

Practical guidance on how to access information from the European Union biocides registration process

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| Acronyms | Explanation |
|-------------------|---|
| a.s. ¹ | Active substance |
| ADI | Acceptable Daily Intake |
| AOEL | Acceptable Operator Exposure Level |
| ARfD | Acute Reference Dose |
| BP | Biocidal Product ² |
| BPC | Biocidal Products Committee at ECHA |
| BPD | Biocidal Products Directive 98/8/EC |
| BPR | Biocidal Products Regulation EU 528/2012 |
| C&L | Classification and labelling |
| CAR | Competent Authority (assessment) Report |
| CLP | Regulation on classification and labelling of chemicals and mixtures |
| COM | The European Commission |
| ECHA | European Chemicals Agency |
| EFSA | European Food Safety Authority |
| eCA | Evaluating Competent Authority (same as RMS or eMS) |
| eMS | Evaluating Member State (same as RMS or eCA) |
| EU | European Union |
| FAO | Food and Agriculture Organisation of the United Nations |
| GHS | United Nations' Globally Harmonised System of classification and labelling of chemicals |
| JMPM | Joint Meeting on Pesticide Management (FAO/WHO) |
| MRL | Maximum residue level of chemicals in food and feedstuff |
| MS | EU Member State |
| OECD | Organisation for Economic Co-operation and Development |
| PBT | Persistent, Bio-accumulative and Toxic substance |
| PPE | Personal protective equipment |
| PPP | Plant protection product ³ |
| PT | Product Type according to the EU system for biocides authorisation |
| RMS | Rapporteur Member State (same as eMS or eCA) |
| WHO | World Health Organisation |
| vPvT | Very Persistent and very Toxic substance |

¹ Active substance is the chemical that has the pesticide properties, i.e. it could be an herbicidal active substance that kills weeds, or it could be an insecticidal active substance that kills insect pests or a fungicidal active substance that reduces fungal damage.

² Biocidal product is the actual product as placed on the market, containing the active substance(s) together with formulation chemicals (such as solvents and emulsifiers).

³ Plant protection product is the actual product as placed on the market, containing the active substance(s) together with formulation chemicals (such as solvents and emulsifiers).

| Legislation no. | Name |
|-----------------|---|
| 1107/2009/EC | REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC |
| 1272/2008/EC | REGULATION (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (CLP-Regulation) |
| 91/414/EEC | Plant protection products directive (PPPD); COUNCIL DIRECTIVE of 15 July 1991 concerning the placing of plant protection products on the market |
| 67/548/EEC | Substances directive |
| 1999/45/EC | Preparations directive |
| 1451/2007/EC | Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (amended 2010 and 2013) |
| EU 528/2012 | Regulation concerning the making available on the market and use of biocidal products (BPR) |
| 98/8/EC | Biocidal Products Directive (BPD); DIRECTIVE 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market |
| EU 354/2013 | Regulation on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council |
| EU 613/2013 | Commission Regulation (EU) No 613/2013 of 25 June 2013 amending Regulation (EC) No 1451/2007 as regards additional active substances of biocidal products to be examined under the review programme |
| EU 298/2010 | Commission Regulation (EU) No 298/2010 of 9 April 2010 amending Regulation (EC) No 1451/2007 as regards the extension of the duration of derogations allowing the placing of biocidal products on the market |
| 2032/2003/EC | Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, and amending Regulation (EC) No 1896/2000 |

1 Introduction

1.1 Aim

The aim of this guidance document is to provide an overview of the procedures for evaluation and decision making for active substances in biocidal products and treated articles at EU-level. Furthermore, the guidance describes which registration data is available from different information sources at EU-level, and how this data can be found. The guidance has primarily been compiled for evaluators and decision makers in biocide registration processes worldwide.

It should, however, be emphasized that each country should assess such information against the specific agronomic, social, and environmental conditions of their country. This document is not intended to provide guidance on national decision making during registration processes.

In order to further illustrate what type of public information can be found in the EU documentation, examples for some selected substances are provided in Appendix 1 to this document.

1.2 International Code of Conduct on Pesticide Management

The International Code of Conduct on Pesticide Management provides a framework for pesticide management for all public and private entities engaged in, or associated with production, regulation and management of pesticides. The term pesticides in this framework encompasses a number of biocides, yet not all biocides.

The latest revision of the Code of Conduct on Pesticide Management was adopted by the Food and Agriculture Organisation of the United Nations (FAO) in June 2013 and endorsed by the World Health Organization (WHO) in January 2014. The Code provides standards of conduct and serves as a point of reference in relation to sound pesticide life cycle management practices, in particular for government authorities and the pesticide industry. The Code of Conduct is supported by technical guidelines that are developed by a FAO/WHO Joint Meeting on Pesticide Management (JMPM).

Regarding the regulatory control of all pesticides, the Code of Conduct states: *(box excerpt)*

6.1 Governments should: ...

6.1.4 establish pesticide registration schemes and infrastructures under which each pesticide product is registered before it can be made available for use;

6.1.5 conduct risk evaluations and make risk management decisions based on all relevant available data and information, as part of the pesticide registration process;

...

Furthermore, is noted that authorities should, if possible, make use of already existing information. The Code of Conduct states: *(box excerpt)*

9.1 Governments should:

9.1.1 promote the establishment or strengthening of networks for information exchange on pesticides and IPM/IVM through national institutions, international, regional and sub-regional organizations and public interest groups;

9.1.2 facilitate the exchange of information between regulatory and implementing authorities to strengthen cooperation.

9.2 In addition, Governments are encouraged to develop:

9.2.1 legislation that permits and regulations to permit information exchange to the public about pesticide risks and benefits as well as to facilitate the participation of the public in the management of pesticides in the country. ...

Risk assessment is a complex process that requires significant human and financial resources. Advanced risk assessment procedures are in place in most developed countries. The European Union established a common registration scheme, which enables extensive and thorough risk assessment by sharing the burden among all Member States. As a result, the EU has one of the most comprehensive risk assessment procedures for biocides, which makes the EU a valuable source of information for countries with limited resources.

1.3 Scope and limitations

This guidance covers EU information for active substances used in biocidal products and treated articles that hereafter are referred to as *biocides*. The process for establishment of EU harmonised maximum residue levels (MRL) for food and feed is not described. Neither does the document contain details on how to conduct risk assessments for human health (operators, bystanders, and consumers) or the environment (air, water, soil, and non-target organisms). Information related to other products and uses (e.g. plant protection products⁴, cosmetics), and information from regions outside the EU is not included.

1.4 Computer software specifications

The software used on this PC to compile this guidance document consisted of Microsoft Office Professional edition for Windows 7, in specific Word, Excel, PowerPoint, and Windows 7 Paint. The used web browser was Internet Explorer 10, version 10.0.18. Note that when using other browser software the shown pages may not look quite like you see them in this document. The opening of PDF-files is done with Adobe Reader XI. Adobe Reader or other PDF-reading software can usually be downloaded for free from the Internet (freeware or shareware).

2 EU-procedures - Active substances

2.1 Background

Since late 1990's, active substances in biocides are evaluated at EU level according to harmonised data requirements, criteria, and guidance documents. The current evaluation process and criteria can be found in Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. The regulation entered into force 1 September 2013, and replaces the previous Biocidal Products Directive (98/8/EC) from 1998. The scope of the regulation has been extended compared to the directive, to cover articles and materials treated with biocidal products (treated articles), including furniture and textiles. The

⁴ A guidance document similar to this one is available for plant protection products, published by the Swedish Chemicals Agency in 2014. Titled: Practical guidance on how to access information from the EU pesticide registration process.

regulation also applies to active substances generated *in situ*, and to biocidal products used in materials that come into contact with food (e.g. food cans).

A decision on approval or non-approval of active substances is taken at EU level, and becomes binding for all Member States. The registration of formulated products is done at member-state level and can thus vary from country to country, as long as it is in compliance with the decisions regarding the active substances taken at EU level. The decision making consists of a mixture of scientific facts, agreed interpretations, and criteria for what is agreed as “acceptable risk” at the time of decision.

At the adoption of the Biocidal Products Directive (98/8/EC) a list of all active substances in biocides on the EU market was drawn up⁵. For substances on the list a dossier had to be submitted by industry in order to review these substances; otherwise they substances were not to be placed on the market any more. This initially resulted in a large reduction of the number of active substances allowed in biocides within EU. Around 70 % of the original 900 active substances have been withdrawn from use, either due to high risks, lack of support by industry, or an incomplete dossier.

At the publication date for this report (2015) only 74 out of the 372 notified substances are approved. A few non-approval decisions have been made. This means that the evaluation of active substances is far from completed to this date. In 2010 and 2013, extensions of the review programme were anticipated, the latest until 2024. From 2014 onward the European Chemicals Agency (ECHA) is in charge of planning and coordinating the review efforts. Until 2013 it was the task of the EU Joint Research Centre, Institute for Health and Consumer Protection.

Since the review programme will be ongoing for a long time, certain exceptions to the principle of EU approved active substances are allowed. For example, active substances under the review programme as well as biocidal products containing these active substances can be placed on the market while awaiting the final decision on the approval by the EU. Provisional product authorisations for new active substances that are still under assessment are also allowed on the market.

2.2 Biocidal product types

Biocides are classified into 22 biocidal product-types, grouped in four main areas⁶. Active substances should be authorised product-type specifically. Therefore it is always necessary to check for the specific product-type information of each active substance.

⁵ The review programme is a Commission work programme for reviewing all existing biocidal active substances. The programme was set up under the Biocidal Products Directive and continues under the Biocidal Products Regulation. Substances which were on the market before 14 May 2000 and are evaluated under the review programme are referred to as existing active substances.

⁶ Annex V of the Biocidal Products Regulation EU 528/2012

2.3 Evaluation procedure for active substances

The evaluation procedure is initiated by an application from a company or group of companies (i.e. applicant) who wishes to place an active substance on the EU market. The application involves submission of a dossier with all the required data regarding the active substance, data for a representative formulation and its intended uses (e.g. concentrations, target pests, dose levels), which then will be the focus of the risk assessment. The application is submitted to ECHA, and after ECHA completeness check/approval forwarded to an evaluating Member State (eMS)⁷.

During the evaluation process, the hazard profile of the active substance is assessed. A risk assessment, based on the intended use of the pesticide, is performed with respect to human health (consumers, operators, and bystanders) and the environment (e.g. groundwater and non-target organisms, such as birds, mammals and bees). A number of guidance documents on different areas (dermal absorption, risk assessment for birds and mammals, aquatic ecotoxicology etc.) are applied.

