DATA REQUIRED FOR THE SYTHETIC PESTICIDES

Information on the Active Ingredient

1. IDENTITY

	Title	Data Required	Conditions
1.1	Trade name.	R	
1.2	Manufacturer, country of origin and source.	R	
1.3	Common name: proposed or accepted by ISO.	R	
1.4	Synonyms.	R	
1.5	Chemical name as proposed or accepted by IUPAC or, in its absence, by another internationally recognized organization.	R	
1.6	Empirical formula and molecular weight.	R	
1.7	Structural formula.	R	
1.8	Chemical family.	R	
1.9	Degree of Purity (Concentration of the Active Ingredient).	R	
1.10	Isomers (when applicable).	R	
1.11	Outstanding and non-outstanding impurities at concentrations above 1 g x Kg of technical material.	R	
1.12	Additives (identify when applicable).	R	

2. PHYSICAL AND CHEMICAL PROPERTIES

	Title	Data Required	Conditions
2.1	Appearance	R	
	2.1.1 Physical state	R	
	2.1.2 Color	R	
	2.1.3 Odor	R	
2.2	Melting point in ºC, when applicable	R	
2.3	Boiling point	R	
2.4	Density	R	
2.5	Vapor pressure, at temperatures between 10 and 30ºC, when applicable.	R	
2.6	Ultraviolet, infrared, magnetic resonance spectrums and mass spectrometry.	R	
2.7	Solubility in water at temperatures between 10 and 30ºC, when applicable.	R	
2.8	Solubility of the active ingredient in various solvents, at temperatures between 10 and 30ºC.	R	
2.9	Partition coefficient between n-octanol/water (pH and temperature), if this has been determined.	R	

2.10	Flash point	R	
2.11	Surface tension (when applicable)	CR	When a.i. is a liquid
2.12	Explosive properties	R	
2.13	Oxidation properties	R	
2.14	Reactivity with container material	R	
2.15	Viscosity (when applicable).	CR	When a.i. is a liquid
2.16	pH	R	
2.17	Hydrolysis rate under stated relevant conditions, when applicable.	R	
2.18	Minimum and maximum active ingredient content, expressed in percentages by weight (w/w) or by volume (w/v).	R	
2.19	Other pertinent properties.	R	

3. **USE-RELATED ASPECTS**

	Title	Data Required	Conditions
3.1	Mode of action.	R	
3.2	Biochemical form of action of the active ingredient on pests.	R	

4. **TOXIC EFFECT ON MAMALIAN SPECIES**

	Title	Data Required	Conditions
4.1	Acute toxicity		
4.1.1	Average acute oral toxicity in rats in mg/kg of body weight.	R	
4.1.2	Average acute dermal toxicity in rats and/or rabbits in mg/kg of body weight.	R	
4.1.3	Average acute lethal concentration by inhalation in mg/l or mg/m^3.	R	
4.1.4	Eye irritation (this study shall be omitted when the materials under analysis are corrosive).	R	
4.1.5	Sensitivity	R	
4.2	Subchronic toxicity (13 to 90 days)		
4.2.1	Average subchronic oral toxicity in rats by mg/kg of body weight.	R	
4.2.2	Average subchronic dermal toxicity in rats and/or rabbits in mg/kg of body weight.	R	
4.2.3	Eye irritation (this study shall be omitted when the materials under analysis are corrosive).	R	
4.3	Chronic toxicity in minimum of two species		
4.3.1	Average chronic oral lethal dosage in rats in mg/kg of body weight	R	

1.3.2 Average chronic dermal lethal dosage in rats and/or rabbits in mg/kg of body weight		R	
4.3.3 Admissible daily intake		R	
4.4	Oncogenicity.	R	
4.5	Mutagenicity (*in vivo* and *in vitro*).	R	
4.6	Toxicological compatibility, potentiation, synergism, additive potential (for mixes of active ingredients), when applicable.	CR	For mixes of a.i.s
4.7	Effect on reproduction	R	
	4.7.1 Tertogenecity	R	
	4.7.2 Study on, at least, two mammalian generations.	R	
4.8	Metabolism in mammals.	R	
	4.8.1 Oral and dermal administration studies.	R	
	4.8.1.1 Absorption.	R	
	4.8.1.2 Distribution.	R	
	4.8.1.3 Excretion.	R	
	4.8.2 Explanation of the metabolic routes.	R	
4.9	Mandatory medical information.	R	
	4.9.1 Diagnosis and symptoms of intoxication.	R	
	4.9.2 Proposed treatment.	R	
	4.9.1.1 First aid.	R	
	4.9.1.2 Medical Treatment.	R	
4.10	Additional studies (when applicable)	CR	
	4.10.1 Studies on neurotoxicity (when available)	CR	
	4.10.2 Special justified studies	CR	
4.11	Available complementary medical information		
	4.11.1 Intoxication diagnosis	CR	
	4.11.1.1 Observations in clinical, accidental, and intentional injury cases.	CR	
	4.11.1.2 Observations from epidemiological studies.	CR	
	4.11.1.3 Observations on allergies.	CR	

