělovací koeficient n-oktanol/voda  | OECD Test Guideline 107: Partition Coefficient (n-octanol/water): Shake-Flask Method (1995)                                                                                  | (A.8) |
|                                        | OECD Test Guideline 123: Partition Coefficient (1-Octanol/Water): Slow-Stirring Method (2022)                                                                                | A.23  |
|                                        | OECD Test Guideline 117: Partition Coefficient (n-octanol/water): HPLC Method (2022)                                                                                         | A.24  |
| Tlak par                               | OECD Test Guideline 104: Vapour Pressure (2006)                                                                                                                              | (A.4) |
| Hustota / relativní hustota            | OECD Test Guideline 109: Density of Liquids and Solids (2012)                                                                                                                | (A.3) |
|                                        | DIN 66137-2 - Determination of solid state density - Part 2: Gas pycnometry                                                                                                  |       |
|                                        | ISO 12154 - Determination of density by volumetric displacement - Skeleton density by gas pycnometry                                                                         |       |
| Charakteristiky částic                 | EU test method A.22. Length Weighted Geometric Mean Diameter of Fibres                                                                                                       | A.22  |
|                                        | ISO 21501 - Determination of Particle Size Distribution - Single Particle Light Interaction Methods                                                                          |       |

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|                                             | OECD Test Guideline 124: Determination of the Volume Specific Surface Area of Manufactured Nanomaterials (2022)                                          |      |
|                                             | OECD Test Guideline 125: Particle Size and Particle Size Distribution of Nanomaterials (2023)                                                            |      |
|                                             | ISO/TR 14187:2020 - Surface chemical analysis - Characterization of nanostructured materials;                                                            |      |
| Prašnost (pro nanoformy látky)              | EN 17199-1:2019 – Workplace exposure - Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles |      |
|                                             | 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                                         |      |
| Povrchové napětí                            | OECD Test Guideline 115: Surface Tension of Aqueous Solutions (1995)                                                                                     | A.5  |
| Disociační konstanta                        | OECD Test Guideline 112: Dissociation Constants in Water. (1981)                                                                                         | A.25 |
| Hydrofobicita                               | OECD Test Guideline 126: Determination of the Hydrophobicity Index of Manufactured Nanomaterials Through an Affinity Measurement (2023)                  |      |
| Vlastnosti fyzikálně-chemické nebezpečnosti |                                                                                                                                                          |      |
| Výbušniny                                   | Test methods for explosives according to section 2.1.2.1. and 2.1.2.3. of Annex I, Part 2 of Regulation (EC) No 1272/2008                                |      |
|                                             | EU Test method A.14 Explosive Properties                                                                                                                 | A.14 |

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| Hořlavé plyny                                         | Test method for the fundamental burning velocity according to section 2.2.4.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008                             |  |
|                                                       | Test method for pyrophoric gases according to section 2.2.4.2. of Annex I, Part 2 of Regulation (EC) No 1272/2008                                             |  |
|                                                       | Test method for the chemical instability according to section 2.2.4.4. of Annex I, Part 2 of Regulation (EC) No 1272/2008                                     |  |
| Oxidující plyny                                       | Test method for oxidising gases according to section 2.4.4. of Annex I, Part 2 of Regulation (EC) No 1272/2008                                                |  |
| Hořlavé kapaliny                                      | Test method for the sustained combustibility according to section 2.6.4.5. of Annex I, Part 2 of Regulation (EC) No 1272/2008                                 |  |
|                                                       | Test methods for determining the flash point of flammable liquids according to section 2.6.4.4. of Annex I, Part 2 of Regulation (EC) No 1272/2008            |  |
| Hořlavé tuhé látky                                    | Test method for flammable solids according to section 2.7.2.3. of Annex I, Part 2 of Regulation (EC) No 1272/2008                                             |  |
| Samovolně reagující látky                             | Test method for self-reactive substances according to section 2.8.4.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008                                     |  |
| Samozápalné kapaliny                                  | Test method for pyrophoric liquids according to section 2.9.2.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008                                           |  |
| Samozápalné tuhé látky                                | Test method for pyrophoric solids according to section 2.10.2.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008                                           |  |
| Samozahřívající se látky                              | Test method for self-heating substances according to section 2.11.2.2 of Annex I, Part 2 of Regulation (EC) No 1272/2008                                      |  |
| Látky, které při styku s vodou uvolňují hořlavé plyny | Test method for substances which in contact with water emit flammable gases according to section 2.12.2.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008 |  |
| Oxidující kapaliny                                    | Test method for oxidising liquids according to section 2.13.2.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008                                           |  |
| Oxidující tuhé látky                                  | Test method for oxidising solids according to section 2.14.2.1. of Annex I, Part 2 of Regulation (EC) No                                                      |  |