Active substances are initially approved for a maximum of 10 years⁸. The extent of the approval period is given in the approval decision. After that period, a review has to be performed and a new decision as to whether to renew the approval of the active substance or not will be made.

2.4 Institutions involved in the risk assessment

2.4.1 Evaluation by evaluating Competent Authority

One eCA is assigned for each active substance. This is a Competent Authority that evaluates the applicant's dossier and prepares a *Competent Authority Report (CAR, see section 2.4.2.1)* containing a summary of evaluated studies and a risk assessment for a representative biocidal product containing the active substance with one or more intended uses in the intended product-type category.

When the evaluation has been finalized, the ECA submits the draft CAR to the ECHA for peer review and decision making.

2.4.2 Assessment reports of active substances

In accordance with Article 16 of Regulation (EC) 1451/2007, the competent authority reports concerning the evaluation of active substances in the review programme shall be made publicly available by electronic means, except for information that is to be treated as confidential. The public reports, as they become available, are posted on EU CIRCABC (See section 4.13).

⁷ After the transfer of duties for the biocidal product authorisation process within the EU from the Commission (JRC-ISPRa) to ECHA, the ECA is also referred to as the "evaluating member state" (eMS)

⁸ According to the Biocidal Products Regulation EU 528/2012, article 12(3).

2.4.2.1 Competent Authority Reports

The pre-Biocidal Products Regulation 528/2012 assessment reports of active substances for biocidal product types were called Competent Authority Reports. These encompassed both draft and final versions. After the 1 September 2013, under the BPR, these reports are referred to as the active substance assessment reports.

2.4.2.1.1 Draft CAR

This section describes the draft competent authority reports (CARs) submitted within the framework of the review programme of existing substances. Reports are grouped by product-type. The draft CAR constitutes the basis for organizing subsequent discussions. In many cases the draft document is amended significantly before the definitive and final version of the CAR is agreed and a final decision is taken concerning the approval of the substance. The draft CARs found on the public CIRCABC website (Library>Review programme>draft CARs>) are made available in the interests of transparency, but given the provisional nature of these documents, readers should exercise caution in using the information contained therein.

2.4.2.1.2 Final CAR

The final, by EU Member States agreed version of the CAR is used for decision making about the approval of the active substance/product-type. This document also contains the most important chemical, biological, and physical characteristics of the active substance. In the final CAR a list of endpoints is published. These endpoints are agreed by all Member States to be used for biocidal product risk evaluation. In case a final CAR is publicly available through EU CIRCABC website, this should always be used instead of a draft CAR.

2.4.3 Review by ECHA Biocidal Products Committee

ECHA, through the Biocidal Products Committee (BPC), is responsible for peer review of the assessment report that has been prepared by the ECA. ECHA organises consultation meetings with experts from other Member States before delivering to the Commission the outcome in an opinion (see section 4.9 on how to find it) containing the conclusion of the validated ECA evaluation. The validation process and its conclusions are based on current guidance documents and agreed criteria for risk assessment.

2.4.4 Decision by the European Commission

The Commission is responsible for the legal aspects of the decision⁹ process. After a member state vote on the approval of an active substance, the decision is published in the Official Journal of the European Union, of which the paper version is legally binding (See section 2.7).

2.5 Classification and labelling

Regulation (EC) No 1272/2008 is the regulation for classification, labelling and packaging of substances and mixtures in the EU and is referred to as the CLP Regulation. The criteria for classification and labelling of active substances are based on the United Nations' Globally Harmonised System (GHS).

⁹ A decision only deals with a particular issue and specifically mentioned persons or organisations.

The classification is harmonised and made obligatory at EU level for all active substances in biocides to ensure an adequate risk management throughout the European Community. Active substances used in biocides are therefore subject both to evaluation under the biocides regulation and to harmonised classification and labelling under the CLP regulation.

Before the CLP regulation entered into force in 2009, classification and labelling of substances was already harmonised at EU level in accordance with EU substance (67/548/EEC) and preparations (1999/45/EC) directives. The system was similar to GHS but used slightly different criteria. Annex VII of the CLP regulation (see EUR-Lex, section 4.12) includes a translation table for classification under Directive 67/548/EEC to classification under the CLP regulation.

2.6 Maximum residue level

The amounts of biocide residues in food must be below established limits deemed safe for consumers, and must be as low as possible. EU Regulations harmonise biocides maximum residue levels (MRL) taking into account the safety of all consumers, including vulnerable groups, such as babies, children, women in childbearing age, and vegetarians. The residue levels of biocides in products are critical for assessing risk to consumers. A maximum residue level (MRL) is the highest level of a residue that is legally tolerated in or on food or feed. A default MRL of 0.01 mg/kg body weight applies where an assessment is not available.

The MRLs for authorised active substances for use in biocides can be found in the product assessment reports for the active substance/product-type combination products. Note that this information is only published in case the use pattern of the biocidal product may lead to contamination or exposure of food and feed resources.

2.7 Decision making

Based on the ECHA BPC evaluation report, the European Commission drafts a proposal for decision on the active substance. The draft decision will either propose to approve the active substance (with possible restrictions) or not approve the active substance (with possible phase out periods for products already on the EU market).

A Standing Committee, in which all EU Member States are represented, votes on the proposed decision. Political positions and the need for the active substance in the different MS may affect the outcome of the voting. The outcome is then formalised by the Commission in a *directive for approval* of the active substance *or a decision for non-approval*.

2.7.1 Approval

The condition for approval of an active substance is that the risk assessment has shown that a representative biocidal product containing the active substance (with one or several intended uses) has “acceptable risks¹⁰” concerning human health and the environment in at least one Member State. The approval may include extensive risk mitigation measures. Areas that

¹⁰ Risks are evaluated according to mutually agreed EU guidelines and principles.

require extensive risk mitigation measures are indicated in the ECHA opinion and in the ECA assessment report.

In certain cases where the data is not complete, it might still be possible to conditionally approve an active substance without a full risk assessment. If it is anticipated that availability of the missing data would not alter the acceptable risk status, the active substance could be approved on the condition that the missing information is provided within a specified period of time. In these cases, the company applying for approval of the active substance must complete the dossier with “confirmatory data”, i.e. the studies required for a complete risk assessment to be performed, within a certain amount of time. Such requirements are listed under “Specific provisions” in the directive for approval and are referred to in the review report under the heading “Requirements for further information”.

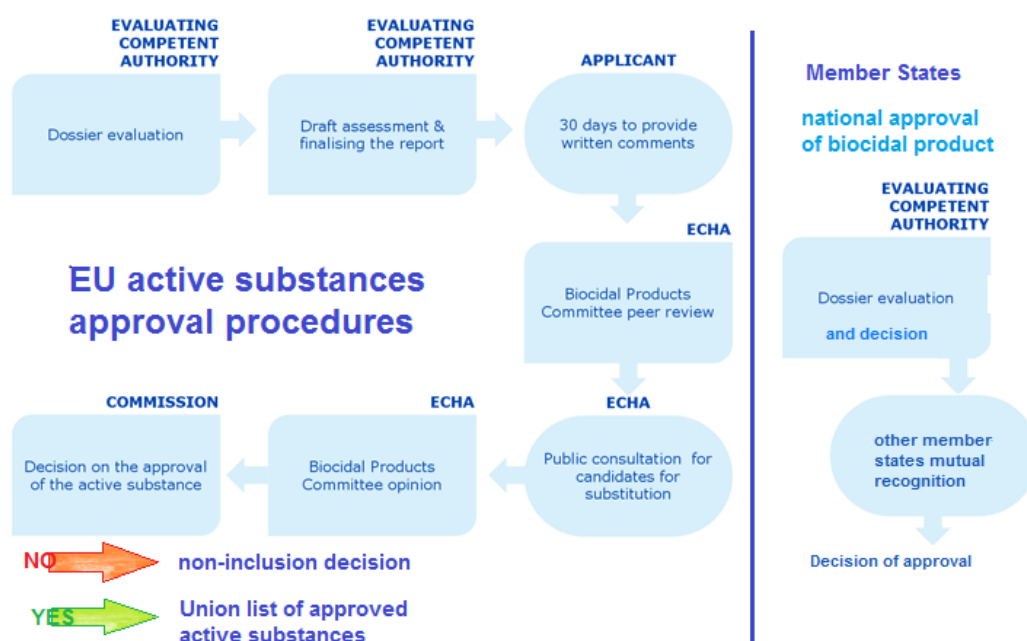


Figure 1 - General procedure for review of an active substance at EU-level and authorisation of a product at the national level. These procedures are repeated in 10 year cycles in order to take new scientific information into account. While the overall responsibility for decision making and providing the public with documentation rests with the European Commission, all the practical details about the review process are the responsibility of ECHA since 2014.

2.7.2 Non-approval

Active substances will not be approved if the risk assessment shows that the representative product cannot be used without “unacceptable risks” to human health and/or the environment.

Another ground for non-approval is withdrawal of the substance from the review process by the applicant. This may happen due to knowledge of “unacceptable risks” or large data gaps. For most of the substances that have been withdrawn no detailed reports are available, only a Commission decision. Non-approval does not imply that the substance is permanently prohibited for use in biocides in EU. There is, in most cases, a possibility to re-apply for

approval of an active substance and submit new data. However, for substances with high risks this rarely happens.

Table 1: Description of the scope, content and owner of the information generated during the EU review process for active substances in biocides.

| Document | Owner | Content/scope |
|---|-------|--|
| CAR (<i>similar to DAR for PPP</i>) | ECA | A product-type specific evaluation, peer-reviewed by other MS, presented as 1) A hazard assessment of the active substance, areas evaluated : - Identity and physical/chemical properties - Classification and proposed labelling - Fate and behaviour in the environment - Ecotoxicology - Mammalian (human) toxicology - Residues and analytical methods 2) Intended uses and efficacy 3) A risk assessment for one product with one or more intended uses. 4) A list of endpoints |
| ECHA BPC opinion (<i>similar to EFSA conclusion report for PPP</i>) | ECHA | Conclusion on the peer review of the active substance, the product and its intended use(s) and the "List of end point" which should be used when carrying out risk assessments for products at MS level. |
| Directive /Implementing Regulation | COM | Legal document for approved active substances. Contains e.g. Purity • Specific provisions • Confirmatory data |
| Decision | COM | Legal document for non-approved active substances. Containing details about withdrawal, and periods of grace for products on the EU-market. |

3 National procedures - Biocidal products

Member States Competent Authorities can only authorise biocidal products containing active substances that are approved at EU level or are under review in the EU review programme for the specific product type. Each applicant should conduct¹¹ a risk assessment for the proposed uses of the concerned product. These uses can nationally be extended to uses other than those assessed at EU-level, unless a restriction is decided at EU-level.