5. **TOXIC EFFECTS ON OTHER SPECIES**

	Title	Data Required	Conditions
5.1	Effects on birds.	R	
	5.1.1 Acute oral toxicity in pheasants, quail, wild ducks or other validated species.	R	
	5.1.2 Short-term toxicity (8-day study on one species) in pheasant, quail, wild duck or other validated species.	CR	

	5.1.3 Effects on the reproduction of pheasants, quails, wild ducks or other validated species (when applicable).	CR	
	5.1.4 Special studies on domestic animals (when justified).	R	
5.2	Effects on aquatic organisms.		
	5.2.1 Acute toxicity for fish, rainbow trout, carp or other validated species (particularly hot-water species).	R	
	5.2.2 Chronic toxicity in fish, rainbow trout, carp or other validated species (hot-water species)	R	
	5.2.3 Effects on the reproduction and growth rate of fish, rainbow trout, carp and other validated species (hot water) (when applicable).	R	
	5.2.4 Bioaccumulation in fish, rainbow trout, carp, and other validated species (when applicable).	R	
	5.2.5 Acute toxicity in *Daphnia magna*, when applicable.	R	
	5.2.6 Chronic studies on *Daphnia magna*, when applicabl.	R	
	5.2.7 Reproduction rate in *Daphnia magna*, when applicable.	R	
	5.2.8 Growth rate in *Daphnia magna*, when applicable.	R	
	5.2.9 Effect on the growth of *Selenastrum capriconutum* algae or another validated species.	R	
5.3	Effects on organisms other than the control organism.		
	5.3.1 Acute toxicity in bees, oral and by contact.	R	
	5.3.2 Toxicity in beneficial arthropods (example: predators)	R	
	5.3.3 Toxicity in earth worms. *Eisetia foetida* or other validated species.	R	
	5.3.4 Toxicity in soil microorganisms (nitrifiers) (when applicable)	R	
5.4	Other studies (when applicable)	CR	

6. RESIDUES IN TREATED PRODUCTS

	Title	Data Required	Conditions
6.1	Identification of the products of degradation and the reaction of metabolites in plants or treated products.	R	
6.2	Behavior of the residues of the active substance and its metabolites from application to harvest, when relevant. Absorption, distribution or conjugation with the plant ingredients and product dissipation in the environment.	R	
6.3	Data on residues, obtained from controlled tests.	R	
6.4	Maximum residue limits set for recommended crops. When none exist, data on residues obtained from protocolized tests according to international standards (FAO Directives) must be filed.	R	

7. EFFECT ON THE ABIOTIC ENVIRONMENT

	Title	Data Required	Conditions
7.1	Behavior in the soil. Data on 3 types of soil patterns.		
	7.1.1 Degradation: rates and channels (up to 90%), including the identification of:	R	
	7.1.1.1 Intervening processes	R	
	7.1.1.2 Metabolites and the products of degradation	R	
	7.1.1.3 Adsorption and desorption, and the mobility of the active substance and, if relevant, of its metabolites.	R	
	7.1.2 Magnitude and nature of the remaining residues.	R	
7.2	Behavior in water and air.		
	7.2.1 Rates and channels of degradation in the aquatic environment	R	
	7.2.2 Hydrolisis and photolosis (if they are not specified in the physical and chemical properties).	R	

