

1 May 2024

## Standard deadlines used in dossier and substance evaluation

The table covers the deadlines of the main studies requested under dossier evaluation and substance evaluation; other studies with their own deadline may still apply.

Annex*	No.	Requirement	Detailed list of requirements	Deadline (months)
VII	7.2 to 7.14	<b>Information on the physicochemical properties of the substance</b>	Melting/freezing point; Boiling point; Relative density; Vapour pressure; Surface tension; Water solubility; Partition coefficient n-octanol/water; Flash-point; Flammability; Explosive properties; Self-ignition temperature; Oxidizing properties; Granulometry	6
	8.1	<b>Skin corrosion/irritation</b>	Skin corrosion/irritation (in vitro test)	6
	8.2	<b>Serious eye damage/eye irritation</b>	Serious eye damage/eye irritation (in vitro test)	6
	8.3	<b>Skin sensitisation</b>	Skin sensitisation (in vivo study);	6
	8.4	<b>Mutagenicity</b>	In vitro gene mutation (bacteria)	6
	8.5	<b>Acute toxicity</b>	Acute oral toxicity	12
	9.1	<b>Aquatic toxicity</b>	Short-term toxicity on invertebrates (Daphnia sp.); Growth inhibition (algae)	6
	9.2	<b>Degradation</b>	Ready biodegradability	6
VIII	8.1	<b>Skin corrosion/irritation</b>	Skin corrosion/irritation (in vivo study)	6
	8.2	<b>Serious eye damage/eye irritation</b>	Serious eye damage/eye irritation (in vivo study)	6
	8.4	<b>Mutagenicity</b>	In vitro cytogenicity (chromosomal aberration or micronucleus) in mammalian cells; In vitro gene mutation (mammalian cells)	12
	8.5	<b>Acute toxicity</b>	Acute inhalation toxicity; Acute dermal toxicity	12
	8.6	<b>Repeated dose toxicity</b>	Short-term repeated dose toxicity (28 day)	12
	8.7	<b>Reproductive toxicity</b>	Screening for reproductive/developmental toxicity	12
	9.1	<b>Aquatic toxicity</b>	Short-term toxicity on fish; Activated sludge respiration inhibition	6
	9.2	<b>Degradation</b>	Hydrolysis as a function of pH	6
	9.3	<b>Fate and behaviour in the environment</b>	Adsorption/desorption screening	6

1 May 2024

<b>Annex*</b>	<b>No.</b>	<b>Requirement</b>	<b>Detailed list of requirements</b>	<b>Deadline (months)</b>
<b>IX</b>	7.1	<b>Information on the physicochemical properties of the substance</b>	Stability in organic solvents and identity of relevant degradation products; Dissociation constant; Viscosity	<b>6</b>
	8.4	<b>Mutagenicity</b>	In vivo mutagenicity (not TGR)	<b>12</b>
			In vivo mutagenicity (TGR); In vivo Micronucleus test combined with in vivo comet assay	<b>18</b>
	8.6	<b>Repeated dose toxicity</b>	Sub-chronic toxicity (90 day)	<b>12</b>
	8.7	<b>Reproductive toxicity</b>	Pre-natal developmental toxicity (rat or rabbit)	<b>18</b>
			Extended One-Generation Reproductive Toxicity Study (EOGRTS)	<b>24</b>
	9.1	<b>Aquatic toxicity</b>	Long-term toxicity on invertebrates (Daphnia sp.); Fish early-life stage (FELS) toxicity;	<b>12</b>
			Further aquatic toxicity (e.g. FSDT)	<b>18</b>
	9.2	<b>Degradation</b>	Simulation testing on ultimate/degradation in surface water; Soil simulation testing; Sediment simulation testing. Generally simulation studies include a request of Identification of degradation products.	<b>18</b>
	9.3	<b>Fate and behaviour in the environment</b>	Bioaccumulation in aquatic species (fish)	<b>12</b>
9.4	<b>Effects on terrestrial organisms</b>	Short-term toxicity to invertebrates; Effects on soil micro-organisms; Short-term toxicity to plants	<b>12</b>	

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<b>Annex*</b>	<b>No.</b>	<b>Requirement</b>	<b>Detailed list of requirements</b>	<b>Deadline (months)</b>
<b>X</b>	8.6	<b>Repeated dose toxicity</b>	Long-term repeated dose toxicity study ( $\geq 12$ months) (chronic)	<b>36</b>
			Long-term repeated dose toxicity study ( $\geq 12$ months) (combined with carcinogenicity)	<b>48</b>
	8.7	<b>Reproductive toxicity</b>	Pre-natal developmental toxicity, rat	<b>12</b>
			Pre-natal developmental toxicity, rabbit	<b>18</b>
			Extended One-Generation Reproductive Toxicity Study	<b>24</b>
	8.9	<b>Carcinogenicity</b>	Carcinogenicity	<b>48</b>
	9.4	<b>Effects on terrestrial organisms</b>	Long-term toxicity testing on invertebrates; Long-term toxicity testing on plants	<b>12</b>
	9.5	<b>Long-term toxicity to sediment organisms</b>	Long-term toxicity to sediment organisms	<b>12</b>

\* Please note that where a study at one Annex is triggered already at a lower Annex, the same deadline applies.