For some kinds of product authorisation the evaluation of applications is either done by Member State Competent Authorities or by ECHA. The latter is that of Union Authorisation; a single decision that is valid in all Member States.

¹¹ The applicant is the party responsible for conducting the risk assessment. Upon receiving the documentation from the applicant, the Member State Competent Authority should check compliance with valid regulations and international agreements.

3.1 Risk assessment

The risk assessment of biocidal products is harmonised at EU-level with regard to data requirements, criteria and guidance documents. Decision-making is done at the national level, with the possibility to take certain national conditions into account (such as climatic and geological conditions).

When performing the risk assessment, all Member States should use agreed values for endpoints, and reference values that are stated in the "list of endpoints". E.g. AOEL, ADI, dermal absorption, rate of degradation in soil, water, and air, toxicity to aquatic organisms.

The authorisation of biocidal products is limited to a maximum of 10 years¹² and may include possible restrictions on the usage of the product.

3.2 Data protection

The EU regulation provides a possibility for Member States to grant a so called 'data protection' to the applicant. This means that the proprietary right of data is recognized to prevent that specific data submitted by the applicant concerned can also be used for the benefit of other applicants. Data protection is usually granted for a period of 10 years. More information is available at the ECHA regulations website (see section 4.9 in this document).

3.3 ECHA Register for biocidal products

ECHA, responsible party for the processing and administration of biocidal product authorisations of all MS, has set up a database and created tools for authorisation management concerning biocidal products. The database is to be used by ECHA, applicants and Competent Authorities in the authorisation process. It is called R4BP3, and the public site is available on the Internet to show authorised biocidal products. It is found at:

<http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-products>

And looks like this:

The screenshot shows the ECHA R4BP3 Biocidal Products search interface. At the top, the breadcrumb navigation reads "ECHA > Information on Chemicals > Biocidal Products". Below this, the title "Biocidal Products" is displayed. The search filter section includes the text "R4BP3" and a description: "The search filter below allows you to search those products authorisations in accordance with Directive 98/8/EC (The Biocidal Products Directive) and Regulation (EU) No 528/2012 (The Biocidal Products Regulation) which are available in the R4BP3 IT system." Below this, it states "Last updated 12 May 2014. List contains 3155 authorised biocidal products." The search form consists of two columns of input fields. The left column includes: Product Name, Asset Number, Type (with a dropdown arrow), National Identifier, Authorising Member State (with a dropdown arrow), and Start of Authorisation (with a red 'X' icon). The right column includes: Active Substance Name, Active Substance EC Number, Active Substance CAS Number, Active Substance Approval ID, and Start of Authorisation (with a red 'X' icon).

¹² According to Biocidal Products Regulation EU 528/2012 article 17(4).

4 How to find EU Biocides information

4.1 Overview

As pointed out earlier in this document, several options are possible for the present status of an active substance designated for use in biocides on the EU market. Active substances are either approved as regular biocidal active substances (on Union list), or as approved substances of low concern (placed on Annex I to BPR), or are still under evaluation in the EU review programme. When none of the above mentioned circumstances are true, the active substance has either not been notified to the Commission for its biocidal use, or a valid decision for non-inclusion has been made for the substance. In the following sections, these specific conditions are described in more details. It is shown how to find the present status of a prospective active substance from the publicly available resources on the Internet (diagram A) and specific conditions set for those active substances that are included in the EU biocides system (diagram B).

Diagram A - Flowchart projection for finding the present status of a specific active substance in the EU system for biocides evaluation and authorisation. In case none of the specified options are answered with a YES, the active substance must be seen as a new active substance, and therefore no further information for this substance is available from the EU-system.

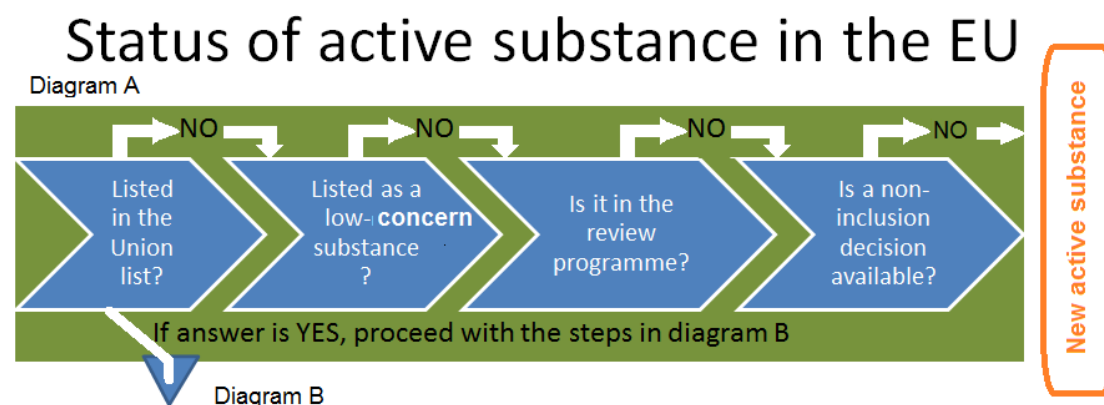


Diagram B - Flowchart projection for finding further details for active substances included in the EU system for biocides evaluation and authorisation in a step-wise sequence.

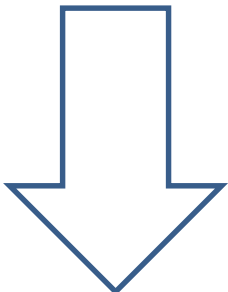

Diagram B



4.2 Finders guide table

In the following table the most important sources for principal information on biocides active substances are listed. A tick mark (✓) indicates that this kind of information is available.

Table 2: An overview of the most important types of biocides information and where they are located.

| Information  | Legal text Decision | Legal text Other | Union list approved a.s. | Assessment Report by ECA for a.s./PT set | Consolidated listing of non-inclusion decisions | Classification and labelling data | Consolidated listing of a.s./PT combinations part of the EU review programme | ECHA Opinion about a.s. inclusion/approval |
|---|-------------------------------|------------------|-------------------------------------|---|---|-----------------------------------|--|--|
| Found where?  | EUR-Lex ¹³ website | EUR-Lex website | ECHA biocides website ¹⁴ | EU documents CIRCABC ¹⁵ public | COM-ENV Biocides ¹⁶ website | ECHA C&L database ¹⁷ | EUR-Lex website | ECHA Regulation website ¹⁸ |
| Status of a.s. in EU | ✓ | | ✓ | ✓ | ✓ | | ✓ | |
| Decision approval | ✓ | | ✓ | | | | | |
| Decision date | ✓ | | ✓ | | | | | |
| Date of expiry | ✓ | | ✓ | | | | | |
| Legal Act No. | ✓ | | ✓ | | | | | |
| Decision data protection | | ✓ | | ✓ | | | | ✓ |
| Identity of RMS/eMS | | | ✓ | ✓ | | | | ✓ |
| Product restrictions | ✓ | | | ✓ | | | | ✓ |
| Dossier owner/applicant identifier | | | | ✓ | | | ✓ | ✓ |
| Maximum Residue Level in food and feed | | ✓ | | ✓ | | | | ✓ |

¹³ For information on how to find EUR-Lex see section 4.12 in this document

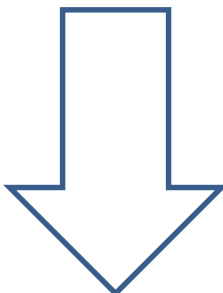
¹⁴ For information on how to find the ECHA Biocides website see section 4.10 in this document

¹⁵ Find CIRCABC with the help of section 4.13 in this document

¹⁶ The biocides pages maintained by the COM are found with the help of section 4.11 in this document

¹⁷ For information on how to find the ECHA C&L website see section 4.14 in this document

¹⁸ For information on how to find the ECHA Regulation website see section 4.9 in this document

| Information | Legal text Decision | Legal text Other | Union list approved a.s. | Assessment Report by ECA for a.s./PT set | Consolidated listing of non-inclusion decisions | Classification and labelling data | Consolidated listing of a.s./PT combinations part of the EU review programme | ECHA Opinion about a.s. inclusion/approval |
|---|---------------------|-------------------------------------|--------------------------|--|---|-------------------------------------|--|--|
|  | | | | | | | | |
| Decision non-approval | | <input checked="" type="checkbox"/> | | | <input checked="" type="checkbox"/> | | | |
| Legal Act no. | | <input checked="" type="checkbox"/> | | | <input checked="" type="checkbox"/> | | | |
| Decision date | | <input checked="" type="checkbox"/> | | | | | | |
| Date of final phase-out | | <input checked="" type="checkbox"/> | | | | | | |
| -continued- | | | | | | | | |
| Assessment | | | | | | | | |
| Risks for health and environment | | | | <input checked="" type="checkbox"/> | | | | <input checked="" type="checkbox"/> |
| List of endpoints | | | | <input checked="" type="checkbox"/> | | | | |
| Chemical properties | | | | <input checked="" type="checkbox"/> | | | | |
| Physical characteristics | | | | <input checked="" type="checkbox"/> | | | | |
| Classification by eCA | | | | <input checked="" type="checkbox"/> | | | | |
| Classification agreed by EU | | | | | | <input checked="" type="checkbox"/> | | |
| Proposed labelling products | | | | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> | | |
| Efficacy data products | | | | <input checked="" type="checkbox"/> | | | | <input checked="" type="checkbox"/> |
| Residues and analysis | | | | <input checked="" type="checkbox"/> | | | | |
| Data gaps | | | | <input checked="" type="checkbox"/> | | | | <input checked="" type="checkbox"/> |

4.3 Approved active substances

Check for the active substance in the approved substances list for the intended product-type. This list is called the **Union list of approved active substances**.

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

The public versions of assessment reports and listings are made available via the EU document sharing database EU CIRCABC. See more details about entering and navigating this database under section 4.13.

4.4 Approved substances of low concern

Check if the active substance is a low concern chemical (amended for listing in annex I to BPR for the specific product-type) by looking into the text of the Biocidal Products Regulation Annex I (see section 4.12, EUR-Lex).

4.5 Non-inclusion decisions

Check if a valid non-inclusion decision is available.