8. INFORMATION ON SAFETY

	Title	Data Required	Conditions
8.1	Procedures for the destruction of active ingredients and for decontamination.	R	
8.2	Possibilities of recovery (if available)	CR	
8.3	Possibilities of neutralization.	R	
8.4	Controlled incineration (conditions).	R	
8.5	Water purification (if available).	R	
8.6	Recommended methods and precautions for handling during handling, storage, transportation and in the case of fire.	R	
8.7	In the case of fire, products of reaction and combustion gases.	R	
8.8	Information on personal protective equipment.	R	
8.9	Hazards and precautions for technical grade products.	R	
8.10	Hazards for humans handling the product, indicating the following:	R	
	a. Body organs and systems that are affected.	R	
	b. Symptoms of acute intoxication by skin, eyes, inhalation.	R	
	c. Routes of product absorption.	R	
8.11	Emergency and first aid procedures in the case of acute intoxication through ingestion, contact or inhalation.	R	
8.12	Information on specific antidotes.	R	
8.13	Information on storage conditions.	R	
8.14	Indication of the type of suitable clothing that should be used for protection during transportation and storage.	R	

9. ANALYTICAL METHODS

	Title	Data Required	Conditions
9.1	Analytical method used to determine the purity of the active substance (active technical ingredient).	R	
9.2	Analytical methods and standards used to determine the products of degradation, isomers, impurities (with toxicological and ecotoxicological importance).	R	
9.3	Analytical method used to determine residues in treated plants, farm products, processed foods, soil and water. The rate of recovery and limits of sensibility to the method will be included.	R	
9.4	Analytical methods for the air, animal or human tissues and fluids (when available).	CR	
9.5	Analytical standards for the pure active ingredient (when asked for by authorities).	CR	
9.6	Method of confinement:		
	9.6.1 The destruction of remnants of unused technical materials.	R	
	9.6.2 The disposal of unusable containers	R	
	9.6.3 Handling and disposal of technical material spills.	R	
	9.6.4 Decontamination and the final destination of used containers.	R	

For formulated products, the following additional information is to be attached to the application for registration, with its respective references (five copies in English):

1. GENERAL DESCRIPTION

	Title	Data Required	Conditions
1.1	Name and address of the formulator.	R	
1.2	Trade name.	R	
1.3	Name of the active ingredient and quality specifications.	R	
1.4	Intended use (example: herbicide, insecticide)	R	
1.5	Type of formulation (example: wettable powder, emulsifiable concentrate)	R	

2. COMPOSITION

	Title	Data Required	Conditions
2.1	Analytical Certificate of Composition	R	
2.2	Nature of the other components in the formulation.	R	

3. PHYSICAL AND CHEMICAL PROPERTIES

	Title	Data Required	Conditions
3.1	Appearance:		
	3.1.1 Physical condition.	R	
	3.1.2 Color	R	
3.2	Stability during storage (regarding composition and the physical properties related to use).	R	
3.3	Relative density.	R	
3.4	Inflammability:	R	
	3.4.1 For liquids, flash point.	CR	For liquids only
	3.4.2 For solids, declare whether or not the product is inflammable	CR	For solids only
3.5	pH	R	
3.6	Explosivity	R	

4. PHYSICAL PROPERTIES OF THE FORMULATED PRODUCT RELATED TO THEIR USE

	Title	Data Required	Conditions
4.1	Moisture content (for dispersable powders).	CR	Dependent on the formulation
4.2	Foaming persistence (for formulations applied in water).	CR	Dependent on the formulation
4.3	Suspension capabilities of dispersable powders, concentrates in suspension, dispersable and encapsulated granules.	CR	Dependent on the formulation
4.4	Wet granular analysis (for dispersable powders and concentrates in suspension).	CR	Dependent on the formulation
4.5	Dry granular analysis. Percentage of disintegration of powders in granules and powders.	CR	Dependent on the formulation
4.6	Stability of the emulsion (in emulsifiable concentrates).	CR	Dependent on the formulation
4.7	Corrosiveness.	R	
4.8	Incompatibility with other products (Example: crop protection products and fertilizer incompatibility)	R	
4.9	Density at 20°C in g/ml (for liquid formulations).	R	
4.10	Flash point (oils and solutions).	CR	Dependent on the formulation

4.11	Viscosity (for suspensions and emulsions).	CR	Dependent on the formulation
4.12	Sulfonation index (oils).	CR	Dependent on the formulation
4.13	Disperson (for dispersable granules).	CR	Dependent on the formulation
4.14	Gas emissions (for granules that generate gas).	CR	Dependent on the formulation
4.15	Looseness or fluidity (for dry powders).	CR	Dependent on the formulation
4.16	Iodine and saponification indexes (for mineral oils).	CR	Dependent on the formulation
4.17	Any other property related to use according to the type of formulation.	CR	Dependent on the formulation

