

Annex 9 to the Ministerial Decree 89/2004. (V. 15.) FVM

Requirements for the data to be submitted for the authorization of products, safeners, synergists, co-formulants, adjuvants, equipment and materials used for plant protection purposes and macro-organisms of plant protection effect not qualified as plant protection products

PART A

Requirements for the data to be submitted for the authorization of products, safeners, synergists, co-formulants, adjuvants of plant protection effect not qualified as plant protection products

1. *General data concerning the product*
 - 1.1 Applicant (name, address, etc.)
 - 1.2 Manufacturer of the formulation and the active substance(s) (name, address, etc. including premises)
 - 1.3 Trade name or proposed trade name, and manufacturer's development code number for the formulation, if appropriate
 - 1.4 Detailed qualitative information on the composition of the formulation (active substance(s). impurities, additives, inert components, etc.); active substance content with tolerance level (in g/kg or g/l)
 - 1.5 Physical state and nature of the formulation (emulsifiable concentrate, wettable powder, solution, etc.)
 - 1.6 Function
2. *Physical, chemical and technical properties of the formulation*
 - 2.1 Appearance (colour and odour)
 - 2.2 Risk of explosion and oxidizing properties
 - 2.3 Flash point and other indications of flammability or spontaneous ignition
 - 2.4 Acidic/alkaline chemical reaction and pH value (1% concentration in water)
 - 2.5 Viscosity, surface tension
 - 2.6 Relative density
 - 2.7 Corrosiveness
 - 2.8 Storage stability - stability and shelf-life; effects of light, temperature and humidity on technical characteristics of the plant protection product
 - 2.8.1 for solid formulations: at high temperature
 - 2.8.2 for liquid formulations: at low temperature, at high temperature

Data on physical and chemical properties necessary for authorization shall be submitted in agreement with the competent authority.

 - 2.9. Physical and chemical compatibility with other products the authorisation for use of which is proposed
 - 2.10 Wetting, adherence and distribution on target plants
3. *Data on application*
 - 3.1 Field of use (e.g. field, glasshouse, food and feed storage, home garden)
 - 3.2 Effects on pests

- 3.3 Details of intended use (e.g. types of harmful organisms to be controlled and/or plants or plant products to be protected)
- 3.4 If necessary, in the light of the test results, any specific agricultural, phytosanitary and/or environmental criteria which are conditions or obstacle to the use of the formulation
- 3.5 Application rate
- 3.6 Concentration of active substance in material used (e.g. in the diluted spray, bait or on the treated seed)
- 3.7 Method of application
- 3.8 Number and timing of applications and duration of protection
- 3.9 Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops
- 3.10 Proposed instructions for use

4. *Further information on the product*

- 4.1 Packaging (type, materials, size, etc.)
- 4.2 Procedures for cleaning application equipment
- 4.3 Waiting periods (re-entry time, pre-harvest interval), or other precautionary measures to protect humans and animals
- 4.4 Recommended methods and precautions concerning handling, storage, transport or fire
- 4.5 Emergency measures in case of accident
- 4.6 Identity of combustion products relevant to cases of fire
- 4.7 Procedures for destruction or decontamination of the plant protection product and the packing
 - 4.7.1 Possibility of destruction
 - 4.7.2 Controlled discharge
 - 4.7.3 Controlled incineration
 - 4.7.4 Water purification
 - 4.7.5 Others

5. *Analytical methods*

- 5.1. Validated analytical method(s) for testing active substance(s)
- 5.2. Analytical method(s) including recovery rates and the limits of determinations for pesticide residues

6. *Efficacy data*

- 6.1 Results of field trials
- 6.2 Phytotoxicity to treated plants (including different crops), or to treated plant products
- 6.3 Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or treated plant parts used for propagating purposes (e.g. seeds, twigs, cuttings)
- 6.4 Summary and evaluation of data under points 6.1 to 6.3