All non-inclusion decisions are available on EUR-Lex (see section 4.12 and Example 3, Malathion as a PT18 (Insecticides) - Withdrawal, and Example 4, Naled as a PT18 (Insecticides) – Non-inclusion decision, on how to consult the listing). In accordance with article 4(2) of Regulation 2032/2003, biocidal products containing active substances for which non-inclusion decisions were taken shall be removed from the market within 12 months of the entering into force of such decision; unless otherwise stipulated in the specific non-inclusion decision.

A consolidated list of existing active substances for which a decision of non-inclusion into Annex I or IA of Directive 98/8/EC was adopted is available as a PDF-file on EU CIRCABC (see section 4.13 and examples in Appendix 1 in this document on how to find the consolidated list).

This list contains the dates by which products, containing these active substances, may no longer be placed on the market for the relevant product-types.

4.6 List of substances included in the review programme

Check whether or not the active substance is under review. For this it is easiest to look in the consolidated listing with all the active substance/product-type combinations that are presently under review. This listing can be found in EUR-Lex database (see section 4.12, search for Commission Regulation 1451/2007)

4.7 New active substances

Active substances that are not part of the review programme, not decided upon, nor have been notified to the Commission as such, cannot be used in biocides imported and/or used on the EU market. These new active substances must first be notified to the Commission, and become scrutinised in the review procedure for new active substances. More information about this is found on the Commissions biocides website (see section 4.11). For these active substances no additional information is available from the EU registration process.

4.8 Specific conditions for accepted active substances

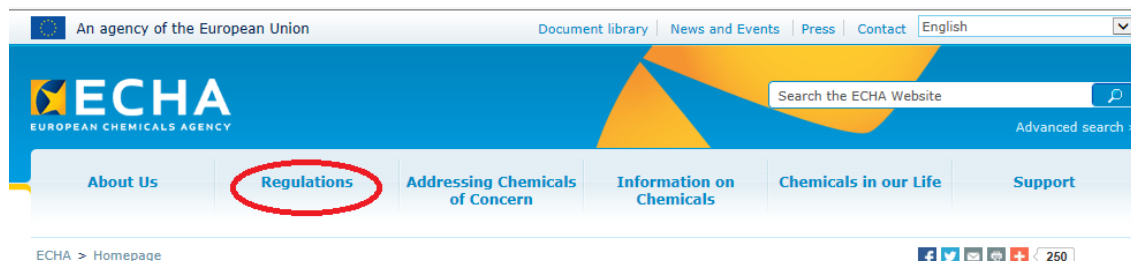
After making sure the active substance you are looking for is somehow part of the approvable set of biocidal active substances (according to Diagram A in section 4.1), it is time to check the specific conditions (data gaps, specific concerns, risk mitigation, etc.) for biocidal active substance approval and their safe use (according to Diagram B in section 4.1).

4.9 EU Biocides Regulation at ECHA

At ECHA it is possible to find background information about the regulatory issues connected to the BPR EU 528/2012. This can be done by going to the ECHA first page.

World-wide website at ECHA (first page): <http://echa.europa.eu/en>

Then choose the main menu item “**Regulations**” (see red circle below)



And the page that opens will look like this:



When clicking on the text link “**Read more**” below the heading Biocidal Products Regulation (see the red arrow), the biocides regulatory page will show, looking like this:

ECHA > Regulations > Biocidal Products Regulation

Biocidal Products Regulation

The Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product.

- > Understanding BPR
- > Legislation

Processes



Companies can apply for the approval or the inclusion in Annex I of an active substance by submitting a dossier to ECHA.

- > Approval of active substances
- > Annex I amendment



After the approval of an active substance, companies wishing to place biocidal products on the market have to apply for product authorisation at national or Union level.

- > Authorisation of biocidal products



Companies can ask ECHA to establish the technical equivalence or the chemical similarity of their active substance.

- > Technical equivalence
- > Chemical similarity check



Manufacturers and importers not involved with the review programme of the previous legislation have to submit certain information to ECHA.

- > Active substances and suppliers



A fundamental and new aspect of the Biocidal Products Regulation is the common obligation to share information about active substances and products approved and authorised in the EU.

- > Data sharing

Choosing the link “Approval of active substances” leads to another menu, where you can choose to see the ECHA Biocidal Products Committees opinions. It looks like this:

EUROPEAN CHEMICALS AGENCY

Advanced search >





About Us | Regulations | Addressing Chemicals of Concern | Information on Chemicals | Chemicals in our Life | Support

ECHA > Regulations > Biocidal Products Regulation > Approval of active substances > BPC opinions on active substance approval

Biocidal Products Committee opinions on active substance approval

The Biocidal Products Committee has issued the following opinions on active substance approval:

Showing 16 results.

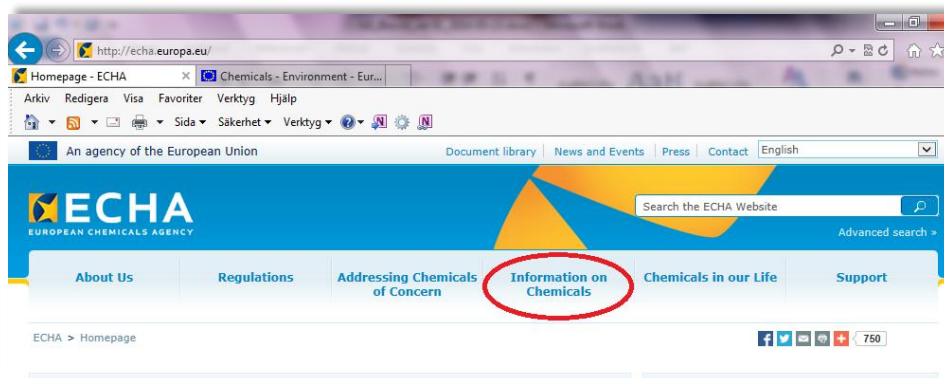
| Active substance | EC Number | CAS Number | Product Type (PT) | BPC Opinion | Date of opinion | BPC minority positions |
|-------------------------------|----------------|----------------|-------------------|---|-----------------|------------------------|
| <i>Bacillus sphaericus</i> | Not applicable | Not applicable | PT 18 |  | 19/06/2014 | |
| <i>Bacillus thuringiensis</i> | Not applicable | Not applicable | PT 18 |  | 19/06/2014 | |
| Alpha-cypermethrin | Not available | 67375-30-8 | PT 18 |  | 17/06/2014 | |
| Carbon dioxide | 204-696-9 | 124-38-9 | PT 15 |  | 17/06/2014 | |

By clicking on the linked PDF-image (see small red circle above) the text of the BPC Opinion will open.

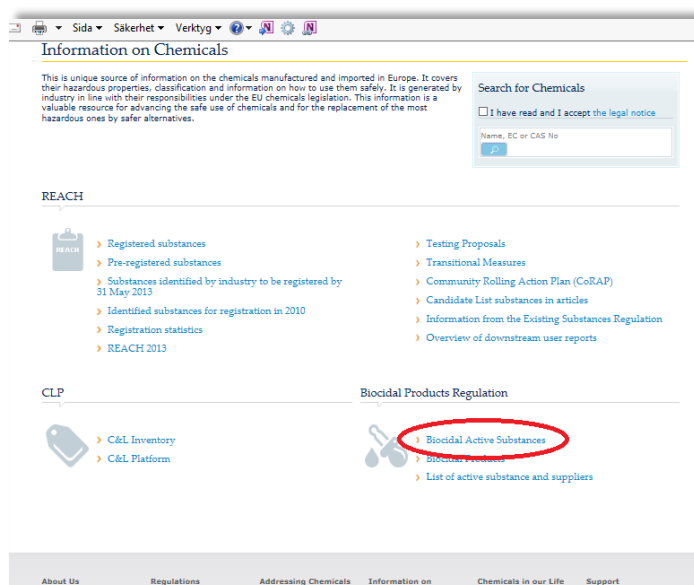
4.10 EU Biocides database at ECHA

The EU Biocides database provides a structured overview of information on all active substances that have been approved for use in biocidal products and treated articles after review. The database, called “**Union list of approved active substances**” is maintained by ECHA and mirrored in a consolidated table by the European Commission, Directorate for the Environment.

World-wide website at ECHA (first page): <http://echa.europa.eu/en>

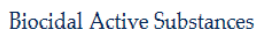


Click on the link marked “**Information on Chemicals**” (see above). Then choose “**Biocidal Active Substances**” under the heading “**Biocidal Products Regulation**” (see red circle below).



What you see then is the search and retrieve template of the **Union list** (see below).

Notice that for active substances approved for biocidal use, the approval always refers to the combination active substance/product-type.



As biocidal active substances are approved, there is an obligation on ECHA to make certain non-confidential data submitted as part of the process of obtaining the approval available. Please be aware that ECHA does not verify the information before dissemination.

Note that the active substance data linked below are the official data sets on which the approval reports are based. Third party active substance data is not yet published but is anticipated to be published in the future.


Last updated 12 May 2014. List contains 64 approved active substances.

| | | | |
|------------------------|----------------------|-------------------------|----------------------|
| EC Number | <input type="text"/> | CAS Number | <input type="text"/> |
| Substance Name | <input type="text"/> | Rapporteur Member State | <input type="text"/> |
| Type | <input type="text"/> | Legislative act | <input type="text"/> |
| Date of approval (min) | <input type="text"/> | Date of approval (max) | <input type="text"/> |
| Expiry Date (min) | <input type="text"/> | Expiry Date (max) | <input type="text"/> |

From the links in the Union list on “current legal documents” you are redirected into the EUR-Lex database (see section 4.12).

A lot of details on the topic of biocides are available at the biocides pages of the Commission:

[A to Z](#) | [About this site](#) | [Contact](#) | [FAQ](#) | [Sitemap](#) | [What's new?](#) | [Search](#) | [Legal notice](#) | [Cookies](#) | [English \(en\)](#)



ENVIRONMENT

[European Commission](#) > [Environment](#) > [Chemicals](#) > [Biocides](#)

[Home](#) | [Who's who](#) | [Policies](#) | [Integration](#) | [Funding](#) | [Law](#) | [Resources](#) | [News & Developments](#)

Chemicals Home

[REACH](#)


[Classification and labelling](#)

Biocides

- [Introduction](#)
- [Regulation](#)
- [Active substances](#)
- [Biocidal products](#)
- [Treated articles](#)
- [ECHA](#)
- [Related legislation](#)
- [Directive 98/8/EC](#)







[Endocrine disruptors](#)

[Nanomaterials](#)




Introduction

Biocides are chemicals used to suppress organisms that are harmful to human or animal health, or that cause damage to natural or manufactured materials. These harmful organisms include pests and germs (i.e. moulds and bacteria). Examples of biocidal products are insect repellents, disinfectants and industrial chemicals like anti-fouling paints for ships and material preservatives.

