

IT
ALLEGATO

L'allegato del regolamento (CE) n. 440/2008 è così modificato:

(1) la parte 0 è così modificata:

(a) la tabella 1 è sostituita dalla seguente:

"TABELLA 1: METODI DI PROVA PER LE PROPRIETÀ FISICO-CHIMICHE DELLA SOSTANZA		
Proprietà chimico-fisiche di base		
Endpoint	Metodo di prova	Capitolo corrispondente, che contiene la descrizione completa del metodo di prova, nella parte A del presente allegato (i riferimenti tra parentesi indicano che un metodo di prova è stato soppresso dalla parte A; casella vuota: nella parte A del presente allegato non figura nessun metodo di prova corrispondente)
Punto di fusione/punto di congelamento	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)	
Punto di ebollizione	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	

Infiammabilità	EN 15188:2020 – Determination of the spontaneous ignition behaviour of dust accumulations	
Limite inferiore e superiore di esplosività	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)	
Punto di infiammabilità	Test methods according to table 2.6.3 of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Temperatura di autoaccensione (liquidi, gas)	ISO/IEC 80079-20-1:2017 – Explosive atmospheres - Part 20-1: Material characteristics for gas and vapour classification - Test methods and data	
Temperatura di decomposizione	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)	
Viscosità cinematica	OECD Test Guideline 114: Viscosity of Liquids (2012)	
Idrosolubilità	OECD Test Guideline 105: Water Solubility (1995)	A.6.
Coefficiente di ripartizione n-ottanolo/acqua	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.
Tensione di vapore	OECD Test Guideline 104: Vapour Pressure (2006)	(A.4)
Densità/densità relativa	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	
Caratteristiche delle	EU test method A.22. Length Weighted Geometric Mean	A.22.

particelle	Diameter of Fibres	
	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	
Polverosità (per le nanoforme di una sostanza)	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	
Tensione superficiale	OECD Test Guideline 115: Surface Tension of Aqueous Solutions (1995)	A.5.
Costante di dissociazione	OECD Test Guideline 112: Dissociation Constants in Water. (1981)	A.25.
Idrofobicità	OECD Test Guideline 126: Determination of the Hydrophobicity Index of Manufactured Nanomaterials Through an Affinity Measurement (2023)	
Proprietà fisico-chimiche pericolose		
Esplosivi	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.
Gas infiammabili	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	
Gas comburenti	Test method for oxidising gases according to section 2.4.4. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Liquidi infiammabili	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	
Solidi infiammabili	Test methods according to section 2.7.2.3. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Sostanze autoreattive	Test methods according to section 2.8.4.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Liquidi piroforici	Test methods according to section 2.9.2.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Solidi piroforici	Test method for pyrophoric solids according to section 2.10.2.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008,	
Sostanze autoriscaldanti	Test method for self-heating substances according to section 2.11.2.2 of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Sostanze che, a contatto con l'acqua, sviluppano gas infiammabili	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	
Liquidi comburenti	Test method for oxidising liquids according to section 2.13.2.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Solidi comburenti	Test methods according to section 2.14.2.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008	

Perossidi organici	Test methods according to section 2.15.4.1. of Annex I, Part 2 of Regulation (EC) No 1272/2008	
Sostanze o miscele corrosive per i metalli	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	
Esplosivi desensibilizzati	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	
Proprietà dei polimeri	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) la tabella 2 è così modificata:

(i) la voce "Lesioni oculari gravi/irritazione oculare" è sostituita dalla seguente:

"Lesioni oculari gravi/irritazione oculare"	<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) alla voce "Sensibilizzazione cutanea", la sezione "*In vitro*" è sostituita dalla seguente:

<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 Skin Sensitisation: In Vitro Skin Sensitisation Assays Addressing the Key Event on Activation of Dendritic Cells on the Adverse Outcome Pathway for Skin Sensitisation</i> (2023)	(B.71.)
OECD Test Guideline 497: Defined Approaches on Skin Sensitisation (2023)";	

(iii) alla voce "Mutagenicità", la riga:

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

è sostituita dalla seguente:

--	--

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

(iv) alla voce "Proprietà di interferenza con il sistema endocrino", le righe:

	"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)"	

sono sostituite dalle seguenti:

	"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) alla voce "Fototossicità", la riga:

	"OECD Test Guideline 498: <i>In Vitro</i> Phototoxicity Test Method Using the Reconstructed Human Epidermis (RhE) (2021)"	
--	---------------------------------------------------------------------------------------------------------------------------	--

è sostituita dalla seguente:

	"OECD Test Guideline 498: <i>In vitro</i> Phototoxicity Reconstructed Human Epidermis Phototoxicity test method (2023)";	
--	--------------------------------------------------------------------------------------------------------------------------	--

(vi) dopo la sezione "Fototossicità" è inserita la voce seguente:

"Immunotossicità	OECD Test Guideline 444 A: <i>In vitro</i> immunotoxicity IL-2 Luc assay (2023)";	
------------------	-----------------------------------------------------------------------------------	--

(c) la tabella 3 è così modificata:

(i) alla voce "Degradazione", la riga:

	"OECD Test Guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis (2008)'	
--	-------------------------------------------------------------------------------------------------	--

è sostituita dalla seguente:

	"OECD Test Guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis (2023)";	
--	--------------------------------------------------------------------------------------------------	--

(ii) alla voce "Effetti sugli organismi presenti nei sedimenti terrestri", le righe:

	"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."

sono sostituite dalle seguenti:

	"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) alla voce "Proprietà di interferenza con il sistema endocrino", la riga:

	"OECD Test Guideline 240: Medaka Extended OneGeneration Reproduction Test (MEOGRT) (2015)	C.52."
--	-------------------------------------------------------------------------------------------	--------

è sostituita dalla seguente:

	"OECD Test Guideline 240: Medaka Extended One Generation Reproduction Test (MEOGRT) (2023)	(C.52.)";
--	--------------------------------------------------------------------------------------------	-----------

- (2) nella parte B, il testo che segue il titolo di ciascuno dei capitoli B.49. e B.57. è sostituito dal seguente: "La descrizione completa del presente metodo di prova è stata soppressa. Il metodo di prova internazionale equivalente figura nella tabella 2 della parte 0.";
- (3) nella parte C, il testo che segue il titolo di ciascuno dei capitoli C.27., C.28. e C.52. è sostituito dal seguente: "La descrizione completa del presente metodo di prova è stata soppressa. Il metodo di prova internazionale equivalente figura nella tabella 3 della parte 0.".