European Biocidal Product Regulation

Factsheet Biocides

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1. Regulatory framework

The Biocidal Product Regulation (BPR – EU 528/2012) on the use and placing on the market of biocidal products repealed and replaced the Biocidal Product Directive (BPD) on biocides (98/8/EC) on 1 September 2013. The transition period has been extended up to 2024.
Details on the legislation can be found on: https://echa.europa.eu/regulations/biocidal-products-regulation/legislation

The regulation should increase the protection of health and environment, and it should be more efficient at the same time, notably through the active involvement of European CHemicals Agency (ECHA - also in charge of REACH). It will retain the two-step authorization process brought in by the Directive, whereby active substances are first tested and approved and included in a Community list or Union list (known as the Annex I under the Directive), with subsequent authorization of the products containing the approved active substance.

Under the BPR the RMS's (Rapporteur Member States) are now called eCA's (evaluating Competent Authorities). An eCA takes care of the initial evaluation of an active substance dossier and prepares the draft CAR (Competent Authority Report). Draft CAR's can be discussed with applicant and/or individual MS and in Working Group meetings to solve open issues before they are brought to BPC (Biocidal Product Committee) for conclusions. According to the Biocidal Products Regulation (BPR), the opinion on the approval of an active substance has to be submitted by ECHA to the Commission within 270 days of the receipt of the conclusions of the evaluating Competent Authority (eCA).
A detailed overview of the different steps in this BPR process for authorization of a biocidal active substance can be found in the "Working procedure for active substance approval" at the ECHA website:
https://echa.europa.eu/documents/10162/4221979/bpc_working_procedure_active_substance_en.pdf/3a35e75d-7c08-4c87-b501-8c24f0081dde

Amendments to the BPR were found to be necessary in an early phase after implementation and entered into force on 25 April 2014.

The legislation and amendments of the BPR can be found via the following link:
http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1409322218709&uri=CELEX:02012R0528-20140425

More information on the BPR can be found via the Questions & answers page on the ECHA website:
https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/topic/biocidalproductsregulation

2. Scope of the Biocidal Product Regulation (BPR)

The scope has been extended to cover articles and materials treated with biocidal products, including furniture and textiles. The regulation will also apply to active substances generated in situ, and to biocidal products used in materials that come into contact with food. But other products that are sufficiently covered by existing legislation (including food and feed, food and feed additives and processing aids) are excluded from the scope of the new regulation. Biocidal products approved under the International Convention for the Control and Management of Ships' Ballast Water and Sediments are considered as authorized

3. The electronic systems to submit data

The registration data-base system to submit dossiers for active substances and biocidal products is part of REACH-IT, the system is paperless and IUCLID based. IUCLID is the electronic data-base system to collect all data and to prepare all biocides dossiers. This is the same electronic system as used for REACH dossiers. Via REACH-IT companies can generate their own account to submit their dossiers.

The IUCLID software is regularly updated by ECHA with new tools or to comply with new requirements.

R4BP (Register for Biocidal Products) is the communication tool to be used for communication with ECHA for all issues on biocides dossiers. It is advised to keep track of these changes to avoid submission issues

ECHA regularly published newsletters on upcoming changes on the website: https://newsletter.echa.europa.eu/home/-/newsletter/tag/biocides

IUCLID can be downloaded from ECHA (https://iuclid6.echa.europa.eu/) for free and access to R4BP3 is possible via ECHA when a REACH-IT account is generated. Also a “cloud” version of IUCLID is available.

For more information on R4BP3: https://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals

4. The guidance documents

ECHA published a lot of guidance documents related to the BPR. They can be found via the following link: https://echa.europa.eu/practical-guides/bpr-practical-guides

A manual to submit national authorisations can be found at the following link: https://echa.europa.eu/support/dossier-submission-tools/r4bp/submit-applications-for-national-authorisation

Some information on Union Authorization:

Under the BPR a possibility for Union Authorization via ECHA was created. The deadlines are laid down in Art. 42 of the BPR. To avoid an overload of ECHA a step-wise planning is laid down. Applicants may apply for Union authorization for biocidal products which have similar conditions of use across the Union with the exception of biocidal products that contain active substances that fall under Article 5 and those of Product Types 14, 15, 17, 20 and 21.

Union authorization may be granted:

- from 1 September 2013, to biocidal products containing one or more new active substances and biocidal products of product-types 1, 3, 4, 5, 18 and 19;
- from 1 January 2017, to biocidal products of product-types 2, 6 and 13; and
- from 1 January 2020, to biocidal products of all remaining product-types (besides those excluded).