NEWS

LINKS



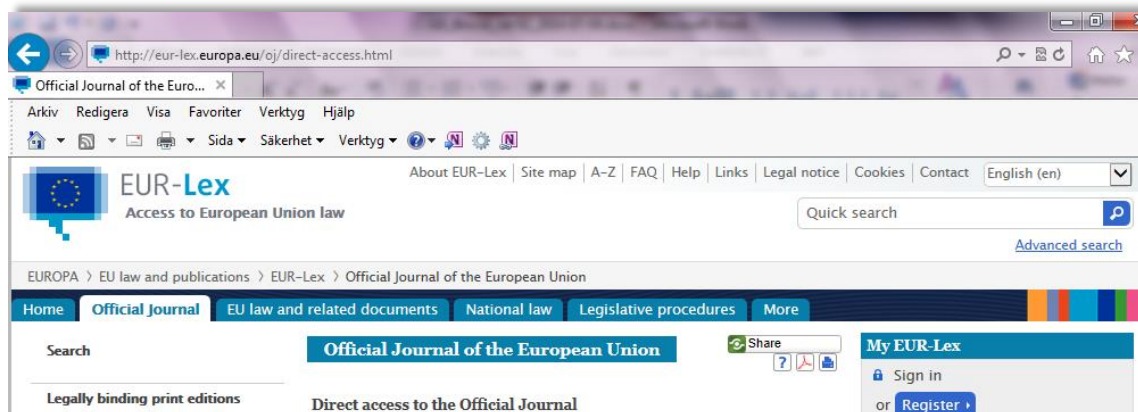
REACH

BIOCIDES

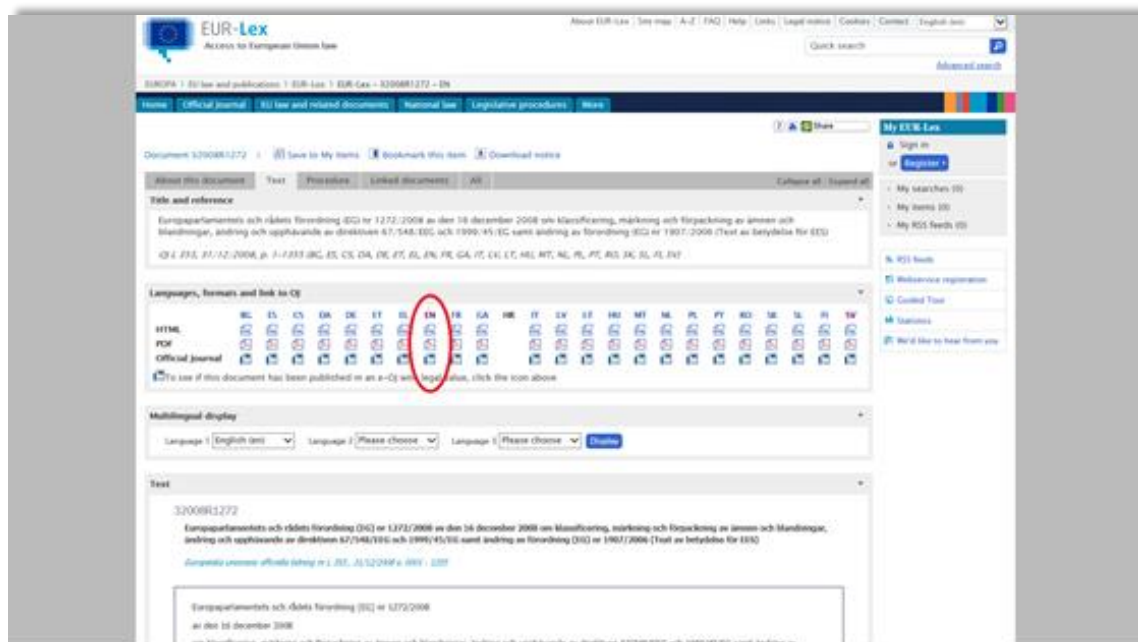
4.12 EUR-Lex database for all EU legislation

All the EU laws and other public EU documents and the authentic electronic Official Journal of the EU – in 24 languages, are made available through EUR-Lex database. **Note** that for the public site, sign in registration is not necessary!

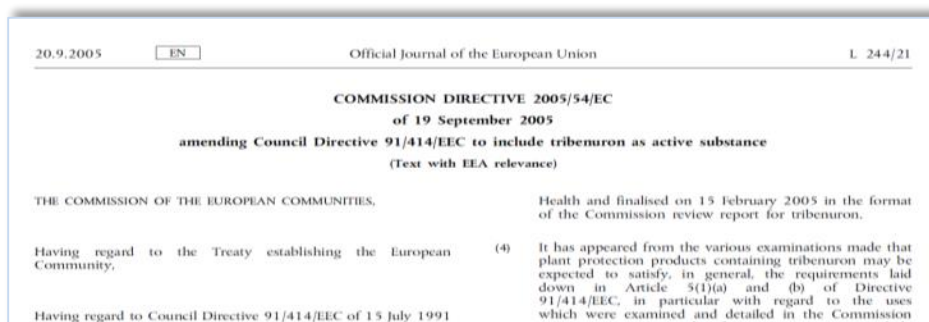
World-wide web (EUR-Lex first page): <http://eur-lex.europa.eu/oj/direct-access.html>



To see the current Legislation, with the formal registration decision, click on the links after “**current legislation**”. Then choose your language and click on preferred format. See the red circle below pointing at the English versions of the particular document. Sometimes it helps narrowing down the search to the year of publication for the document you are searching for.



Clicking on the preferred link will open the electronic version of the particular document. It may look like this:



Note that it is the paper version of this official Journal publication that is the legally binding document.

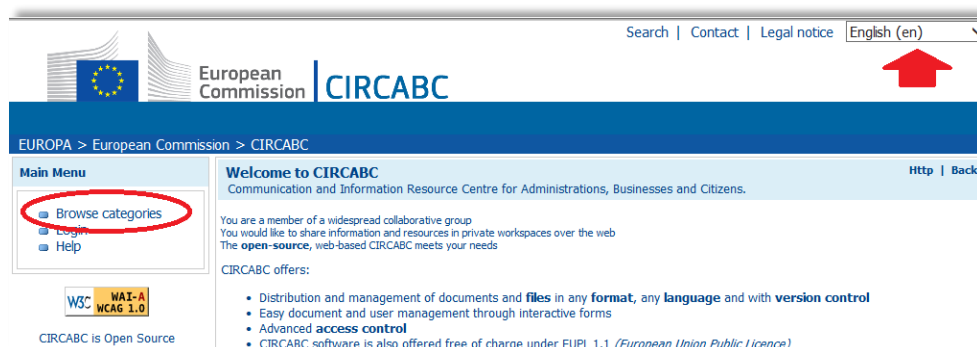
4.13 European Commission document database CIRCABC

The public site of the European Commission document database can be found at

World-wide website: <https://circabc.europa.eu>

Note that for the public site, sign in registration is not necessary!

To find the specific documents first choose language “English (en)” in the upper right-hand corner. You can also choose another language, but the examples here are from the English versions only.



Then, click on the “**Browse categories**” link in the left hand **Main menu** (see above). This opens a listing of different categories and topics. Scroll down to the “**European Commission**” category, and choose the topic “**Health and Food Safety**”. The page showing looks like this:

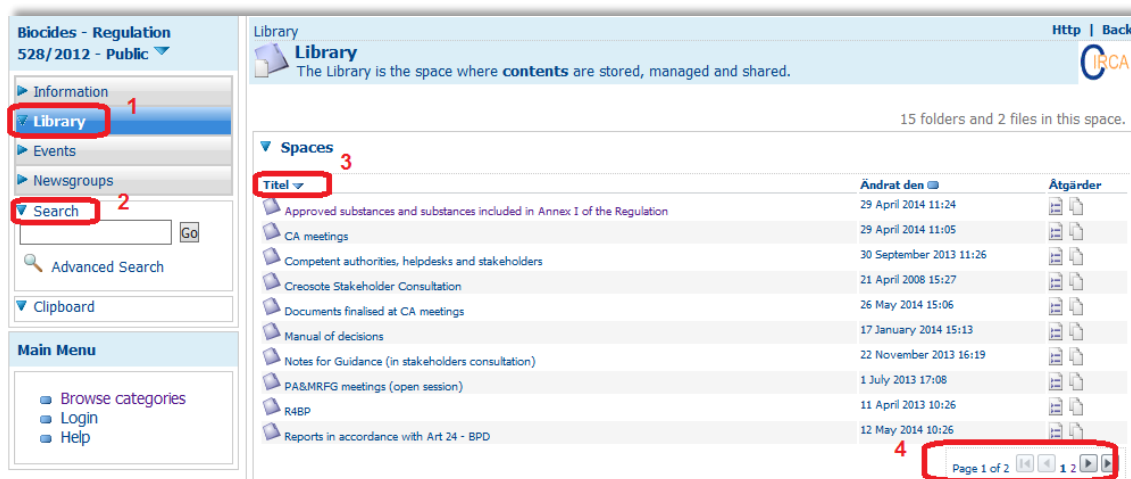


Scroll down the page to find the **Public Access** topic “**Biocides – Regulation 528/2012 – Public**” and click on this text link. Upon which the following page shows (BPR – Public):



Choose the Category “**Library**” in the Main menu on the left (see red circle above).

Here, a listing of the document types in this public domain (Library, red box 1) of the Biocides database shows. Notice that from this page you can perform a global search (see red box no 2) to find specific documents sorted by title (called “Spaces” – red box no 3), or flip through the different pages with contents (see page block no 4 in lower right-hand corner).



4.14 ECHA CLP information

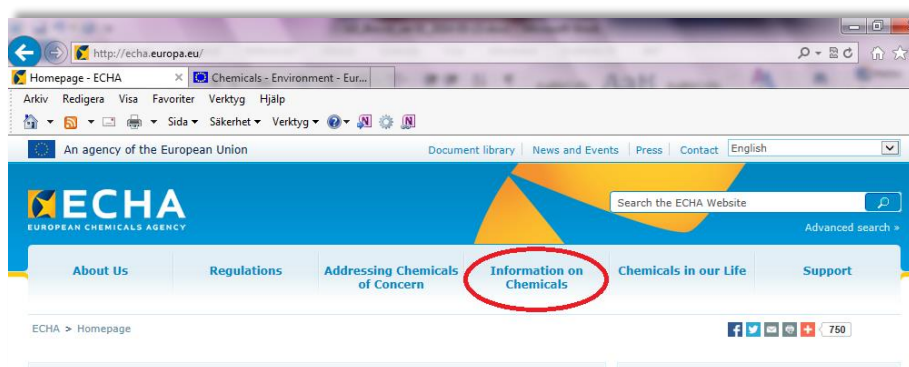
ECHA is responsible for the systematic processing of biocidal data, and also for maintaining a Classification & Labelling Inventory. Find the ECHA C&L information as shown below.

