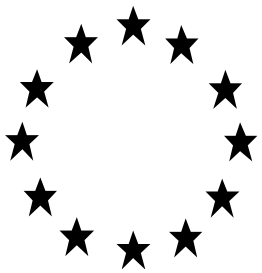
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

ADMINISTRATIVE CHANGE ADDENDUM PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



TEKNOL AQUA 1410-01 Family

Product type 8

3-iodo-2-propynylbutylcarbamate (IPBC) and propiconazole as included in the Union list of approved active substances

Case Number in R4BP: [BC-KR060685-14]

Evaluating Competent Authority: Finland

Date: [23/6/2021]

Note to the reader:

Please note that Finland has replaced the former refMS (UK). Below is provided a table specifying the history of the asset.

In 31/3/2012, UK as refMS, authorised the product Teknol Aqua 1410-01 as a frame formulation (UK-0000438-0000) and then mutual recognition in sequence were approved in several concerned Member States (Austria AT-0002325-0000, Switzerland CH-0008318-0000, Czech Republic CZ-0000173-0000, Germany DE-0000476-0000, Denmark DK-0001802-0000, Estonia EE-0000431-0000, Finland FI-0000150-0000, Hungary HU-0000497-0000, Ireland IE-0000236-0000, Italy IT-0005009-0000, Lithuania LT-0001751-0000, Latvia LV-0000035-0000, Norway NO-0004202-0000, Poland PL-0000490-0000, Sweden SE-0000118-0000, Slovenia SI-0001879-0000, Slovakia SK-0000418-0000).

In 19/08/2016 UK as refMS, changed the frame formulation into a product family Teknol Aqua 1410-01 Family (UK-0014070-0000). Of the above-mentioned concerned Member States the frame formulation was changed into a product family in Finland 2016 (FI-0013416-0000), in Poland (PL-0017674-0000) and in Austria 2020 (AT-0024336-0000).

Since 31 January 2020, the UK cannot act as the reference Member State as it is no longer an EU Member State. As proposed in the procedure agreed in CG42 (CG-42-2020-08 AP 6.2) and first noted during the 89th CA meeting (CA-Sept20-Doc.7.8) and preliminary agreed in the closed session of the 90th CA-meeting (CA-Dec20.Doc.7.2[1]), Finland agreed to take over the role of Reference Member State for this product family.

The applicant has applied for an administrative change (NA-ADC) and proposed amendments to the SPC for the product family. The changes in classification and labelling are due to the harmonised classification of propiconazole (ATP 13 of CLP) which also results in removal of the user category general public (consumers).

Please note that Finland as new refMS provided this addendum to the original PAR related to the administrative change assessment. The update of other parts of the assessment or SPC would only be performed at the renewal stage of the product.

The amendments made are only related to the applied administrative change concerning changes in classification and labelling due to the harmonised classification of propiconazole (ATP 13 of CLP).

The history of the dossier:

Application type	refMS/cMS	Case / Assset number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	UK	UK-0000438-0000	31/3/2012	Assessment report prepared by UK
NA-MRS	FI	FI-0000150-0000	14/12/2012	Mutually recognised in Finland
NA-ADC	FI	BC-YF006062-50	2/7/2014	New AS supplier (propiconazole) added

[1] https://circabc.europa.eu/w/browse/c63a1f06-4ae7-43c7-b436-d20829fec75b

NA-MRG	FI	BC-DK021555-47 / FI-0013416-0000	23/2/2016	Changed from a frame formulation to a product family
NA-ADC	FI	BC-KP022531-39	24/5/2016	New formulation site and CLP classification added
NA-RNL	FI	BC-HU043003-36	TBD	
NA-AAT	FI	BC-RQ057815-07	18/3/2020	Expiration date of the asset extended to 30/10/2025
NA-ADC	FI		23/6/2021	Assessment report amended by FI as new refMS

Change to the classification and labelling due to the harmonised classification of Propiconazole, ATP 13 of CLP:

According to the 13th ATP of Regulation (EC) No 1272/2008 the active substance propiconazole is classified with Repr. 1B, H360D: May damage the unborn child. Since the general concentration limit for this classification is 0.3%, also this biocidal product containing 0.9% propiconazole requires this classification.

TEKNOL AQUA 1410-01: Classification and Labelling according to Regulation (EC) No 1272/2008

Classification	
Hazard category	Repr. 1B Aquatic Chronic 3
Hazard statement	H360D: May damage the unborn child. H412: Harmful to aquatic life with long lasting effects.
Labelling	
Signal words	Danger
Pictogram	GHS08
Hazard statements	H360D: May damage the unborn child. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P201: Obtain special instructions before use. P280: Wear protective gloves/protective clothing/eye protection/face protection. P273: Avoid release to the environment. P308+P313: IF exposed or concerned: Get medical advice/attention. P405: Store locked up. P501: Dispose of contents/container to … … in accordance with local/regional/ national/international regulations (to be specified).
Additional labelling requirements	EUH208: Contains propiconazole, 3-iodo-2-propynyl butylcarbamate (IPBC) and 1,2-benzisothiazol-3(2H)-one (BIT). May produce an allergic reaction.
Note	

Removal of a category of users, specifically to use(s) related to the general public (consumer):

According to Regulation (EU) No 528/2012 Article 19(4)(b) a biocidal product classified as toxic for reproduction category 1A or 1B shall not be authorised for making available on the market for use by the general public. Therefore, the non-professional user (general public, consumer) category is removed from the authorised uses.