|  |  |
| --- | --- |
| **Finnish Safety and Chemicals Agency (Tukes)  P.O.Box 66 FI-00521 HELSINKI, Finland** | Authority notes: |
| Reg.No: |
| DNo: |

**Application**

| No. | Information |
| --- | --- |
| 1 | Type of application (See below)   |  |  |  | | --- | --- | --- | |  |  |  | | Technical material from a new/different manufacturer |  |  | | Data from industrial scale production vs pilot scale production |  |  | | Change in the manufacturing process, and/or manufacturing location |  |  | |  |  |  | | Applicant is the owner of the reference specification: Yes  / No |  |  | |

### **Active substance**

| No. | Information | |
| --- | --- | --- |
| 2 | Name of the substance | CAS No |

|  |  |
| --- | --- |
| **Before submitting an application, please contact us via email at ppp.activesubstance(at)tukes.fi to reserve a time slot for the assessment.**  Dossier can be submitted by sending it to ppp.activesubstance(at)tukes.fi via secure email (<https://turvaviesti.tukes.fi/>). The maximum size of email attachments is 500 MB. Larger files should be compressed or sent in multiple emails. The dossier can also be submitted by providing a link with which the documents can be downloaded from the applicant’s own secure server. | **Payment:**  Please do not pay the application fee before receiving an invoice from the Finnish Safety and Chemicals Agency.[[1]](#footnote-1) |

#### **Applicant (manufacturer of the active substance)**

| No. | Information | |
| --- | --- | --- |
| 3 | Company name |  |
| Mailing address | Telephone number |
| Postal code and town | Contact person |
| Country | E-mail address |

#### **Invoicing information of the applicant**

| No. | | Information | |
| --- | --- | --- | --- |
| 4 | Invoicing address: | | VAT: |

### **Agent (if exists)**

| No. | Information | |
| --- | --- | --- |
| 5 | Company name |  |
| Mailing address | Telephone number |
| Postal code and town | Contact person |
| Country | E-mail address |

### **Signature and permission for electronical transactions**3

| No. | Information | |
| --- | --- | --- |
| 6 | Applicant | Date |
| Signature[[2]](#footnote-2) | Name |
|  | Permission for transactions via email[[3]](#footnote-3)  Yes  No |  |

|  | Mandatory attachments |
| --- | --- |
| a) | Draft equivalence assessment report |
| b) | 5-batch analysis |
| c) | Description of manufacturing process |
| d) | Screening study for impurities (if not included in the 5-batch analysis) |
| e) | Up to date SDS for all materials used in the manufacturing process |

1. Current fees for the assessment of the equivalence of an active substance are shown on Tukes website at <https://tukes.fi/en/online-services/fees#plant-protection-products>. [↑](#footnote-ref-1)
2. If the signature is done by someone other than the applying company, a letter of authorisation confirming the right to sign the application on behalf of the applicant should be submitted.

   3 Permission to have transactions via email is mainly utilized for supplementary information requests between Tukes and the applicant. You will also receive official documentations (for example hearing and decision) by e-mail if permitted. Confidential materials will be sent by secure mail. [↑](#footnote-ref-2)
3. [↑](#footnote-ref-3)