7. *Toxicological data*

- 7.1 Acute toxicity
 - 7.1.1 Oral

- 7.1.2 Dermal
- 7.1.3 Inhalation
- 7.1.4 Skin and eye irritation
- 7.1.5 Skin sensitisation
- 7.1.6 Where appropriate, acute dermal toxicity, skin and eye irritation for combinations of plant protection products for which authorization for use is sought in such combinations
- 7.2. Available toxicological data relating to additives and co-formulants
- 8. *Residues in or on treated plants, plant products, food and feed*
 - 8.1. Metabolism, distribution and expression of residues in plants or livestock
 - 8.2. Residue analytical studies, if relevant
- 9. *Ecotoxicological studies*
 - 9.1 Toxicity to aquatic organisms
 - 9.1.1. Acute toxicity to rainbow trout or zebrafish
 - 9.1.2. Acute toxicity to *Daphnia magna*
 - 9.1.3. Growth inhibition to algae
 - 9.1.4. Other aquatic toxicity studies
 - 9.2 Toxicity to terrestrial organisms
 - 9.2.1. Acute oral and contact toxicity to honey-bees
 - 9.2.2. Toxicity data concerning other terrestrial organisms, review of literature
 - 9.3 Data on the environmental fate and behaviour of the active substance
 - 9.4 Risk assessment
- 10. *Further information*
 - 10.1 Information on authorization in other countries
 - 10.2 Information on established maximum residue levels (MLR) in other countries
 - 10.3 Proposals including justification for the classification and labelling
 - Hazard symbol(s)
 - Indications to hazard
 - Risk (R) phrases
 - Safety (S) phrases
 - 10.4 Proposals for risk and safety phrases
 - 10.5 Specimens of proposed packaging
 - 10.6 Safety data sheet of the product

PART B

Requirements for the data to be submitted for the authorization of equipment used for plant protection purposes

- 1. *Identity of the equipment used for plant protection purposes*
 - 1.1 Applicant (name, address, etc.)
 - 1.2 Manufacturer of the equipment and the active substance(s) (name, address, etc. including premises)

- 1.3 Trade name or proposed trade name
- 1.4 Function (attractant, repellent, etc.)
- 2. *Data on application*
 - 2.1 Field of use (e.g. field, glasshouse, food and feed storage, home garden)
 - 2.2 If necessary, in the light of the test results, any specific agricultural, phytosanitary and/or environmental criteria which are conditions or obstacle to the use of the formulation
 - 2.3 Materials used for the operation of the equipment
 - 2.4 Method of application
 - 2.5 Proposed instructions for use
 - 2.6 Qualification referring to use
 - 2.2 Detailed technical description of the equipment used for plant protection purposes

PART C

Requirements for the data to be submitted for the authorization of formulations containing macro-organisms

- 1. *General data on the formulation containing macro-organisms*
 - 1.1. Trade name of the product
 - 1.2. Use category
 - 1.3. Concentration of the macro-organisms
 - 1.4. Formulation
 - 1.5. Name, address, premises, etc. of the manufacturer of the macro-organism and the formulations
 - 1.6. Name and address of the distributor
 - 1.7. Data of the packaging unit
 - 1.7.1. filling weight and volume
 - 1.7.2. sizes
 - 1.7.3. materials used for packaging
 - 1.7.4. mode of sealing
 - 1.7.5. test results certifying reliability of packaging
 - 1.8. Risk category used in international transport
 - 1.9. Mode of storage
 - 1.10. Shelf-life
 - 1.11. If the formulation is patent protected in Hungary, date of patent registration
- 2. *Biological properties*
 - 2.1. Scientific (Latin and Hungarian) names, indicating the strain, of the macro-organism
 - 2.2. Mode of the identification and description of the macro-organism (morphology)
 - 2.3. Origin and natural occurrence of the macro-organism (geographical region, host, etc.)
 - 2.3. Range of hosts and prays
 - 2.4. Code/strain number
 - 2.5. Mode of mass reproduction of the macro-organism (natural collection, availability of mass culturing)
 - 2.6. Geographical distribution of the macro-organism

