

Identical product

Written by DPR Biocides - Anses - Last Updated Wednesday, 18 July 2018 13:26

Regulations: Regulation (EU) No 414/2013

Comments

Identical products are products with the same properties. The reference product must have a national MA (or be undergoing assessment) in order to apply for the same biocidal product.

Timeframe

- 4 months

- [The detailed procedure](#) 

is available.

Validity of the MA

Expiry date identical to that of the reference MA.

Fees payable to ANSES

For each application for an identical product: 800 euros

Composition of the dossier

Identical product

Written by DPR Biocides - Anses - Last Updated Wednesday, 18 July 2018 13:26

Documents to be submitted on R4BP

Language

Draft SPC (xml format)

– for BBP

EN

Draft RCP (xml format)

– for BBS

FR

Supporting document (see ECHA website): “supporting document for the application for national authorisation”

FR or EN

Letter of access for active substances

FR or EN

Product formulation

FR or EN

Identical product

Written by DPR Biocides - Anses - Last Updated Wednesday, 18 July 2018 13:26

[Certificate from applicant](#) 

which confirms that the product is identical to the reference product excepted for possible administrative

FR

List of all trade names included in each meta-SPC of the product family – only for family

FR

Letter of access for the original reference product if holders are different – if necessary

FR or EN

Letter of access for the related product, if holders are different – in case of same on same for example

FR or EN

‘Permission to refer’ decision granted by ECHA – if necessary

FR or EN

Identical product

Written by DPR Biocides - Anses - Last Updated Wednesday, 18 July 2018 13:26

ECHA decision concerning technical equivalence – if necessary

FR or EN