DATA REQUIREMENTS FOR PLANT GROWTH REGULATORS IN AGRICULTURE USE

1. Technical Requirements

1. Active Ingredient	
a. Identity and composition	
i. Commercial name	
ii. Chemical name; based on IUPAC nomenclature; CAS nomenclature may be used in the absence of the former. If none of the above exists, then the most recent nomenclature shall be used;	
iii. Common name proposed or accepted by ISO and its synonyms	
iv. Structural formula	
v. Condensed formula	
vi. Chromatogram or atomic absorption spectrum (as may apply);	
vii. Minimum and maximum content of active ingredient; expressed in mass/mass percentage and its equivalent in g/L or g/Kg	
viii. Identity and number of isomers, impurities and other by-products expressed in mass/mass percentage (as may apply)	
b. Physical and chemical properties	
i. Molecular weight	
ii. Physical state	
iii. Colour	
iv. Odour	
v. pH	
vi. point of fusion	
vii. boiling point	
viii. point of decomposition	
ix. vapour pressure (20-250C)	
x. partition coefficient n-octanol/water	
xi. Density; in the case of liquids	
xii. Specific weight; in the case of solids	
xiii. Flammability	
xiv. Explosivity	
xv. Reactivity	
xvi. Oxidizing and corrosive properties	

2. Formulated Product

c. Identity and Composition	
i. Type of formulation	
ii. Minimum and maximum content of active ingredient; expressed in mass/mass percentage and its equivalent in g/L or g/Kg; chemical	

name; based on IUPAC nomenclature; CAS nomenclature may be used in the absence of the former; common name	
iii. Inert ingredients: chemical name; based on IUPAC nomenclature; CAS nomenclature may be used in the absence of the former; common name and percentile content, as well as its functions	
iv. Density for liquids and specific weight for solids	
d. Physical properties related to its use:	
i. Moisture content; for powders and granules	
ii. Humectability; for wettable powders	
iii. Persistence of froth; for formulae applied with water	
iv. Suspensibility; for wettable powders and suspended concentrates	
v. Moist granulometric analysis; for wettable powders and suspended concentrates	
vi. Dry granulometric analysis and average particle size in microns; for granules and powders	
vii. Stability of the emulsion and re-dispersion properties; for emulsifiable concentrates	
viii. Incompatibility with other products	
ix. Stability tests to determine the useful life, in weeks, of the product, with analysis of physical characteristics and the percentile content of the active ingredient before and after the test	
e. Other	
i. Description of container used	
ii. Analytical methods for quality control of the formulated product	
iii. Crop, dos, frequency, time and method of application	
iv. Procedure for the decontamination or destruction of the product or its container	
v. Procedure for the cleansing of application equipment	
vi. Phytotoxicity, as may apply	
vii. Methods and precautions recommended in relation to its handling, storage and transportation	
viii. Biological efficacy tests	
ix. Analytical methods for the determination of the active ingredient	
2. Toxicity	
a. Primary toxicological data (phase 1)	
1. Toxicological studies for active ingredient and formulated product	
i. Acute oral toxicity	
ii. Acute dermal toxicity	
iii. Acute respiratory toxicity	
iv. Primary dermal irritation	
v. Primary eye irritation	
2. The complementary conditional compulsory (CC) tests shall not be necessary (Phase 2): if phase 1 testing of the active ingredient and/or formulated indicate limited effect and no further testing will be necessary.	

b. Toxicological data (CC) phase 2	
1. Short term toxicity of active ingredient and formulated product; compulsory with conditions (CC) Phase 2 as may apply: these complementary toxicological tests shall become necessary when Phase 1 testing of the active ingredient and the formulated product indicated persistent toxicity. One or more toxicological tests may be required in Phase 2.	
i. Cumulative oral toxicity (28-day testing);	
ii. Oral administration on two species; one rodent (preferably mice), one non-rodent; normally 90-day testing	
2. Chronic toxicity of the active ingredient and the formulated product; conditional compulsory (CC) Phase 2 as may apply: these complementary toxicological tests shall become necessary when Phase 1 testing of the active ingredient and the formulated product indicates persistent toxicity. One or more toxicological tests may be required in Phase 2.	
i. Chronic toxicity (as may apply)	
a. Long term toxicity and carcinogenicity (mice and other mammalian species); other pathways as may apply	
b. Mutagenicity: test to assess for genetic mutations, chromosomal aberrations and DNA alterations	
ii. Toxicity and reproduction (as may apply)	
c. Teratogenicity testing: rabbit and one non-rodent species; oral and dermal as may apply	
d. Testing of several generations of mammals (at least two generations)	
iii. Metabolic testing in mammals (as may apply)	
e. Absorption, distribution and excretion tests following oral and dermal exposure	
f. Explanation of metabolic pathways	
iv. Neurotoxicity testing (as may apply)	
g. Delayed neurotoxicity testing on adult hens as may apply	
v. Additional testing (as may apply)	
h. Toxic effects of metabolites from treated plants when said effects are different from those identified during testing with animals	
i. Immunotoxicity, e.g., allergenic properties	
3. Other requirements	
1. Medical data	
i. Medical history of personnel engaged in manufacturing facility	
ii. Sanitary inspection records of the facility; from the pesticide industry as well as from agriculture	
iii. Diagnosis of intoxication, specific symptoms of intoxication, clinical tests as may apply	
iv. Observations of sensitization and allergenic properties, if prudent	

v. Proposed treatment: first aid actions, antidotes, medical treatment where applicable	
vi. Summary of toxicology on mammals and conclusions.	
2. Residue data when product is applied	
i. Evaluation and summary of the fate of residues	
ii. Information relevant to its presence in the food chain	
iii. Analytical methods and tolerance limits if applicable	
3. Ecotoxity data	
i. Oral toxicity in birds	
ii. Toxicity in fresh water and marine fish	
iii. Toxicity in earthworms	
iv. Toxicity in freshwater invertebrates (Daphnia spp.)	
v. Testing with non-target insects	
vi. Testing with non-target plants	
vii. Toxicity in bees	