The C&L Inventory is a database with information on classification and labelling for substances notified under the CLP Regulation. It also contains the list of legally binding harmonised classifications, Annex VI to the CLP Regulation. The C&L Inventory is the best place to find the GHS classification of active substances in biocides, as far as these are yet available.

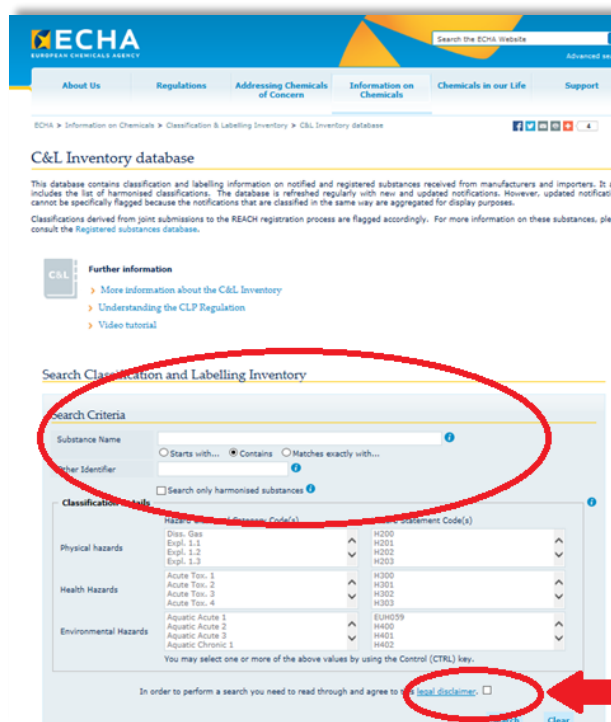
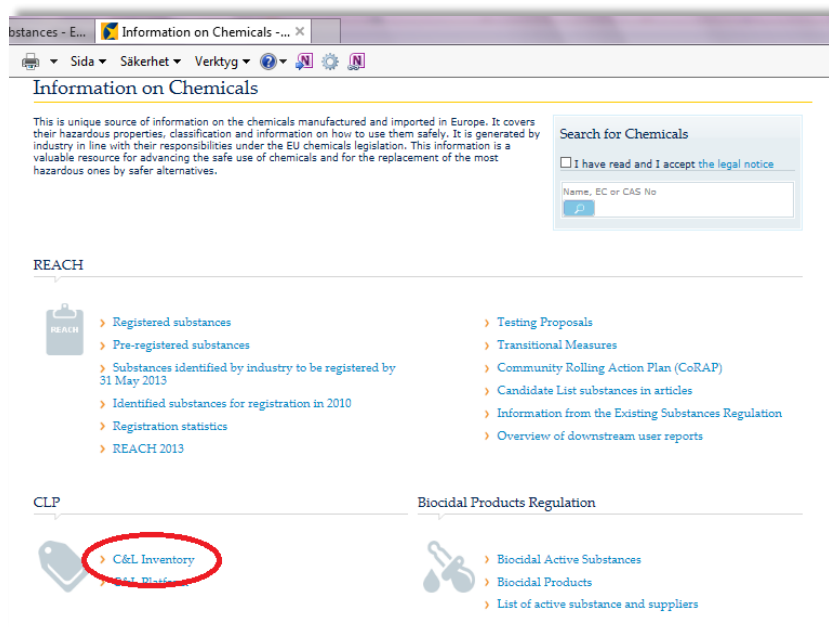
The C&L Inventory provides multiple search options based on both substance identity and classification. A user can search using the full or partial EC name, the CLP Annex VI Index name and IUPAC name.

World-wide web (ECHA first page): <http://echa.europa.eu/en>

From the main page, choose “**Information on Chemicals**” (see red circle below).



Choose “**C&L Inventory**” (See red circle below) to enter the database search form.



From the search form do as follows:

- Type the name of the substance or other identifier
- Note that the box legal disclaimer must be ticked (at the red arrow)
- Click on **Search**
- Then click on **View**
-

Example of classification and labelling, result:

Summary Of Classification and Labelling

Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

General Information

| EC Number | CAS Number | Index Number | International Chemical Identification |
|-----------|-------------|--------------|--|
| 401-190-1 | 101200-48-0 | 607-177-00-9 | tribenuron-methyl (190) 2-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)methylcarbamoylsulfamoylbenzoic acid methyl ester methyl 2-(2-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-3-methylureidosulfonyl)benzoate |

ATP Inserted / Updated: CLP06/ATP01
CLP Classification (Table 3.1)

| Classification | | | Labelling | | Specific Concentration Limits, M-Factors | Notes |
|------------------------------------|---------------------------|---------------------------|---|----------------------------------|--|-------|
| Hazard Class and Category Code (x) | Hazard Statement Code (x) | Hazard Statement Code (x) | Supplementary Hazard Statement Code (x) | Pictograms, Signal Word Code (x) | | |
| Skin Sens. 1 | H317 | H317 | | GH507 GH509 Wng | M=100 | |
| Aquatic Acute 1 | H400 | | | | | |
| Aquatic Chronic 1 | H410 | H410 | | | | |

Signal Words

Warning

Pictograms

Exclamation mark

Environment

DSD Classification (Table 3.2) and Seveso II Data

| Classification | Risk Phrases | Safety Phrases | Indication of danger | Concentration Limits | |
|------------------|--------------|-----------------------------------|----------------------|------------------------|----------------|
| | | | | Concentration | Classification |
| R43 N; R50-53 | 43 50/53 | (2) 24 37 46 60 61 | Xi N | C ≥ 0.25 % | N; R50-53 |
| | | | | 0.025 % ≤ C < 0.25 % | N; R51-53 |
| | | | | 0.0025 % ≤ C < 0.025 % | R52-53 |

Seveso Data

| Seveso Substance | Main Seveso Category | Other Seveso Categories | Seveso Concentration | Categories |
|------------------|----------------------|-------------------------|----------------------|------------|
| No | - | - | - | - |

As information is made available, it will be added to the ECHA database. For those substances that are not yet available here, an inventory of older C&L is given in the assessment report for the specific active substance/product-type combination (see Example 2, Difenacoum as a PT14 (Rodenticides) – Extensive risk mitigation, and Example 6, Propiconazole as a PT8 (wood protection products) – Substitution candidate, in Appendix 1 to this document).

Appendix 1 - Examples

The examples given below are intended to show in more detail where and which type of information can be found in the EU documentation. The aim is, however, not to give a complete guidance on how the information can be used for decision making. In order to base a decision on this information, national considerations need to be taken into account.

The following examples show relevant documents and text, applied in a stepwise assessment procedure, following the flowcharts (diagrams A and B in section 4.1 of this document).

Example 1, Lauric acid as a PT19 (Repellents/Attractants)

✓ Check status of the active substance in EU

In the EU Union list of approved substances it is possible to see that Lauric acid was approved in 2014 as active substance in product-type 19 biocides in the EU. Search for Product-type 19 active substances and find Lauric acid in the listing (see section 4.10). Note that the box “I have read and I accept the legal notice” must be ticked. Choose “Search” (see the red arrow below).

| Substance Name | EC Number | CAS Number | Type | Legislative act | Date of approval | Expiry date | Rapporteur Member State | Data | Related authorised products |
|----------------|-----------|------------|---------------------------------|-----------------|------------------|-------------|-------------------------|------|-----------------------------|
| Lauric acid | 205-582-1 | 143-07-7 | 19 - Repellents and attractants | 405/2014 | | | DE | | |

Showing 1 result.

The substances are listed in alphabetical order. Here you can normally find the dates of approval and expiration of the approval, the ECA (Germany), EC and CAS numbers, and the linked legislative act of the approval decision by the Commission. This link will redirect to the EUR-Lex database site for the proper document (see section 4.12). As the decision is quite new, the details for the dates of the decision and the date of expiry haven't yet been added to the dataset (see the former picture). Opening the decision PDF-file, it will look like below.

L 121/8

EN

Official Journal of the European Union

24.4.2014

COMMISSION IMPLEMENTING REGULATION (EU) No 405/2014

of 23 April 2014

approving lauric acid as an existing active substance for use in biocidal products for product-type 19

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


















Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1451/2007 ⁽²⁾ establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the

✓ **Check comparability (e.g. use, identity) in EU to the actual use or identity in your region or country**

Go to the CIRCABC homepage and download the Lauric acid PT19 assessment report (see section 4.13 on how to do this). Notice that other product types may be available for this substance! The assessment report listing in CIRCABC will look like this.

| | | | | |
|--|--|-----------|------------------------|---|
|  IPBC - PT6 (assessment report as finalised on 27.09.13) | IPBC - PT6 (assessment report as finalised on 27.09.13).pdf | 869,75 KB | 6 November 2013 12:09 |  |
|  IR3535 - PT19 (assessment report as finalised on 13.03.2014) | IR3535 - PT19 (assessment report as finalised on 13.03.2014).pdf | 0,96 MB | 24 July 2014 10:14 |  |
|  K-HDO (assessment report as finalised on 22.02.08) | Final assessment report K-HDO 22.02.2008.pdf | 255,22 KB | 26 August 2008 16:21 |  |
|  Lambda-cyhalothrin (assessment report as finalised on 06.05.11) | Post SCB Lambda cyhalothrin PT 18 111013-cleanfor publ.pdf | 517,93 KB | 15 November 2011 10:15 |  |
|   Lauric acid - PT 19 (assessment report as finalised on 13.03.2014) | Lauric acid - PT 19 (assessment report as finalised on 13.03.2014).pdf | 693,55 KB | 24 July 2014 10:28 |  |
|  Magnesium phosphide (assessment report as finalised on 17.09.09) | Final assessment_report_Mg3P2_18_rev-post SCB.pdf | 410,08 KB | 3 March 2010 16:08 |  |
|  Margosa extract (assessment report as finalised on 09.12.12).pdf | Margosa extract (assessment report as finalised on 09.12.12).pdf | 432,24 KB | 16 August 2012 13:17 |  |
|  Methyl nonyl ketone (assessment report as finalised on 09.12.11) | Methyl nonyl ketone (assessment report as finalised on 09.12.11).pdf | 330,99 KB | 22 August 2013 15:16 |  |

Click on the PDF-link at the red arrow to download/open the PDF-document.

