TÜVRheinland®
Precisely Right.

TÜV Rheinland LGA Products - Information

05/2021

Ten Active Substances no longer approved

The European Commission has designated ten active substances that will no longer be authorized for certain uses under the Biocidal Products Regulation. The Commission will amend Annex II to the BPR to reflect the non-approvals.

The implementing decision is expected to be adopted in June and enter into force 20 days after its publication in the Official Journal. From that date, the use of these biocides for the related product types will no longer be allowed (Transition periods, compare page 2)

Affected are the following substances:

Substance	Product type
Bronopol	PT9
Thiram	PT9
Metam sodium	PT9 und PT11
Nano-silver	PT2, PT4 und PT9
2,2-Dibromo-2-cyanoacetamide (DBNPA)	PT13
Eucalyptus citriodora oil and citronellal, hydrated, cyclized	PT19
2-Hydroxy-α,α,4-trimethylcyclohexanemethanol	PT19
Peroxyoctanoic acid	PT2, PT3 und PT4
Chlorine dioxide generated from sodium chlorite and sodium persulfate	PT2, PT3, PT 4, PT5 und PT11
Malt, extractives and their physically modified derivatives	PT19

PT2	Disinfectants and algaecides not intended for direct application to humans or animals
PT3	Products for veterinary hygiene
PT4	Disinfectants food and feed area
PT5	Drinking water disinfectants
PT9	Preservative for fibers, leather, rubber and polymerized materials
PT11	Preservative for liquid cooling and processing systems
PT13	Preservative for working or cutting fluid preservatives
PT19	Repellents and attractants

For further details, please also refer to the drafts of the Implementing Decision.

Notice:
We recommend that you identify which of your products contain these biocides, identify alternatives and switch accordingly. It is also necessary to clarify by what date existing stocks and goods placed on the market can be sold off.

Transition periods

Whether and which transitional periods can be applied for the individual substances must be examined in detail. According to Article 89 of Regulation (EU) No 528/2012, as a rule, a biocidal product containing such a substance that has not been further authorised can still be marketed twelve months after the publication of the non-authorisation decision.

Helpdesk response number 0436 provides further guidance on this:

"Article 89 of Regulation (EU) No 528/2012 defines sell-by dates for different situations:

1. During the evaluation of an existing active substance, it is found that its use poses an unacceptable risk and that it is not included in the positive list of approved active substances. In this case, a biocidal product containing this active substance may still be marketed twelve months after the publication of the non-approval decision. This does not apply to active substances for which the decision already specifies a concrete date from which the corresponding products may no longer be marketed.
2. When a decision has been taken to approve an active substance, applications for authorisation of biocidal products containing these active substances must be submitted by the date specified as the approval date (approximately 1.5 years after the decision). Products without applications for authorisation may not continue to benefit from the transitional arrangements and lose their marketability. The sell-off period for these products is that they may still be marketed 180 days after the date of approval of the active substance and stocks may still be used 365 days after the date of approval of the active substance.
3. If a competent authority, after evaluating an application for authorisation, decides not to grant an authorisation for the relevant product, the biocidal product may only be marketed for 180 days from the date of rejection of the application and stocks may be used for 365 days from the date of rejection of the application.

https://www.reach-clp-biozid-helpdesk.de/DE/Biozide/FAQ/Verkehrsfaehigkeit/Verkehrsfaehigkeit.html?view=pdf
(German language only)

Further technical information can be obtained from:

TÜV Rheinland LGA Products GmbH
Technical Competence Center Softlines
Am Grauen Stein
D-51105 Köln
service@de.tuv.com