# Supporting document for the application for a major change to a Union authorisation under Regulation (EU) No 354/2013

*Please note that your application cannot be processed if the supporting document is not included or properly filled in.*

**Authorisation affected by the proposed change(s)**

|  |  |  |
| --- | --- | --- |
| **Product name\*** | **Asset number\*** | **Evaluating Member State** |
|  |  |  |

\*as indicated in R4BP 3.

**Description of all the proposed changes to the product**

1. **Major change(s)**

Please provide a detailed description of the proposed change(s) clearly indicating whether the change is an addition or modification. In addition, please justify that the proposed change(s) do not adversely affect the conclusions previously reached concerning the compliance with the conditions set out in Article 19 of Regulation (EU) No 528/2012 (“BPR”). You should reflect on all following items:

* Do the physico-chemical properties, physical hazards and chemical identity fulfil the conditions of Art. 19(1)(c),(d) of the BPR following the change?
* Is efficacy of the product(s) still sufficiently demonstrated following the change?
* Does the human health risk assessment fulfil the conditions of Art. 19(1) of the BPR following the change?
* Does the environmental risk assessment fulfil the conditions of Art. 19(1) of the BPR following the change?

For a biocidal product family, please indicate the meta SPC(s)/product(s) concerned by the change.

| **#** | **Detailed description of the change** | **Detailed justifications** |
| --- | --- | --- |
|  |  | **Physico-chemical properties, physical hazards and chemical identity:** |
| **Efficacy:** |
| **Human Health:** |
| **Environment:** |

1. **New information on the active substance submitted as part of the application:**

Indicate whether new information on the active substance is submitted as part of the application:

[ ]  yes

[ ]  no

N.B.: new information on the active substance is information that was not assessed during the approval of the active substance.

List in the table below all the new information on active substance submitted in the application.

| **Active substance[[1]](#footnote-2)** | **Location in the IUCLID dossier** | **File name in the IUCLID dossier** | **Title and author of the document** | **Area the new information concerns** | **Aim of the new information** |
| --- | --- | --- | --- | --- | --- |
| *Indicate here the name and respective CAS number of the active substance the new information is pertinent to.* | *Indicate here under which section of the active substance data set section of the IUCLID dossier is the document available.* | *Indicate here the file name of the document.* | *Indicate here the title and the author of the document concerning new information on the active substance.* | *Indicate here all the areas the new information on the active substance concerns. Indicate “APCP” if the new information concerns Analytical methods and Physico-Chemical Properties, “EFF” if it concerns efficacy, “ENV” if it concerns environment, “HH” if it concerns human health and “Animal health” if it concerns animal health.* | *Describe here more which endpoint value the new information on the active substance affects and in what way (e.g., refinement of an existing endpoint value, data for an endpoint not considered during the active substance approval etc.).* |
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**Indicate in the table below if the new information on the active substance submitted in your application has been submitted for another application and include the details of those applications:**

| **Application type** | **New information submitted in another application****(Y)** | **Name of applicant** | **Asset/case number** | **Date of submission** |
| --- | --- | --- | --- | --- |
| Technical equivalence assessment application that has been closed with the decision that technical assessment was established**[[2]](#footnote-3)** | *Indicate “Y” where the new information on the active substance submitted in your application was submitted in this application type and fill out the row accordingly, otherwise leave the entire row empty.*  | *Indicate the asset owner as stated in R4BP 3.* | *Provide the asset number assigned by R4BP 3. For ongoing applications provide the case number assigned by R4BP 3.* | *Indicate the date of submission as stated in R4BP 3.* |
| Inclusion in the Article 95 (active substance supplier) list application closed with the decision of inclusion on the Article 95 list2 | *Indicate “Y” where the new information on the active substance submitted in your application was submitted in this application type and fill out the row accordingly, otherwise leave the entire row empty.*  |  |  |  |
| Biocidal product/biocidal product family authorisation, renewal or change application2 | *Indicate “Y” where the new information on the active substance submitted in your application was submitted in this application type and fill out the row accordingly, otherwise leave the entire row empty. In case your product/product family contains more than one active substance indicate here which active substance the new information is pertinent to.* |  |  |  |

In case you indicated above that the new information on the active substance was submitted in a biocidal product or biocidal product family authorisation, change or renewal application, fill out the additional table below:

|  |  |  |  |
| --- | --- | --- | --- |
| **Asset/case number[[3]](#footnote-4)** | **Procedure type** | **Product name** | **Reference Member State/ evaluating Competent Authority** |
| *Provide the asset numbers assigned by R4BP 3 of all the relevant applications. For ongoing applications provide the case number assigned by R4BP 3 of all the relevant application types.* | *Indicate “NA” if the application concerns a national authorisation procedure. Indicate “SA” if the application concerns a simplified authorisation procedure. Indicate “UA” if the application concerns a Union authorisation procedure.* | *Indicate the product name as stated in R4BP 3.* | *Indicate here the reference Member State for the relevant national authorisation (NA) application, or evaluating Competent Authority for the relevant simplified (SA) or Union authorisation (UA) application.* |
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**Annex I. List of all approved or pending changes for the biocidal product/family, following the first authorisation or the last renewal of the product/family**

Please list all changes that you applied for since the first authorisation or the last renewal of the biocidal product/family, whichever is the latest. For each change, please indicate the case number, the type: administrative (ADC), minor (MIC) or major change (MAC), the status: approved / pending and provide a brief description of the change.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **#** | **R4BP 3 case No** | **Type of change** | **Status** | **Brief description of the change** |
|  |  | Choose an item. | Choose an item. |  |
|  |  | Choose an item. | Choose an item. |  |

1. Add rows if necessary [↑](#footnote-ref-2)
2. Add rows if you the new information on the active substance submitted in your application has been submitted for more than one application of this type. [↑](#footnote-ref-3)
3. Add rows if necessary. [↑](#footnote-ref-4)