After download of the assessment report the first page will look like below.

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

Evaluation of active substances

Assessment Report



Lauric acid Product-type 19

In this assessment report a listing of various important topics can be found under the heading “**Chapter 3. Decision**” specifically for the following points (see red box).

| | | |
|---|---|-----------|
| 2.2.2.2. | Evaluation of emission due to leaching from treated wood..... | 16 |
| 2.2.2.3. | Risk characterization for the environment..... | 16 |
| 2.2.2.4. | Risk characterization for groundwater used as drinking water..... | 17 |
| 2.2.2.5. | Atmosphere..... | 18 |
| 2.2.2.6. | Risk of secondary poisoning..... | 18 |
| 2.2.2.7. | Waste disposal stage..... | 18 |
| 2.2.3. | List of endpoints..... | 18 |
| 3. | DECISION..... | 18 |
| 3.1. | BACKGROUND TO THE DECISION..... | 18 |
| 3.2. | DECISION REGARDING INCLUSION IN ANNEX I..... | 19 |
| 3.3. | ELEMENTS TO BE TAKEN INTO ACCOUNT BY MEMBER STATES WHEN AUTHORISING PRODUCTS..... | 20 |
| 3.4. | REQUIREMENT FOR FURTHER INFORMATION..... | 21 |
| 3.5. | UPDATING THIS ASSESSMENT REPORT..... | 21 |
| APPENDIX I: LIST OF END POINTS | | 22 |
| CHAPTER 1: IDENTITY, PHYSICAL AND CHEMICAL PROPERTIES, CLASSIFICATION AND | | |

✓ **Check areas of concern and classification**

Information on which areas need to be considered in particular for the national authorisation of products with this active substance, i.e. areas for which risk mitigation measures might be needed, can be found in chapter 3 of the assessment report. The European Commission gives the following message to the Member States in the assessment report under the heading “**3.3 Elements to be taken into account by Member States when authorising products**”:

(box excerpt from the assessment report)

For the representative biocidal product ContraZeck Zeckenschutz Lotion no test for the technical characteristics was submitted. The only general description of emulsifiability und flowability/pourability could not be validated as these presented not results of accepted test methods. This was accepted by the ECA in line with the decision of the 22nd CA meeting that for the purposes of inclusion into Annex I of directive 98/8/EC, an entirely complete product dossier is not mandatory. Further information about the applicability of the validation data to the technical material could be requested by the corresponding MS CA at product authorisation stage.

Currently, no valid test for the determination of the adsorption coefficient KOC for lauric acid is available. The environmental exposure assessment was performed with calculated results by a QSAR-method implemented in the ACD software for the non-ionised form as well as for the ionised form of lauric acid (please see chapter 2.2.2.1 of this document). This topic was discussed on TM III 08 and the decision can be found in the Final Minutes of TM III 08 (8. Outcome of e-consultation: regarding substitution of the adsorption/desorption test by QSAR for formaldehyde and lauric acid).). When authorising products a refinement of Koc might become necessary by demanding an adsorption-desorption test according OECD Guideline No. 106.

As soon as the new ESD for PT 19 is endorsed at EU level, before authorising products containing lauric acid, the direct emission pathway to surface water in the environmental risk assessment should be considered when uses of products suggest this release pathway to be relevant.

The assessment of the data provided in support of the effectiveness of the accompanying product establishes that the product may be expected to display efficacy. However, all claims made for the product will need to be supported at product authorisation stage. Relevant product performance assessment should be based on tests that offer reasonable predictions of the benefits when using the product, i.e. reasonably sound estimations of the “duration of the effect” and “re-application time”.

The Classification proposed below is in accordance with Directive 67/548/EEC.

2.1.3. Classification and Labelling**Classification and Labelling of lauric acid**

The participant's proposal for classification and labelling of lauric acid isn't equivalent to the criteria of EU Directive 67/548/EEC and Regulation (EC) No. 1272/2008. Based on the data available for this evaluation the following classification/ labelling is proposed by the RMS:

Table 1 Proposed classification of lauric acid based on Directive 67/548/EEC

| | Classification | Wording |
|--|----------------|---------------------------------|
| Hazard Symbols, Indications of danger | Xi | Irritant |
| | N | Dangerous for the Environment |
| R-phrases | R38 | Irritating to skin |
| | R41 | Risk of serious damage to eyes |
| | R50 | Very toxic to aquatic organisms |

Remark: The proposed classification and labelling of lauric acid is a result of the evaluation done by the RMS.

The ECA has also provided a classification scheme according to the CLP Regulation (see below)

Table 2 Proposed classification of lauric acid based on Regulation (EC) No 1272/2008

| | Classification | Wording |
|-----------------------------------|--|---|
| Hazard classes, Hazard categories | Skin Irrit. 2 Eye Dam. 1 Aquatic Acute 1 | |
| Hazard statements | H315 H318 H400 | Causes skin irritation Causes serious eye damage Very toxic to aquatic life |

Remark: The proposed classification and labelling of lauric acid is a result of the evaluation done by the RMS.

✓ **Check data gaps**

No data gaps have been identified for the evaluated uses, this information can be inferred from the assessment report under the heading **"3.4 Requirements for further information"**, notice that some requirements are listed for product authorisation level assessment.

(box excerpt from the assessment report)

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the approval.

For the stage of product authorisation a refinement of the environmental exposure assessment may be necessary. Additionally studies about the technical characteristics of the biocidal products need to be submitted.

Therefore, the ECA suggests to perform the following studies for the stage of product authorisation:

- Adsorption-Desorption test according OECD Guideline 106 with radio labelled material.
- Bioaccumulation study in fish according to OECD Guideline 305, unless a risk for bioaccumulation can be excluded by other data.
- Technical characteristics of the biocidal product.

✓ **Check risk mitigation measures**

For the uses evaluated in the EU the risk mitigation measures listed above (under heading “**3.3 Elements to be taken into account by Member States when authorising products**”) were considered essential. For national authorization other risk mitigation measure might be needed, depending on national conditions and the specific biocidal product use.

It is also a good practice to read through the Summary document to get an understanding of the major risks associated with the use of this active substance in biocidal products.

Example 2, Difenacoum as a PT14 (Rodenticides) – Extensive risk mitigation

Difenacoum is one of the high risk active substances that have been allowed for use as rodenticides, due to a lack of alternatives to suppress harmful rodent infestations. This principally concerns all second-generation anticoagulant rodenticide active substances.

✓ Check status of the active substance in EU

First, check if this active substance is on the Union list of approved active substances for biocides in product type 14 (Rodenticides) by following the guidance in section 4.10. So it is. See below.

| | | | | | |
|---|----|------------|--------------------------|--------------------------------------|----------------------------|
| | | | | | 2011/81/EU |
| Dichlofluaniid | 8 | 1085-98-9 | 214-118-7 | Directive 2007/20/EC | |
| Didecyldimethylammonium Chloride (DDAC) | 8 | 7173-51-5 | 230-525-2 | Directive 2009/14/EU | |
| Difenacoum | 14 | 56073-07-5 | 259-978-4 | Directive 2008/81/EC | |
| Difethialone | 14 | 68-1036-3 | Plant protection product | Directive 2007/69/EC | |

Clicking on the link to the legal act will show the following document:

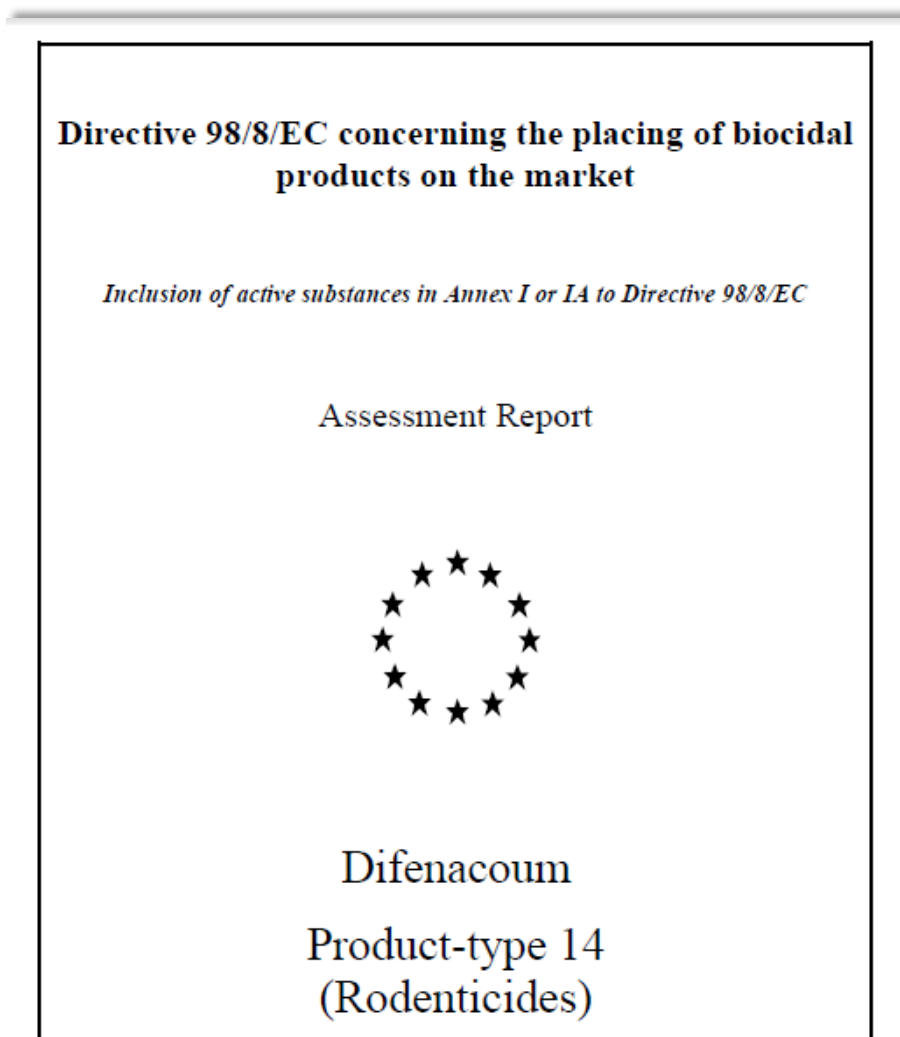


✓ Check comparability (e.g. use, identity) in EU to the actual use or identity in your region or country

Go to the CIRCABC homepage and download the Difenacoum PT14 assessment report (see section 4.13 on how to do this). It will look like this.

| | | | |
|---|---|-----------|------------------------|
| DEET (assessment report as finalised on 11.03.10) | DEET Assessment Report.pdf | 332.92 KB | 11 oktober 2010 13:16 |
| Deltamethrin (assessment report as finalised on 06.05.11) | Deltamethrin PT 18 final AR - converted-confirmed.pdf | 869.36 KB | 24 oktober 2011 12:04 |
| Dichlofluaniid (Assessment report as finalised on 28.11.06) | Dichlofluaniid_assessment_report_pt8.pdf | 299.23 KB | 26 augusti 2008 16:28 |
| Difenacoum (assessment report as revised on 17.09.2009) | Final-AR-difenacoumSep09public.pdf | 1.1 MB | 20 oktober 2009 14:41 |
| Difethialone (assessment report as finalised on 21.06.07) | Difethialone assessment report as finalised on 21.06.07.pdf | 493.81 KB | 10 december 2007 10:27 |
| Diflubenzuron (assessment report as finalised on 21.09.12) | CA-Sept12-Doc.3.4a - Diflubenzuron PT18 AR post SCB.pdf | 909.93 KB | 9 januari 2014 14:32 |
| Diflubenzuron (assessment report as finalised on 21.09.12) | Draft assessment report DOT.pdf | 504.53 KB | 20 augusti 2009 |

Click on the PDF-link at the red arrow to download/open the PDF-document. After download of the assessment report, the first page will look like below.



