MIP-0031-E

Application for authorisation of a new plant protection product

According to article 33 in Regulation (EC) No 1107/2009

# Application for authorisation of a new plant protection product

The first page of this application form shall be submitted as a signed original. All other documents, including the remainder of this application form may be submitted in digital form, preferably through any cloud service.

## Signature

If the signature is done by someone other than the applying company, a power of attorney confirming the right to sign the application on behalf of the applicant, shall be submitted.

|  |  |
| --- | --- |
| Product name | Product code |
| Applying company | Date |
| Signature | |
| Name | |

## 

## Postal address

Swedish Chemicals Agency  
Box 2  
SE-172 13 Sundbyberg  
SwedenDelivery address

Swedish Chemicals Agency  
Löfströms Allé 5  
SE-172 66 Sundbyberg  
Sweden

## Submission of documentation

Please use a safe file share service to submit the remainder of the documentation. If you wish to use our file share service, please contact [kemi@kemi.se](mailto:kemi@kemi.se). You may also submit the documentation on, for example, CD. In that case, please use the above address.

## Application overview

|  |  |  |
| --- | --- | --- |
| Product name | | Product code |
| Type of product (more than one option may be applicable)  Chemical  Microorganism  Low-risk product | Type of application  Interzonal  Northern zone | Proposed zRMS |
| The application is based on a product currently authorised in Sweden, a so-called clone authorisation  Please state Swedish reference product registration no: | | |
| Active substance approved as  Candidate for substitution  Low risk substance | | |
| Total cultivated area available for the product in Sweden < 3000 ha?  If yes, a justification of the statement shall be submitted  Yes No | | |

## Applicant

Future authorisation holder, i.e. the party **responsible** for placing the plant protection product on the market

|  |  |
| --- | --- |
| Name | Company´s registration no. |
| Address | Telephone no. (incl. country code) |
| Postal code and town | Contact person |
| Country | E-mail address |
| A company/corporation certificate shall be submitted by applicants that have not previously submitted an application to the Swedish Chemicals Agency. A company/corporation certificate is also required, if there has been changes since the previous certificate was submitted.  **Company´s/corporation´s certificate** is attached | |

## **Temporary** representative (if applicable)

Representing the authorisation holder (i.e. the applicant above) **only during the application procedure.** The authorisation holder is fully responsible for placing the plant protection product on the market.

|  |  |
| --- | --- |
| Company name | Company´s registration no. |
| Address | Telephone no. (incl. country code) |
| Postal code and town | Contact person |
| Country | E-mail address |
| A representative shall prove the appointed level of representation by the applicant.  **Power of attorney as temporary representative** is attached | |

## **Permanent** representative (if applicable)

Representing the authorisation holder (i.e. the applicant above) **during the authorisation period** (“ombud” in Swedish).

|  |  |
| --- | --- |
| Company name | Company´s registration no. |
| Address | Telephone no. (incl. country code) |
| Postal code and town | Contact person |
| Country | E-mail address |
| A company/corporation certificate shall be submitted by applicants that have not previously submitted an application to the Swedish Chemicals Agency. A company/corporation certificate is also required, if there has been changes since the previous certificate was submitted.  **Representing company’s/corporation’s certificate** is attached | |
| A representative shall prove the appointed level of representation by the applicant in original.  **Power of attorney as permanent representative** is attached | |

## Invoicing information for application fee[[1]](#footnote-1)

On our website, there is a tool and a list that can give you an estimate of the application fee.

|  |  |
| --- | --- |
| Company name | VAT no. |
| Invoicing address | Contact person (name/e-mail/tel) |
| Postal code and town | Country |
| Peppol-invoice | Peppol-invoice no. |
| Invoice reference (purchase order no./your reference) | |

## Product information

|  |  |  |
| --- | --- | --- |
| Function | Additional function (if applicable) | |
| Active substance/organism 1 | CAS no./Strain and culture collection 1 | Concentration (in g/kg, g/L or %) |
| Active substance/organism 2 | CAS no./Strain and culture collection 2 | Concentration (in g/kg, g/L or %) |
| Active substance/organism 3 | CAS no./Strain and culture collection 3 | Concentration (in g/kg, g/L or %) |

## Concerned Member States

|  |
| --- |
| Is the application submitted to other Member States in the Northern zone?  Yes No  **If yes** 🡪 indicate to which Member State(s):  DK – Denmark  EE – Estonia  FI – Finland  IS – Iceland  LT – Lithuania  LV – Latvia  NO – Norway  SE – Sweden |
| Is the product intended for use in green house, pre- or post harvest, in storage rooms or as seed treatment?  Yes No  **If yes** 🡪 indicate to which Member State(s):  AT Austria  BE Belgium  BG Bulgaria  CY Cyprus  CZ Czech Republic  DE Germany  DK Denmark  EE Estonia  EL Greece  ES Spain  FI Finland  FR France  HR Croatia  HU Hungary  IE Ireland  IS Iceland  IT Italy  LT Lithuania  LU Luxembourg  LV Latvia  MT Malta  NL Netherlands  NO Norway  PL Poland  PT Portugal  RO Romania  SE Sweden  SI Slovenia  SK Slovakia |

## Intended uses, label, and user category

|  |
| --- |
| Intended uses – GAP  **Complete zonal GAP**, including indication of relevant Member States, is attached  **Zonal core GAP** (risk envelope GAP) is attached (if relevant) |
| Label  **Proposed national label(s)** is/are attached  **Draft master label** is attached |
| User category  **Professional**  **Non-professional** |

## Active substance no. 1: <Name of the active substance>

If the product contains more than one active substance, please duplicate this section for each substance.

### Sources of active substance

|  |
| --- |
| Have all sources been evaluated?  Yes No  **If yes 🡪** all relevant **equivalence reports** shall be submitted  **If no 🡪** all relevant **documentation** shall be submitted |

### Active substance data

|  |
| --- |
| Do you refer to a data matching dossier?  Yes No  **If yes 🡪 Report on data match** shall be submitted |

### Active substance data

|  |
| --- |
| Is data submitted in support of the application protected in Sweden and not owned by you?  Yes No  **If yes 🡪** A **letter of Access** shall be submitted |

### New studies

|  |
| --- |
| Are studies on vertebrates included?  Yes No  **If yes 🡪 justifications of new vertebrate studies** and/or **information of efforts reaching an agreement** shall be submitted |

## Product documentation

### Data access

|  |
| --- |
| Is data submitted in supported of the application protected in Sweden and not owned by you?  Yes No  **If yes** 🡪 **A Letter of Access** shall be submitted |

### Vertebrate studies

|  |
| --- |
| Are new studies on vertebrates included?  Yes No  **If yes 🡪 justifications of new vertebrate studies** and/or **information of efforts reaching an agreement** shall be submitted |

### Request that certain information should be treated confidential

You may request that certain parts of the information submitted with the application should be treated as confidential. The form to be used is available in the Guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009, SANCO/13169/2010 Rev. 11.

|  |
| --- |
| A form requesting that certain parts of the information submitted with the application should be treated as confidential is submitted.  Yes No |

1. According to Ordinance (2013:63) on Pesticide Fees [↑](#footnote-ref-1)