## How to declare an in situ generated biocidal product

## Definition

Type 1: *in situ* system with one or more precursors placed on the market for the purpose of forming a biocidal product.

Type 2: *in situ* system with one or more substances in the form of a tablet or a powder mixture. To produce the active substance, reaction with a solvent (water) is necessary.

## Procedure

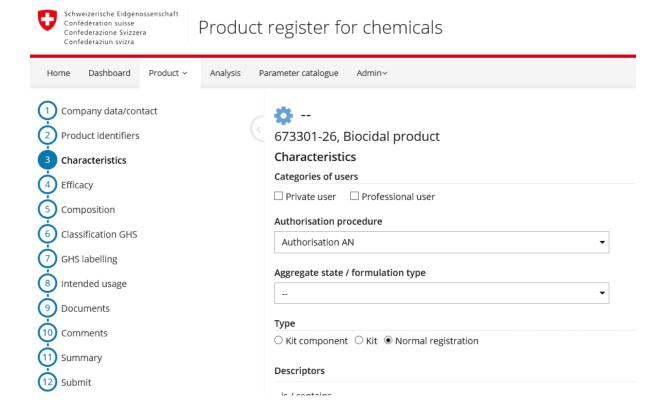
For type 1, each precursor is declared in an RPC form.

For type 2, the tablet or the powder is declared in a single RPC form.

- Under Characteristics, enter under Authorisation procedure "Authorisation AN".
- Under Type, select "Normal registration".
- It would be useful to append "Part A", "Part B" to the name to indicate that the component in question is to be used with another component.

For type 3, the precursor(s) is/are declared in an RPC form.

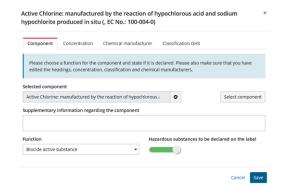
For type 4, the precursor does not have to be declared in an RPC form (only the *in situ* generated active solution has to be declared in an RPC form; see point 2 below).



## 1. For each precursor:

Under Composition, add the components, which should sum to 100%.

- For precursors, under Function, select "Biocide active substance" and select "Substance to be declared on the label".
- The active substance generated by the system must be indicated with concentration = 0
  - The function "Biocide active substance" is selected.
  - o As manufacturer, in situ is entered.
  - The box Declared is checked.



A label and the safety data sheet (SDS) are to be uploaded in the Documents section.

2. For the *in situ* generated active solution:

Once the precursors have been entered in the RPC, a new form (Authorisation  $A_N$ , Normal registration) is to be created, including the following elements:

- The composition, which may be approximate (between 98% and 102%).
- The concentration of the active substance is given as a value typical of its use.
- In the field "Comments regarding the composition" on the page Composition, the names and CPID numbers of the precursors are to be given.
- In the Documents section, the following are to be uploaded:
  - The draft label (including claims and instructions for use production and use of the *in situ* generated active substance)
  - The efficacy tests (only for product types 1–5)
  - The safety data sheet SDS (if available)
  - $\circ$  The document "Further data relating to an electronic application for authorisation  $A_N$  for a biocidal product"
  - The Excel file indicating the supplier of the active substance included in the list specified in Art. 95 (cf. evidence specified in Art. 62d of the Ordinance on Biocidal Products).

Having submitted electronic applications via the RPC, please send the following information

- a) The trade name and CPID number of the in situ generated biocidal product
- b) The name and CPID number of each precursor (type 1 *in situ* system) or the name and CPID number of the tablet or powder mixture (type 2 *in situ* system)
- c) An indication that this is a first application for authorisation  $A_N$  of an *in situ* generated biocidal product

by e-mail to the Notification Authority for chemicals at: cheminfo@bag.admin.ch