

Toxicology

Annex	No.	Study	Guideline
	8.1	Skin irritation / corrosion	
VII	8.1	Skin irritation / corrosion (<i>in vitro</i>)	OECD 431 OECD 439
VIII	8.1.1	Acute skin irritation / corrosion (<i>in vivo</i>)	OECD 404 EEC B.4
	8.2	Eye irritation / corrosion	
VII	8.2	Eye irritation / corrosion (<i>in vitro</i>)	OECD 437, HETCAM, EpiOcular
VIII	8.2.1	Acute eye irritation / corrosion (<i>in vivo</i>)	OECD 405 EEC B.5
	8.3	Skin sensitization	
VII	8.3	Skin sensitization <ul style="list-style-type: none"> - Local Lymph Node Assay - Magnusson / Kligman - Buehler method 	OECD 429 OECD 406, EEC B.6 OECD 406
	8.4	Mutagenicity	
VII	8.4.1	Bacterial reverse mutation test (Ames-test)	OECD 471 EEC B.13/ 14
VIII	8.4.2	Cytogenetic testing in mammalian cells: Chromosome Aberration Test (<i>in vitro</i>)	OECD 473 EEC B.10
VIII	8.4.2	Micronucleus test (<i>in vitro</i>)	OECD 487 EEC B.10
VIII	8.4.3	Gene mutation test in mammalian cells: Mouse Lymphoma Assay (<i>in vitro</i>)	OECD 476 EEC B.17
IX/X	8.4	<i>In vivo</i> mutagenicity studies	OECD 474, OECD 475, OECD 486
	8.5	Acute toxicity	
VII	8.5.1	Acute oral toxicity <ul style="list-style-type: none"> - Acute Toxic Class Method "ATC" - Fixed dose procedure - Up and down procedure 	OECD 423 OECD 420 OECD 425
VIII	8.5.2	Acute inhalation toxicity	OECD 403
VIII	8.5.3	Acute dermal toxicity	OECD 402, OECD 434 EEC B.3

Annex	No.	Study	Guideline
	8.6	Repeated dose toxicity	
VIII / IX	8.6.1	28-day oral toxicity study	OECD 407 EEC B.7
VIII / IX	8.6.1	28-day dermal toxicity study	OECD 410
VIII / IX	8.6.1	28-day inhalation toxicity study	OECD 412
IX	8.6.2	90-day oral toxicity study	OECD 408 EEC B.26
IX	8.6.2	90-day dermal toxicity study	OECD 411
IX	8.6.2	90-day inhalation toxicity study	OECD 413
X	8.6.3	52-week oral toxicity study	OECD 452
	8.7	Reproductive toxicity	
VIII	8.7.1	Reproductive and developmental toxicity screening study	OECD 421 OPPTS 870.3550
VIII	8.7.1	Combined repeated dose toxicity study with reproductive / developmental toxicity screening study	OECD 422 OPPTS 870.3650
IX / X	8.7.2	Prenatal development toxicity study	OECD 414 OPPTS 870.3700 EV B.31
IX / X	8.7.3	Two generation reproductive toxicity study	OECD 416
	8.8	Toxicokinetic studies	
VIII	8.8.1	Assessment of the toxicokinetic behaviour	OECD 417
	8.9	Carcinogenicity	
X	8.9.1	2-year carcinogenicity study	OECD 451