Some information on Article 95:

Active substance suppliers not having an own dossier or a Letter of Access had to phase out by September 2015. In order to be able to check if suppliers have submitted dossiers under the BPD/BPR a list is prepared by ECHA with approved suppliers and this list is regularly updated.

With the amended BPR there are now also possibilities to apply for listing by formulators of some biocidal products. This possibility is mainly generated for importers of formulations for which the active substance is not supported by the non- EU manufacturers.

It is very important for formulators of biocidal products to check if their suppliers are included in the Article 95 list for the product types of their interest. The list is legally binding since 1st September 2015. If the active substance supplier is not on the list the formulator is no longer allowed to use the active ingredient from this supplier.

On the ECHA website a list of notifications for Article 95 and the latest list of approved suppliers can be found on:
https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/list-of-approved-active-substances

Since the updated Article 95 list of 25th of July 2019 you can find our substances under the new Nouryon Surface Chemistry AB name.

To comply with the legal status of Article 95 several member states have initiated to collect Declarations of Delivery (DoD) from the registration holders to confirm they are buying from Art 95 listed suppliers. For our customers we make available on request a statement on the Art 95 notification and/or Declarations of Delivery for the active substances supported by Nouryon Surface Chemistry AB.

If a company wants to remain active in the biocides market on the longer term, it will be a legal obligation in all member states of interest to have approval for all the formulations with biocidal claims. In the biocidal product dossier, the access to the active substance dossier will have to be covered with a Letter of Access from the actual supplier of the active ingredient (unless the active substance dossier is also owned by the applicant). Details for the Letter of Access are laid down in Art 61 of the BPR.

More details on biocidal product authorization can be found via:
https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products

5. Review program

Under the BPR, the application areas are called Product Types (PT). The different PT's we support for our active substances are given in Table 3. A detailed description of the PT's can be found on: http://echa.europa.eu/regulations/biocidal-products-regulation/product-types

As Nouryon Surface Chemistry AB we support three quaternary ammonium compounds:

DDAC = Didecyldimethylammonium chloride (CAS number 7173-51-5)

BKC = $C_{12\text{-}16}$-alkyldimethylbenzylammonium chloride (CAS number 68424-85-1)

TMAC = Cocoalkyltrimethylammonium chloride (CAS number 61789-18-2)

For simplicity we will remain calling these single substances in this factsheet BKC, DDAC and TMAC.

The three quaternary ammonium compounds are being evaluated by Italy. Italy has informed us that they intend to follow the priority setting made by ECHA to meet the 2024 deadline (see listing below).

Next to the 3 quaternary ammonium compounds we also support:

Triameen Y12D = N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (CAS no 2372-82-9)

This substance is sometimes abbreviated in the review program as Diamine. The evaluation of Triameen Y12D is done by Portugal.

Timing:

Although a proposal for a decision on inclusion officially had to be taken by the RMS within 1 year after accepting dossiers as complete, unfortunately this did not happen in practice.

To be able to meet the new deadline for the review program of 2024 ECHA has set priorities for the different application areas (PT's) in the new review program.

Table 1:

Priority	Existing active substances for product types	Deadline for submission of all draft CARs by eCA to ECHA	Deadline for ECHA to deliver its opinions
1	8, 14, 16, 18, 19, 21	31/12/2014	30/09/2015
2	3, 4, 5	31/12/2016	30/09/2017
3	1, 2	31/12/2018	30/09/2019
4	6, 13	31/12/2019	30/09/2020
5	7, 9, 10	31/12/2020	30/09/2021
6	11	31/12/2022	30/09/2023
7	12,15,17,22, 23	31/12/2023	30/09/2024

When several active substances are included in a biocidal product, then the deadline for BPR product dossiers is related to the official approval of the last approved active substance. When the formulation is used for several PT's the deadline for product dossier submission is related to the approval the last PT. In the meantime, of course, the national rules have to be followed.

Based on the current status of the program and the recent implementation of the Endocrine Disruptor Criteria it is unlikely that the deadline of 2024 will be met.

6. Status of the Nouryon dossiers:

In the overview below (under chapter 9) all the different steps (actions) in the evaluation process under the BPR are listed in a flow chart. The implementation of the BPR has slightly changed the evaluation process and the system of TM meetings and CA meetings is replaced by a system of WG (Working Group) and BPC (Biocidal Product Committee) meetings at ECHA. It is planned that the frequency of meetings will increase to speed up the process in order to try to meet the 2024 deadline. In the new process the BPC meets about 5 times per year (instead of 3 times for the previous TM meetings) to discuss the technical issues and decide on a final version of the CAR (Competent Authority Report).

