

ACTIVE INGREDIENT: DOSSIER INDEX

The dossier accompanying the application must provide full details (as applicable) of the information requested in the lists, i.e., details on the methods used, summaries of methods and results used in toxicology and ecotoxicology studies, methods of analyses, etc. Applicants are advised to use CIPAC methods for physical and chemical properties. Numbering used in the dossier must correspond to that used in the application form. If the product contains more than one active ingredient, compile a separate dossier for each active ingredient.

ACTIVE INGREDIENT (a.i.) (Technical Grade)	Annex No. in dossier if study is included	Official use only
1. DESIGNATION		
a. Common name (ISO)		
b. Manufacturer or development code		
c. Chemical name (IUPAC)		
d. Chemical group		
e. Structural formula		
f. Empirical formula		
g. Patent status Is the a.i. under patent? Who is the patent holder? Expiry date		

2. PHYSICAL AND CHEMICAL PROPERTIES (Active ingredient - technical grade)		
a. Physical state		
b. Colour		
c. Odour		
d. Density at 20 °C		
e. Vapour pressure at 20/25 °C		
f. Volatility		
g. Hydrolysis DT ₅₀ .Days .°C .pH		
h. Photolysis		
i. Solubility in water .°C .pH		
j. Solubility in organic solvents		
k. n-octanol/water partition coefficient		
l. Boiling point °C		
m. Melting point °C		
n. Decomposition temperature °C		
o. Method of analysis and impurities		

3. TOXICOLOGY (Active Ingredient - technical grade)		
a. ADI		
b. Acute oral LD ₅₀ mg/kg rat/rabbit		
c. Acute dermal LD ₅₀ mg/kg rat		
d. Inhalation LC ₅₀ mg/ℓ/hour (rat)		
e. Skin irritation (rabbit)		
f. Eye irritation (rabbit)		
g. Sensitization (guinea pig)		
h. Reproduction (specify species)		
i. Subchronic toxicity 90 day NOEL mg/kg/day		
j. Chronic toxicity NOEL mg/kg/day		
k. Carcinogenicity (life time) NOEL mg/kg/day		
l. Neurotoxicity NOEL mg/kg/day		
m. Teratogenicity NOEL mg/kg/day		
n. Mutagenicity/Genotoxicity		
o. Metabolism (rat)		
p. Other studies		

LIST I

ACTIVE INGREDIENT (Technical Grade)		Annex No. in dossier if study is included	Official use only
4. ECOTOXICOLOGY (Active ingredient-technical grade)			
a. Birds (2 species)	LD ₅₀ mg/kg		
	NOEL		
	LD ₅₀ mg/kg		
	NOEL		
	Reproduction		
b. Fish (2 species)	LD ₅₀ mg/kg		
	NOEL		
	LD ₅₀ mg/kg		
	NOEL		
	Reproduction BCF		
c. Daphnia	LC ₅₀ mg/l		
	NOEL		
d. Algae	LC ₅₀ mg/l		
	NOEL		
e. Bees	LD ₅₀ µg/bees		
	NOEL		
f. Earthworms	LC ₅₀ mg/kg		
g. Soil micro-organisms	EC/LC ₅₀ mg/kg		

5. BEHAVIOUR IN ENVIRONMENT (Active ingredient - technical grade)		
Behaviour, ways of degradation, degradation products in soil:		
a. Major metabolites		
b. DT ₅₀ (days)		
c. Mobility		
d. Absorption		
e. Mobility of metabolites		
Behaviour, ways of degradation, degradation products in water:		
f. Major Metabolites		
g. DT ₅₀ (days)		
h. Surface		
i. Ground		

6. MODE OF ACTION		
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7. PLANT RESIDUES		
a. Major metabolites		
b. Metabolism		
c. Behaviour of residues		
d. Crop		
e. MRL Codex		
f. MRL country		
g. PHI & MRL proposed		
h. Method of residue analysis		

8. COUNTRY SPECIFIC REQUIREMENTS		
a.		
b.		
c.		
d.		
e.		
f.		