



Council of the
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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	12 March 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

Subject:	ANNEX to the Commission Regulation (EU) .../... of XXX amending Regulation (EC) No 440/2008 as regards the test methods, to adapt them to technical progress
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Delegations will find attached document [...](2023) XXX - D 095103 ANNEX.

Encl.: [...](2023) XXX - D 095103 ANNEX

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ANNEX

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

- (1) Part 0 is amended as follows:
- (a) Table 1 is replaced by the following:

‘TABLE 1: TEST METHODS FOR PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE		
Basic physicochemical properties		
Endpoint	Test method	Corresponding chapter, containing the full description of the test method, in Part A of this Annex (numbers in brackets indicate that the full description of the test method has been deleted from Part A; empty cell: no corresponding test method in Part A of this Annex)
Melting point/freezing point	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)	
Boiling point	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	
Flammability	EN 15188:2020 – Determination of the spontaneous ignition behaviour of dust accumulations	
Lower and upper	Test methods according to section 2.2.4.1. of Annex I, Part 2	

explosion limit	of Regulation (EC) No 1272/2008 (ISO 10156 and EN 1839)	
Flash point	Test methods according to table 2.6.3 of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Auto-ignition temperature (liquids, gases)	ISO/IEC 80079-20-1:2017 – Explosive atmospheres - Part 20-1: Material characteristics for gas and vapour classification - Test methods and data	
Decomposition temperature	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)	
Kinematic Viscosity	OECD Test Guideline 114: Viscosity of Liquids (2012)	
Water solubility	OECD Test Guideline 105: Water Solubility (1995)	A.6.
Partition coefficient n-octanol/water	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.
Vapour pressure	OECD Test Guideline 104: Vapour Pressure (2006)	(A.4)
Density/Relative density	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	
Particle characteristics	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	
	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	
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 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	
Surface tension	OECD Test Guideline 115: Surface Tension of Aqueous Solutions (1995)	A.5.
Dissociation constant	OECD Test Guideline 112: Dissociation Constants in Water. (1981)	A.25.
Hydrophobicity	OECD Test Guideline 126: Determination of the Hydrophobicity Index of Manufactured Nanomaterials Through an Affinity Measurement (2023)	
Physicochemical hazard properties		
Explosives	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
Flammable gases	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	
Oxidising gases	Test method for oxidising gases according to section 2.4.4. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Flammable liquids	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	
Flammable solids	Test method for flammable solids according to section 2.7.2.3. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Self-reactive substances	Test method for self-reactive substances according to section 2.8.4.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Pyrophoric liquids	Test method for pyrophoric liquids according to section 2.9.2.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Pyrophoric solids	Test method for pyrophoric solids according to section 2.10.2.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008,	
Self-heating substances	Test method for self-heating substances according to section 2.11.2.2 of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Substances which in contact with water emit flammable gases	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	
Oxidising liquids	Test method for oxidising liquids according to section 2.13.2.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Oxidising solids	Test method for oxidising solids according to section 2.14.2.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Organic peroxides	Test methods according to section 2.15.4.1 of Annex I, Part 2 of Regulation (EC) No 1272/2008	

Corrosive to metals	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	
Desensitised explosives	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	
Properties of polymers	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.)’;

(b) Table 2 is amended as follows:

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

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

<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) in the entry ‘Mutagenicity’, the row:

	‘OECD Test Guideline 487. <i>In vitro</i> Mammalian Cell Micronucleus Test (2016)	B.49.’

is replaced by the following:

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

- (iv) in the entry ‘Endocrine disrupting properties’, the rows:

	'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)'	

are replaced by the following:

	'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) in the entry 'Phototoxicity', the row:

	'OECD Test Guideline 498: <i>In Vitro</i> Phototoxicity Test Method Using the Reconstructed Human Epidermis (RhE) (2021)'	
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is replaced by the following:

	'OECD Test Guideline 498: <i>In Vitro</i> Phototoxicity Reconstructed Human Epidermis Phototoxicity test method (2023)';	
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(vi) the following entry is inserted after the section 'Phototoxicity',:

'Immunotoxicity	OECD Test Guideline 444A: <i>In vitro</i> immunotoxicity IL-2 Luc assay (2023)';	
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(c) Table 3 is amended as follows:

(i) in the entry 'Degradation', the row:

	'OECD Test Guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis (2008)'	
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is replaced by the following:

	'OECD Test Guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis (2023)';	
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(ii) in the entry 'Effects on sediment organisms', the rows:

	‘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.’

are replaced by the following:

	‘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.)’;

(iii) in the entry ‘Endocrine disrupting properties’, the row:

	‘OECD Test Guideline 240: Medaka Extended OneGeneration Reproduction Test (MEOGRT) (2015)	C.52.’
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is replaced by the following:

	‘OECD Test Guideline 240: Medaka Extended One Generation Reproduction Test (MEOGRT) (2023)	(C.52.)’;
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- (2) in part B, the text below the headings of each of the Chapters B.49. and B.57. 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 C, the text below the headings of each of the Chapters C.27., C.28. and C.52. 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 3.’