The implementation of the new Endocrine Disruption (ED) criteria:

On 4 September 2017, the Commission adopted a Delegated Regulation on scientific criteria to identify endocrine disruptors for biocidal products. Neither the Council nor the European Parliament objected to the Delegated Regulation during the scrutiny period which ended on 4 November 2017.

The criteria for biocidal products are published and entered into force on 7 December 2017.

The European Commission has published information on ED:
https://ec.europa.eu/health/endocrine_disruptors/process_en

They apply from 7th June 2018 to all new and ongoing applications for biocides.

- Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017
- Decision-making process on the BP criteria

ECHA has also published quite some information on this topic:
https://echa.europa.eu/understanding-ed-assessment

It is expected that this ED process will significantly delay the review program.

- **6a) PT8 - Wood preservation**:

For BKC and DDAC:
Two consortia are involved in these two active substances, an US consortium (US-ISC) and the European QUAT Consortium (EQC). We as Nouryon Nobel Surface Chemistry AB are member and chair of the EQC.

In February 2013 the decisions on Union list inclusion of CAS number 68424-85-1 (BKC) and CAS number 7173-51-5 (DDAC) for PT 8 became final. The deadline for biocidal product dossiers under the review program of the BPR was February 1st 2015.

The official decisions for PT8 can be found here:

BKC:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:049:0066:0069:EN:PDF

DDAC:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:044:0010:0013:EN:PDF

For TMAC:
The BPC decision for approval for PT8 was taken in the BPC meeting of April 2016. The deadline for biocidal product dossiers under the review program of the BPR was 1st of May 2018.
The official decisions for PT8 can be found here:

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1934&from=EN

For access to the latest public combined assessment reports of TMAC, DDAC and BKC for PT8 you can use the following link:

http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances

- **6b) PT 3 Veterinary hygiene; PT4 Food and feed area**

For BKC and DDAC

The substances were discussed at the BPC meeting of December 2018 for PT3 and 4. All open points were discussed and closed except the ED Assessment. Performing a proper ED assessment following the criteria and guidance on ED is a time consuming task. The ED assessments for both substances were prepared and submitted to Italy and ECHA end 2018. At the big biocides conference of Chemical Watch in Rome in May 2019 both ECHA (presentation of the chair of BPC Erik vander Plassche) and in the presentation of RMS Italy (presentation Maristella Rubbiani) it was confirmed that no ED properties are expected for the quats. As this EDA is a new requirement all parties involved have to gain experience and follow the new procedures. Due to lack of capacity at the RMS to evaluate the ED assessments help of ECHA is asked by the RMS. Beginning of August 2019 we learned from ECHA that the substances are planned for the March 2020 Working Group meeting to finalize the ED assessment and for the BPC meeting of June 2020 to agree on the BPC opinion.
The best estimate on product deadline for PT 3 and 4 that can be given at this moment is June 2022.

Triameen Y12D:
For the evaluation of Triameen Y12D (N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine) with CAS no 2372-82-9 we have not received any Assessment Report yet. Portugal informed us years ago that they intend to come with draft Competent Authority Reports for all Product Types supported in one go, but they could not give an indication when the draft CAR's will be made available.
Since the official deadlines are not followed by the authorities, it is difficult / not possible for us to predict dates for final Union listing for the remaining PT's supported.

- **6c) Other application areas: PT 1,2,6,10,11,12,13:**

For BKC and DDAC:

Italy has informed us that they intend to follow the priority setting made by ECHA to meet the 2024 deadline. The consequence is that PT 1,2 and PT 3,4 will be discussed and approved separately. In the current ECHA working program of Working Group meetings and BPC meetings no WG meeting for PT1 and 2 can be found yet. It is assumed first the ED assessment will be finalized before they continue to evaluate PT1 and 2. The best estimate for product deadline for PT 1 and 2 that can be given at the moment is June 2023.
For the other PT's 10, 11 and 12 we are at the start of the evaluation process, we received completeness for the dossiers submitted under the review program, but no draft Assessment Reports are received yet.

Triameen Y12D:

For the evaluation of Triameen Y12D (N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine) with CAS no 2372-82-9 we have not received any Assessment Report yet for any PT's involved in. Portugal informed us years ago that they intend to come with draft Competent Authority Reports for all Product Types supported in one go, but they could not give an indication when the draft CAR's will be made available.
In May 2019 we were asked to submit a full ED assessment following the new criteria for Triameen Y12D. This ED assessment was submitted in August. Since the official deadlines are not followed by the authority, it is difficult / not possible for us to predict dates for final Union listing for the PT's supported by Nouryon.