5. INFORMATION ON THE APPLICATION OF THE FORMULATED PRODUCT

	Title	Data Required	Conditions
5.1	Application conditions.	R	
5.2	Pests that are controlled.	R	
5.3	Conditions under which the product can be used	R	
5.4	Dosage	R	
5.5	Number and timing of applications	R	
5.6	Application methods	R	
5.7	Instructions for use.	R	
5.8	Re-entry interval into treated area (when applicable).	R	
5.9	Pre-harvest intervals.	R	
5.10	Effects on succesive crops.	R	
5.11	Phytotoxicity and compatibility.	R	
5.12	Proposed and approved uses in other countries, especially from the region of Central America.	R	
5.13	Trial reports on biological efficacy (if carried out locally, use standard protocols for efficacy trials).	R	
5.14	Resistance (information on the development of resistance and monitoring strategies), when available.	R	

6. PROPOSED LABELLING AND PACKAGING FOR THE FORMULATED PRODUCT

	Title	Data Required	Conditions
6.1	Proposed harmonized label and pamphlet as per harmonized regional guidelines.		
6.2	Containers		
	6.2.1 Type.	R	
	6.2.2 Materials.	R	
	6.2.3 Capacity.	R	
	6.2.4 Resistance.	R	
6.3	Packaging.		
	6.3.1 Type.	R	
	6.3.2 Materials.	R	
	6.3.3 Capacity.	R	
	6.3.4 Resistance.	R	
6.4	Action of the product on container materials.	R	
6.5	Decontamination and container handling procedures (triple rinsing and other techniques according to local current laws) .	R	

7. DATA ON FORMULATED PRODUCT REMNANT MANAGEMENT

	Title	Data Required	Conditions
7.1	Procedures for the destruction of active substances and for decontamination.	R	
7.2	Recovery possibilities (if available).	CR	
7.3	Neutralization possibilities.	R	
7.4	Controlled incineration (conditions).	R	
7.5	Water purification (if available).	CR	
7.6	Recommended methods and precautions during handling, storage, transportation and in the case of fire.	R	
7.7	In case of fire, reactive products and combustion gases.	R	
7.8	Information on personal protective equipment.	R	
7.9	Application equipment cleaning procedures.	R	

8. TOXICOLOGICAL DATA ON THE FORMULATED PRODUCT

	Title	Data Required	Conditions
8.1	Acute toxicity in mammals.		
	8.1.1 Average acute oral toxicity in rats in mg/Kg of body weight.	R	
	8.1.2 Average acute dermal toxicity in rats and rabbits in mg/Kg of body weight.	R	

8.1.3 Average acute lethal concentration by inhalation in mg/l or mg/m3.		R	
8.1.4 Eye irritation (this study shall be omitted when the materials being evaluated are corrosive)		R	
8.1.5 Skin sensitivity.		R	
8.2	R		
8.2.1 Diagnosis and symptoms of intoxication.		R	
8.3	Available complementary medical information.		
8.3.1 Information on clinical, accidental and intentional cases (when available).		CR	

9. DATA ON THE EFFECTS OF THE FORMULATED PRODUCT ON THE ENVIRONMENT

	Title	Data Required	Conditions
9.1	Toxic effects on non-mammalian species (when required).	R	
9.2	Toxic effects on mammalian species: other than those indicated in point 8 (when required).	R	
9.3	Effects on the environment (when required).	R	

10. ADDITIONAL INFORMATION ON OTHER COMPONENT SUBSTANCES OF THE FORMULATION, IN CASES WHERE THEY ARE OF TOXICOLOGICAL IMPORTANCE.

	Title	Data Required	Conditions
10.1	Information regarding solvents, emulsifiers, adhesives, stabilizers, colorants and any other substance included in the formulation of toxicological and ecotoxicological importance.		
10.1.1 Acute toxicity (oral, dermal, inhalation) (when applicable)		R	
10.1.2 Oncogenesis (when applicable)		R	
10.1.3 Biodegradability (when applicable)		R	
10.1.4 Partition coefficient.		R	