- 2.7. Mode of spreading of the released macro-organism
- 2.8. Biological description of life cycle and host specificity
- 2.9. Natural enemies (hyperpredator, hyperparasite)
- 2.10. Function of the macro-organism
- 2.11. Its role in spreading other pests
- 2.12. Composition of co-formulant
- 2.13. Moisture content
- 2.14. Cold and heat resistance/tolerance
- 2.15. Packing unit
- 2.16. Light tolerance
- 2.17. Storage stability (temperature, humidity, duration)
- 2.18. Other indication of fire safety, as stated on the packaging
- 2.19. Short description of the production
- 2.20. Description of quality control

3. *Biological activity of the product containing the macro-organism*
 - 3.1. Mode of action
 - 3.2. Mode of biological activity
 - 3.3. Duration of the biological control effect of the macro-organism
 - 3.4. Biological efficiency on the target organism
 - 3.5. Optimal environmental conditions of the biological effect, developmental stage of the host animal
 - 3.6. Data on resistance and tolerance (climatic and other environmental parameters, etc.)
 - 3.7. Recommendation for use
 - 3.7.1. mode of use (mode and place of application, light sensitivity, pesticide sensitivity)
 - 3.7.2. field of use envisaged (greenhouse, field, indoor, etc.)
 - 3.7.3. crop (e.g. tomatoes, etc)
 - 3.7.4. target pest(s)
 - 3.7.5. dose (area m² or plant)
 - 3.7.6. number of releases on the treated area
 - 3.7.7. date of treatment, number of replicates
 - 3.7.8. efficacy guaranteed by the distributor
 - 3.7.9. suitability for using in integrated production
 - 3.8. Mode and parameters of application
 - 3.9. Proposal for combined use with other macro-organisms
 - 3.10. Waste management and decontamination of packaging

4. *Toxicological data of the macro-organisms concerning pesticides and other chemicals and micro-organisms to (IOBC risk scale 1-4)*

5. *Environmental data of the macro-organism*
 - 5.1. Effects on human and animal health
 - 5.1.1. Irritation (skin, eye)
 - 5.1.2. Toxicity
 - 5.1.3. Allergenic effect
 - 5.1.4. Infectiveness
 - 5.1.5. Carcinogenicity
 - 5.1.6. Teratogenicity

- 5.1.7. Food contamination
 - 5.2. Effects on non-target organisms
 - 5.2.1. Mobility, spreading capacity of the macro-organism
 - 5.2.2. Effects on vertebrates
 - 5.1.2.1. Warm-blooded animals
 - 5.1.2.2. Cold-blooded animals
 - 5.2.3. Effects on invertebrates
 - 5.2.3.1. Arthropods (predators, parasitoids, pollinating insects and other species)
 - 5.2.3.2. Other invertebrates (earthworms, etc.)
 - 5.2.4. Effects on plants
 - 5.2.5. Effects on micro-organisms
 - 5.3. Other environmental effects
 - 5.3.1. Migration capacity of the macro-organism
 - 5.3.1.1. temporary
 - 5.3.1.2. permanent
 - 5.3.2. Effects on the balance of ecosystem
 - 5.3.2.1. temporary
 - 5.3.2.2. permanent
 - 5.4. Effects on groundwater
 - 5.5. Effects on soil fauna
 - 5.6. Capacity of the macro-organism to transfer genetic material
6. *Food-hygienic aspects of the use of products containing macro-organisms*
- 6.1. Occurrence of macro-organisms and their non-viable residues on the crop at harvest
7. *Other information*
- 7.1. Information on the authorization and eventual restrictions of the product in other countries
 - 7.2. Other proposals, data
8. *Annexes required*
- 8.1. Draft label, in case of small packing unit, draft label for the small packaging
 - 8.2. Proposal for test methods of official quality controls (quantitative: population number, body size, etc.; methods for quality evaluation: viability, release rate, mobility, fecundity, longevity, activity, etc.)
 - 8.3. References and publications
 - 8.4. Certificate for dispatching the samples necessary for authorization.