The ECHA working program (giving the dates for the BPC and WG meetings can be found here:
https://echa.europa.eu/documents/10162/17287015/wp_active_substance_approvals_2018_19_en.pdf/e914fc27-2c38-6728-2a73-ae9480df171f

7. Services that can be provided for customers:

- **Letter of Access** = LoA to the active substance under the national system (needed for national approvals as long as the active substance/PT combination is not approved yet under the BPR and a national approval system exists)

- **Letter of Access** = LoA to the active substance under the BPR (needed for PT8 biocidal products based on BKC and/or DDAC for which all other actives are already approved, and no other PT's are involved)

- **Statement on Art 95** (needed to proof that you are using an approved supplier of the active substance)

- **Declaration of Delivery** (required by some national authorities to proof the supplier used is on Art. 95)

- **Listing of Endpoints** = LoE (needed to perform the risk assessments of the biocidal products to be registered under the BPR but might also be needed/used for national registration scheme or for preparation of your own product SDS). This LoE contains all conclusions to be taken into account for product authorization. This means: the conclusions from all physical-chemical studies and all endpoints from all Toxicity and Ecotoxicity studies. It further contains the Classification and Labelling details of the active substance.

- **Robust Study Summary** of analytical methods = RSS (these RSS are needed in your biocidal product dossier to be able to check the concentrations of the active substance in your biocidal product)

Please contact your local sales/account manager in case you need such statements/letters. They can also give you more information on the terms/conditions involved.

8. List of abbreviations used

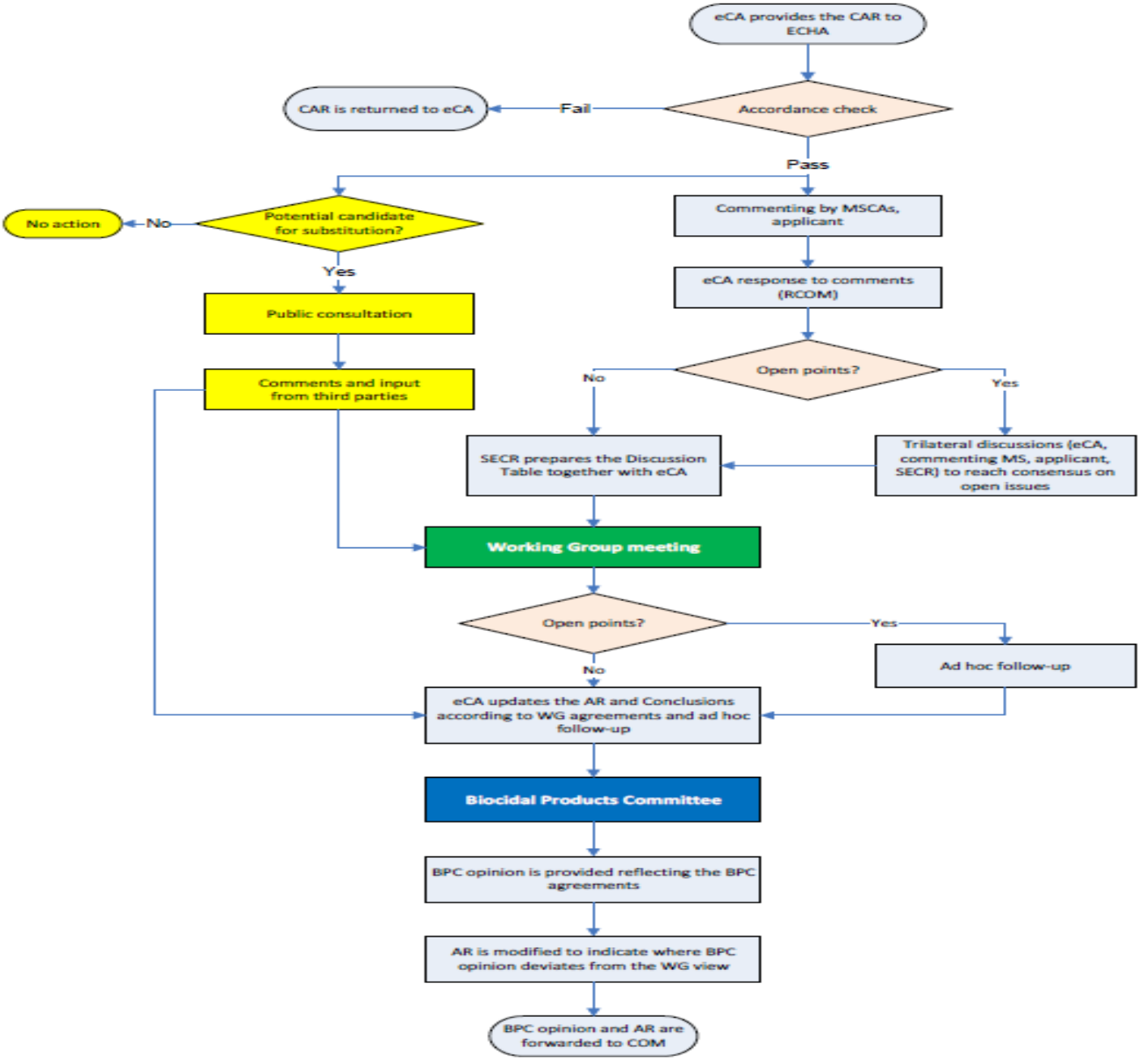
AR	Assessment Report
BPC	Biocidal Product Committee (selected experts of the MS's that meet about 5 times per year at ECHA to propose active substance opinions)
BPD	Biocidal Product Directive
BPR	Biocidal Product Regulation
CA	Competent Authority
CAR	Competent Authority Report
COM	Commission (In the overview COM is used but where relevant to be more specific also COM- ENV (Directorate General Environment) and COM-JRC (Joint Research Centre) are used.
eCA	evaluating Competent Authority
ECHA	European Chemicals Agency
ED	Endocrine Disruption
EDA	Endocrine Disruption Assessment
EDC	Endocrine Disruption Criteria
EQC	European QUAT consortium
LOE	Listing of Endpoints
MS	Member State
MSCA	Member State Competent Authority
PT	Product Type (application area)
RCOM	response to commenting table (consolidated commenting table)
RMS	Rapporteur Member State
RSS	Robust Study Summary
SECR	ECHA secretariat
TM	Technical Meeting (representatives are present of all MS)
US-ISC	United States based QUAT Consortium
WG	Working Group meeting (selected technical experts of the MS's that meet about 5 times per year at ECHA to discuss technical issues of the BPR dossiers)

