Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

Product identifier in R4BP	SOFAST
Product type(s):	18 (Insecticides, acaricides and products to control other arthropods)
Active ingredient(s):	Imidacloprid; Cis-tricos-9-ene
Case No. in R4BP	BC-LS052997-00
Asset No. in R4BP	DE-0008815-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/18.00007 710-05-18-00007-00-01-00-0000
Date	02.07.2021 (Major change)

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Overview of applications

Table 1 - Overview regarding all relevant applications

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment)	Page
NA-APP	DE	BC-XV010731-14	29.09.2017	First authorisation	See separate file
NA-MAC	DE	BC-LS052997-00	02.07.2021	Mayor change (composition, storage stability, live stock facilities)	5

Current consolidated Summary of the product assessment

See separate consolidated PAR file.

Changes after first authorisation

1 Change 1 - NA-MAC - BC-LS052997-00

Case No.	BC-LS052997-00
Internal registration/file no:	5.0-710 05/18.00007 710-05-18-00007-00-01-00-0000
Case type(s)	Major change (NA-MAC)
CMS	Czech Republic (CZ), Poland (PL), Spain (ES)
Entry into force of change / amendment	02.07.2021

1.1 Changes sought

- Replacement of a non-active substance
- Change of storage stability/shelf life
- Addition of use in livestock facilities

1.2 Assessment

- Regarding the replacement of a non-active substance please consider the confidential annex (page 6).
- Regarding the change of storage stability/shelf life please consider the confidential annex (page 8).
- Regarding the assessment of the use in livestock facilities consider the separate consolidated PAR file.

1.3 Conclusion

- The change regarding the replacement of a non-active substance cannot be approved. Please consider the confidential annex (page 6) for the detailed justification.
- The change regarding storage stability/shelf life cannot be approved. Please consider the confidential annex (page 8) for the detailed justification.

Concerning the conclusions regarding the use in livestock facilities please consider the separate consolidated PAR file.