

## **First simplified MA application**

Written by DPR Biocides - Anses - Last Updated Monday, 15 June 2020 08:45

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**Regulations:** Chapter V, Articles 25 to 27 of Regulation (EU) No 528/2012

### **Timeframe**

Around 4 months with the possibility of a maximum 3-month suspension of the assessment if additional information is necessary.

### **Comments**

- The product must specifically meet the conditions set out in Article 25 of the BPR.
- Making the product available on the market of other Member States is done by notification according to Article 27 of the BPR. There is no procedure for mutual recognition.

**Validity of the MA:** 10 years.

### **Fees payable to ANSES**

- for one PT and one category of users: 12,000 euros
- Per additional PT, for one category of users: + 2400 euros
- For one PT, per additional category of users: + 6000 euros
  
- Notification of a product that was subject to a simplified MA procedure – no payment

### **Composition of the dossier**

Initially, written agreement should be sought from the competent authority chosen for the assessment work. This document should be submitted to ECHA.

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Documents to be submitted on R4BP

Language

Draft SPC (xml format)

EN

Draft RCP (xml format)

FR

Completed IUCLID dossier. In section 13:

- Product MSDS in French
- MSDS of each ingredient
- Label / draft label in French (and instructions for use in French, if appropriate)
- 'Permission to refer' decision granted by ECHA – if necessary
- Written confirmation from the evaluating RMS stating their agreement to evaluate the application

FR or EN

Table of intended uses in Word format

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FR or EN

Detailed composition form in Excel or Word format

FR or EN