**APPLICATION FOR AUTHORISATION OF A PLANT PROTECTION PRODUCT IN ACCORDANCE WITH ARTICLE 53**

**Product details**

|  |  |
| --- | --- |
| **Field/item** | **Information to be provided** |
| Formulation type | *Formulation type* |
| Function | *Function or action of the product* |
| Substances | *Active Substance, Safener or Synergist* |

**Classification and Labelling**

|  |  |
| --- | --- |
| **Field/item** | **Information to be provided** |
| Classification | *Classification(s) that apply to the product in accordance with Regulation (EC) No 1272/2008* |
| GHS pictograms | *Relevant pictorial required based on the*  *classification to communicate information on the hazard(s) concerned taking into account Articles 19 and*  *26 of Regulation (EC) No 1272/2008 and ECHA “Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/200812”.* |
| Signal | *Relevant signal word indicating the relative level of severity for hazards of the product in accordance with Article 20 of Regulation (EC) No 1272/2008 and ECHA “Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008”* |
| Hazard statement | *Relevant hazard statements to describe the nature and severity of hazards for the product., taking into account Regulation (EC) 1272/2008, in particular Articles 21 and 27 and ECHA “Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008”* |
| Precautionary statement | *Relevant precautionary statements which provide advice on measures to prevent or minimise adverse effects to human or the environment arising from that hazards of the product, taking into account Regulation (EC) 1272/2008, in particular Articles 22 and 28 and ECHA “Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008”* |

**GAP Table**

|  |  |
| --- | --- |
| **Field/item** | **Information to be provided** |
| Type of use | *Indicate whether the use is major or minor.* |
| Crops | *Crop or situation for which the product is used. The codes for crops are taken from the EPPO Database.* |
| Growing Crops | *Identify whether the crop is grown in open field or in*  *greenhouses or whether the product is used indoors (e.g. in storage facilities)* |
| Pests / Harmful organisms | *Pests (or purpose) for which the product is used. The codes for pests are taken from the EPPO database.* |
| Method / Kind | *Application method detailing how the plant protection product is applied (spraying, soil sterilisation, etc)* |
| Timing / Growth stage of crop  and season | *BBCH growth stage ranges in which application is intended.* |
| Maximum number per use | *Maximum number of applications per growing*  *season/cycle used for the named crop/pest combination intended under practical conditions of use. It should be indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.* |
| Maximum number per crop /  season | *Maximum number of uses in the crop including applications on all pests/targets on the same crop.* |
| Minimum interval between  applications | *Minimum interval (in days) between applications of the same product* |
| Maximum application rate per  product | *Maximum rate of application of the product per application/treatment* |
| Maximum total rate per product  per crop/season | *Maximum rate of application of the product per*  *growing season or per crop cycle* |
| Maximum application rate per  active substance | *Maximum amount of active substance applied per treatment.* |
| Maximum total rate per active  substance per crop/season | *Maximum amount of active substance applied per crop/season.* |
| Minimum water volume | *Numeric value in l/ha* |
| Maximum water volume | *Numeric value in l/ha* |
| Whether or not the water volume  is dependent upon the development stage of crop | *Water volume range depends on the development stage of the crop (i.e. low volume – early crops stage, high volume – late crop stage)* |
| PHI (days) | *Minimum pre-harvest interval.*  *For some crop situations a specific PHI may not be relevant. If so an explanation (e.g. the PHI is covered by the time remaining between application and harvest.)*  *should be given.* |
| Seed treatment | *Seed density in kg/ha.* |
| Remarks | *Any key information to further explain the use of*  *the product e.g. details of growing cycles, restrictions, mandatory tank mixes.* |