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|                        | 1272/2008                                                                                                                                                                  |          |
| Organické peroxidy     | Test methods according to section 2.15.4.1 of Annex I, Part 2 of Regulation (EC) No 1272/2008                                                                              |          |
| Korozivní pro kovy     | Test method for substances corrosive to metals according to section 2.16.2.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008                                           |          |
| Znecitlivělé výbušniny | Test methods according to section 2.17.2.1 (b) and (c) and according to section 2.17.2.2 of Annex I, Part 2 of Regulation (EC) No 1272/2008                                |          |
| Vlastnosti polymerů    | OECD Test Guideline 118: Determination of the Number-Average Molecular Weight and the Molecular Weight Distribution of Polymers using Gel Permeation Chromatography (1996) | A.18     |
|                        | OECD Test Guideline 119: Determination of the Low Molecular Weight Content of a Polymer Using Gel Permeation Chromatography (1996)                                         | A.19     |
|                        | OECD Test Guideline 120: Solution/Extraction Behaviour of Polymers in Water (2000)                                                                                         | (A.20)“; |

tabulka 2 se mění takto:

i) položka „Vážné poškození očí/podráždění očí“ se nahrazuje tímto:

|                                       |                                                                                                                                                                                                                                      |        |
|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| „Vážné poškození očí / podráždění očí | <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) |

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|  | 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)          | (B.69)  |
|  | OECD Test Guideline 492B: Reconstructed Human Cornea-like Epithelium (RHCE) Test Method for Eye Hazard Identification (2022)                                                                                         |         |
|  | 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 (2023) |         |
|  | OECD Test Guideline 467: Defined Approaches for Serious Eye Damage and Eye Irritation (2022)                                                                                                                         |         |
|  | <i>In vivo:</i>                                                                                                                                                                                                      |         |
|  | OECD Test Guideline 405: Acute Eye Irritation/Corrosion (2023)                                                                                                                                                       | (B.5)“; |

ii) v položce „Senzibilizace kůže“ se oddíl „*In vitro*“ nahrazuje tímto:

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| <i>„In vitro:</i>                                                                                                                                                                                                              |        |  |
| OECD Test Guideline 442C: <i>In Chemico</i> Skin Sensitisation Assays addressing the Adverse Outcome Pathway key event on covalent binding to proteins (2023)                                                                  | (B.59) |  |
| OECD Test Guideline 442D: <i>In Vitro</i> Skin Sensitisation Assays Addressing the AOP Key Event on Keratinocyte Activation (2022)                                                                                             | (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 (2023) | (B.71) |  |
| OECD Test Guideline 497: Defined Approaches on Skin Sensitisation (2023)“;                                                                                                                                                     |        |  |

iii) v položce „Mutagenita“ se řádek:

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|  | „OECD Test Guideline 487. <i>In vitro</i> Mammalian Cell Micronucleus Test (2016) | B.49“ |

nahrazuje tímto:

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|  |                                                                                   |          |
|  | „OECD Test Guideline 487. <i>In vitro</i> Mammalian Cell Micronucleus Test (2023) | (B.49)“; |

iv) v položce „Vlastnosti vyvolávající narušení činnosti endokrinního systému“ se řádky:

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|  | „OECD Test Guideline 456: H295R Steroidogenesis Assay (2022)                                                                                                                          | B.57 |
|  | OECD Test Guideline 458: Stably Transfected Human Androgen Receptor Transcriptional Activation Assay for Detection of Androgenic Agonist and Antagonist Activity of Chemicals (2020)“ |      |

nahrazují tímto:

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|  |                                                                                                                                                                                        |        |
|  | „OECD Test Guideline 456: H295R Steroidogenesis Assay (2023)                                                                                                                           | (B.57) |
|  | OECD Test Guideline 458: Stably Transfected Human Androgen Receptor Transcriptional Activation Assay for Detection of Androgenic Agonist and Antagonist Activity of Chemicals (2023)“; |        |

v) v položce „Fototoxická“ se řádek:

|  |                                                                                                                           |  |
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|  | „OECD Test Guideline 498: <i>In Vitro</i> Phototoxicity Test Method Using the Reconstructed Human Epidermis (RhE) (2021)“ |  |
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nahrazuje tímto:

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|  | „OECD Test Guideline 498: <i>In Vitro</i> Phototoxicity Reconstructed Human Epidermis Phototoxicity test method (2023)“; |  |
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vi) za oddíl „Fototoxická“ se doplňuje nová položka, která zní:

|                |                                                                                  |  |
|----------------|----------------------------------------------------------------------------------|--|
| „Imunotoxicita | OECD Test Guideline 444A: <i>In vitro</i> immunotoxicity IL-2 Luc assay (2023)“; |  |
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tabulka 3 se mění takto:

vii) v položce „Rozklad“ se řádek:

|  |                                                                                                 |  |
|--|-------------------------------------------------------------------------------------------------|--|
|  | „OECD Test Guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis (2008)“ |  |
|--|-------------------------------------------------------------------------------------------------|--|

nahrazuje tímto:

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|--|--------------------------------------------------------------------------------------------------|--|
|  | „OECD Test Guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis (2023)“; |  |
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viii) v položce „Účinky na organismy v sedimentu“ se řádky:

|  |                                                                                            |       |
|--|--------------------------------------------------------------------------------------------|-------|
|  | „OECD Test Guideline 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment (2004)“ | C.27  |
|  | OECD Test Guideline 219: Sediment-Water Chironomid Toxicity Using Spiked Water (2004)      | C.28“ |

nahrazují tímto:

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|--|-------------------------------------------------------------------------------------------------|----------|
|  | „OECD Test Guideline 218: Sediment-Water Chironomid Toxicity Test Using Spiked Sediment (2023)“ | (C.27)   |
|  | OECD Test Guideline 219: Sediment-Water Chironomid Toxicity Test Using Spiked Water (2023)      | (C.28)“; |

ix) v položce „Vlastnosti vyvolávající narušení činnosti endokrinního systému“ se řádek:

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|  | „OECD Test Guideline 240: Medaka Extended OneGeneration Reproduction Test (MEOGRT) (2015)“ | C.52“ |
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nahrazuje tímto:

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|--|---------------------------------------------------------------------------------------------|----------|
|  | „OECD Test Guideline 240: Medaka Extended One Generation Reproduction Test (MEOGRT) (2023)“ | (C.52)“. |
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- 2) V části B se text pod nadpisem každé z kapitol B.49 a B.57 nahrazuje tímto: „Úplný popis této zkušební metody byl odstraněn. Rovnocenná mezinárodní zkušební metoda je uvedena v tabulce 2 části 0.“
- 3) V části C se text pod nadpisem každé z kapitol C.27, C.28 a C.52 nahrazuje tímto: „Úplný popis této zkušební metody byl odstraněn. Rovnocenná mezinárodní zkušební metoda je uvedena v tabulce 3 části 0.“