9. Time lines for Active substance

Description of the steps / timelines in the peer review process of an activesubstance approval can be found in the guidance called "working procedure foractive substance approval". The latest version can be found at:
https://echa.europa.eu/documents/10162/4221979/bpc_working_procedure_active_substance_en.pdf/3a35e75d-7c08-4c87-b501-8c24f0081dde

Below you can find a detailed flowchart from the ECHA guidance that gives a clear picture of the steps involved in the active

Figure 1. *Flowchart of the biocidal active substance approval process.*



10. Time lines for the Biocidal Product phase:

Table 2:

Action	Deadline
Biocidal Product authorization: Biocidal product suppliers have to apply for authorization at country authority level of the country/countries of interest for marketing the biocidal product. Alternatively an Union authorization can be applied for at ECHA.	The official approval date (for inclusion in the Union list) of the active substance is in general 24 months after approval in the BPC meeting. The official approval is generally published 5-6 months after agreement in the BPC meeting is reached. Latest at the date of official Union List inclusion of the active substance, all biocidal product dossiers have to be submitted that would like to profit from the review program. From this official publication date, generally about 18 months are left to submit the biocidal product dossiers. Authorities then have maximum 36 months to finalize the evaluations of the biocidal product dossiers submitted.

11. Product Types supported by Nouryon Surface Chemistry AB

Table 3:

Product Type (PT)	BKC CAS no: 68424-85-1	DDAC CAS no: 7173-51-5	TMAC CAS no: 61789-18-2	Triameen Y12D CAS no: 2372-82-9
Main group I: Disinfectants and general biocidal products				
1. Human hygiene	x	x		
2. Disinfectants and algaecide not intended for direct application on humansor animals (previously called Private and public health area)	x	x		x
3. Veterinary hygiene	x	x		x
4. Food and feed area	x	x		x
5. Drinking water				
Main group II: Preservatives				
6. Preservatives for products in storage (previously called: In can preservatives)				x
7. Film preservatives				
8. Wood preservatives	x	x	x	
9. Fiber, leather, rubber and polymerized material preservatives				
10. Construction material preservatives (previously called: Masonry preservatives)	x	x		
11. Preservatives for liquid cooling and processing systems	x	x		x
12. Slimicides	x	x		x
13. Working and cutting fluid preservatives (previously called: Metalworking fluid preservatives)				x
Main group III: Pest control				
14. Rodenticides				
15. Avicides				
16. Molluscicides, vermicides and products to control other invertebrates				
17. Piscides				
18. Insecticides, acaricides and products to control other arthropods				
19. Repellants and attractants				
Main group IV: Other biocidal products				
20. Control of other vertebrates				
21. Antifouling products				
22. Embalming and taxidermist fluids				

12. Disclaimer:

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