**Consumer safety and justification**

|  |  |  |
| --- | --- | --- |
| **Field/item** | | **Information to be provided** |
| **Consumer safety** | | |
| Compliance with the MRL:  reference to products | | *Compliance with the maximum residue level (MRL) in*  *place for each crop defined in the GAP table taking into account the active substances in the PPP should be confirmed.* |
| Value of tMRL if needed, | | *Indicate the necessary tMRL that is required, if relevant.*  *Include information on the measures taken in order to confine the commodities resulting from the treated crop to the territory of the Member State in which the application is submitted pending the possible setting of a tMRL at EU level. (PRIMo EFSA calculations to be included).* |
| Validated analytical method | | *Provide details of the availability of the method for*  *monitoring of residues in plants and plant products, in case a tMRL is established.* |
| Measures taken to ensure consumer safety | | *Include a description of measures taken to ensure*  *consumer protection.*  *It should be indicated if the active substance(s) contained in the plant protection product being authorised is listed in Annex IV to Regulation (EC) No*  *396/2005 (i.e. no MRLs are required), or would be expected to be listed in that Annex.* |
| **Justification** | | |
| Type of danger to plant production or ecosystem. | *Provide reasoning for what category the 120-day*  *authorisation is given: quarantine pest; emergent pest, either invading non-native, or native; emerging resistance in a pest, etc. Whereas reference to the EU plant health regime may suffice for quarantine pests, more elaborate reasoning should be provided for the category 'any harmful pest'.* | |
| Size and effect of danger | *Describe the area affected (or predicted to be affected),*  *the development over time of the infestation, and the agronomic and economic effects it has or is predicted to have. Indicate the magnitude and the type of danger that*  *the pest poses to the particular crop/use, and the likely*  *duration for the danger.*  *Indication of potential impacts should be provided e.g. impacts on the ecosystem, potential loss in yield and quality, financial consequences, socio-economic consequences, particularly in case of repetition of an application for emergency authorisation.*  *It may be indicated if the plant protection need (crop/pest combinations) has been declared by Member States and is listed in the European Minor Uses database EUMUDA ([www.eumuda.eu).](http://www.eumuda.eu/)* | |
| Absence of any other reasonable means | *Describe the alternative control measures (chemical,*  *non-chemical, including biological control and cultural methods) that have been considered and indicate why they do not (by themselves or in combination) suffice or why non-control would cause an unacceptable damage to plant production or ecosystems. Describe which, if any, alternative methods and/or authorisations of plant protection products for the pest to be controlled exist in other Member States.*  *The protocols developed by EFSA for the purposes of evaluating whether the conditions under Article 4.7 of Regulation 1107/2009 are met may be taken into account to enable a consideration of suitable alternatives to the substance being considered for emergency authorisation.*  Fungicides:  <https://www.efsa.europa.eu/en/supporting/pub/en-1345>  Herbicides:  <https://www.efsa.europa.eu/de/supporting/pub/en-1060>  Insecticide:  <http://www.efsa.europa.eu/de/supporting/pub/en-1201> | |
| Rationale | *Provide the rationale based on the available information*  *to justify the emergency authorisation.*  *A description of the consequence if authorisation is not given (e.g. crop losses, costs, environmental risks) should be considered.*  *Describe what measures are taken to limit and control use.* | |
| Mitigation measures | *Describe the mitigation measures necessary for*  *minimising risk to humans, animals, and the environment.*  *Details of how the supply of the product(s) and the use will be limited should be provided, where applicable.* | |
| Applications in progress | *The use notified may have been applied for already, or a*  *suitable alternative PPP may be in the process of authorisation under a regular procedure. Describe such applications, including the date the application was submitted, or if known the anticipated date of a decision.*  *In case of applications for emergency authorisations that are in fact extensions of already authorised uses of products containing approved substances, reference to an ongoing Article 51 (minor use) or Article 33 (other uses) or Article 40 (mutual recognition) procedure should be given, where applicable.* | |
| Research activities | *Describe the research efforts undertaken and/or in*  *progress to find alternative solutions, their aims, their funding, and their expected date of results. This is needed for all categories of dangers, except quarantine pests that can still be eliminated, or infrequent pests, for which no application for a regular authorisation or extension of use of the plant protection product exists.*  *In case of a repeated application: the status of the research projects should always be indicated.* | |
| Area permitted to be treated | *Add the maximum permitted area to be treated (number of*  *hectares) under the conditions of the emergency authorisation.*  *For products for which use cannot be expressed in hectares (e.g. volume treated), the appropriate value and unit should be provided.* | |