✓ **Check areas of concern and classification**

In this assessment report a listing of various important topics can be found under the heading “**Chapter 3. Decision**” specifically for the following points (see red box below).

| | | |
|-----------|---|-----------|
| 2.2.2.2. | Evaluation of emission due to leaching from treated wood..... | 16 |
| 2.2.2.3. | Risk characterization for the environment..... | 16 |
| 2.2.2.4. | Risk characterization for groundwater used as drinking water..... | 17 |
| 2.2.2.5. | Atmosphere..... | 18 |
| 2.2.2.6. | Risk of secondary poisoning..... | 18 |
| 2.2.2.7. | Waste disposal stage..... | 18 |
| 2.2.3. | List of endpoints..... | 18 |
| 3. | DECISION..... | 18 |
| 3.1. | BACKGROUND TO THE DECISION..... | 18 |
| 3.2. | DECISION REGARDING INCLUSION IN ANNEX I..... | 19 |
| 3.3. | ELEMENTS TO BE TAKEN INTO ACCOUNT BY MEMBER STATES WHEN AUTHORISING PRODUCTS..... | 20 |
| 3.4. | REQUIREMENT FOR FURTHER INFORMATION..... | 21 |
| 3.5. | UPDATING THIS ASSESSMENT REPORT..... | 21 |
| | APPENDIX I: LIST OF END POINTS..... | 22 |
| | CHAPTER 1: IDENTITY, PHYSICAL AND CHEMICAL PROPERTIES, CLASSIFICATION AND | |

✓ **Check areas of concern and classification**

Information on which areas that needs to be considered in particular for the national authorisation of products with this active substance, i.e. areas for which risk mitigation measures might be needed, can be found in chapter 3 of the assessment report. The European Commission gives the following message to the Member States in the assessment report under the heading **“3.3 Elements to be taken into account by Member States when authorising products”**:

(box excerpt from the assessment report)

The use of appropriate personal protective equipment should be advised in the use instructions.

As professional users are likely to be exposed more often, products containing difenacoum may be used by professional users if data are provided to show that calculated occupational exposure based on the operator exposure study, is acceptable.

The restriction of products to specific areas and manners of use and also restrictions of products to professionals or trained professionals only, should be considered.

The size of the package placed on the market should be proportionate to the duration of the treatment and appropriate to the pattern of use of particular user groups.

Product design and use restrictions should be optimised in order to ensure sufficient efficient rodent control while at the same time minimizing the risk for primary poisoning. This could include the use of tamper resistant bait boxes and the need to secure the baits so that rodents cannot remove the bait from the bait box.

When tamper-resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.

Difenacoum baits should not be placed where food, feeding-stuffs or drinking water could be contaminated.

In case no standard safety phrases are required on the product label, adequate safety instructions should be provided in the use instructions.

In addition to the elements already listed in Article 20(3) of Directive 98/8/EC, all packaging of anticoagulant rodenticides should be marked with the following standard phrases to protect humans, animals or the environment:

Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.

Search for and remove dead rodents at frequent intervals during treatment (unless used in sewers), at least as often as when baits are checked and/or replenished. Dispose of dead rodents in accordance with local requirements.

Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits.

Remove all baits after treatment and dispose of them in accordance with local requirements.

Keep out of the reach of children.

This last safety precaution should always be carried on the label of the products, if not already legally required by Directive 1999/45/EC. The others could be stated elsewhere on the packaging or on an accompanying leaflet together with the other directions for use and disposal of the product required by article 20(3) of Directive 98/8/EC.

Member States should encourage the application of Codes of Good Practices in rodent control. These measures could include (but should not be restricted to) the following factors:

- The population size of the target rodent should be evaluated before a control campaign. The number of baits and the timing of the control campaign should be in proportion to the size of the infestation.
- A complete elimination of rodents in the infested area should be achieved.
- The use instruction of products should contain guidance on resistance management for rodenticides.

Resistant management strategies should be developed, and difenacoum should not be used in an area where resistance to this substance is suspected.

The authorisation holder shall report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management.

When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

“Difenacoum is suggested as a candidate for the comparative assessment due to the potential PBT properties, unacceptable risk for secondary poisoning of the non-target vertebrates and risk for secondary exposure of humans. A more detailed risk benefit analysis should be made as a part of the comparative assessment when more information is available on alternative substances.”

The current harmonized classification from 2009 is found below. This example shows that the classification was made 2009 according to the old system of classification given in Annex I of Directive 67/548/EEC. The ECA had proposed amendments to the applicant's classification.

| Difenacoum | Product-type 14 | 17 September 2009 |
|--|---|---------------------------------------|
| 2.1.3. Classification and Labelling | | |
| On the basis of review of the submitted data and read-across of data from warfarin, the Rapporteur Member State (RMS) suggests that the current classification of difenacoum (health hazard) in Annex I to Directive 67/548/EEC is revised. Specific concentration limits have been proposed for the environmental classification. | | |
| Classification | T+; R26/27/28, Repr. Cat. 1; R61, T; 48/23/24/25, N; R50/53 | |
| Category of danger | Very Toxic, Dangerous for the Environment | |
| R phrases | R26/27/28, Very Toxic by inhalation, in contact with skin and if swallowed. R48/23/24/25, Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed. R61, May cause harm to the unborn child. R50/53, Very Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. | |
| S phrases | S45, In case of accident or if you feel unwell, seek medical advice immediately (show label where possible). S53, Avoid exposure - obtain special instruction before use. S60, This material and/or its container must be disposed of as hazardous waste. S61 Avoid release to the environment. Refer to special instructions/safety data sheet. | |
| Specific concentration limits for the human and environmental classification | $C \geq 2.5\%$ | T+, N; R26/27/28-48/23/24/25-61-50-53 |
| | $0.5\% \leq C < 2.5\%$ | T+, N; R26/27/28-48/23/24/25-61-51-53 |
| | $0.25\% \leq C < 0.5\%$ | T+, N; R26/27/28-48/23/24/25-51-53 |
| | $0.025\% \leq C < 0.25\%$ | T; R23/24/25-48/20/21/22-52-53 |
| | $0.0025\% \leq C < 0.025\%$ | Xn; R20/21/22 |
| No classification of products containing 50 mg/kg or 75 mg/kg difenacoum would be necessary according to Directive 1999/45/EC. However, specific concentration limits of difenacoum have been agreed by the Technical Committee on Classification and Labelling. | | |

✓ **Check data gaps**

Some data gaps have been identified for the evaluated uses, this information can be inferred from the assessment report under the heading “**3.4 Requirements for further information**”

(box excerpt from the assessment report)

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of difenacoum in Annex I to Directive 98/8/EC. However, in order to refine the risk assessment for the terrestrial compartment in the open area use Sorex Limited and Hentschke & Sawatzki KG will provide an earthworm reproduction test for the product authorisation phase. Data on dermal absorption for the wax block product containing 75 mg/kg difenacoum (Hentschke & Sawatzki KG) are required for the product authorization phase. The Activa/Pelgar Task Force has not submitted some studies that are required for the PT 14 and therefore the studies are required for the product authorisation phase.

- Analytical data to prove the isomeric composition and impurity profile from the task force member Activa (A2.8).
- For appearance ownership of data, for the technical substance, should be demonstrated or a study should be submitted (A3.3).
- A validated method for the analysis of difenacoum in animal and human tissues (A4.2d).
- Validation data for the analytical method for determination of residues of difenacoum in meat and oil-seed rape (food/feeding stuffs) (B4.2e).
- Validation data for analytical method for determination of difenacoum in sediment (based on the analysis method for difenacoum in soil) (A4.2c).

For each of these data gaps the reader should investigate whether or not the points are relevant for the national or regional authorisation process.

✓ **Check risk mitigation measures**

For the uses evaluated in the EU the risk mitigation measures listed above (under heading “**3.3 Elements to be taken into account by Member States when authorising products**”) were considered essential. For national authorization other risk mitigation measure might however be needed depending on national conditions and the specific product use.

It is also a good practice to read through the Summary document to get an understanding of the major risks associated with the use of this active substance in biocidal products aimed at rodent control.

Since difenacoum is a potential PBT substance it is on the list for substitution. Also, a special decision was made by the Commission about the urgency of risk mitigating measures for the high risks for human and animal health and the environment.

Specific risk mitigating measures are necessary to minimize the exposure of humans and environment for this potential PBT substance. This can be done in different ways, and the choice of the best regional solution lies with the Competent Authorities that deal with product authorisation. Examples of risk mitigating measures are the regulation of where the products may be applied, and where not, and by who (e.g. only trained professionals), maximum sizes of consumer packages, etc.

Special note on Difenacoum: When looking in the Union list of approved active substances at ECHA (in the heading), a notation was added about a specific decision by the Commission about the validity period of difenacoum and difethialone, now extended to 2018 (see below).

Biocidal Active Substances

The list contains those substances approved in accordance with Directive 98/8/EC (The Biocidal Products Directive) and Regulation (EU) No 528/2012 (The Biocidal Products Regulation). For each substance a brief summary and links to the Assessment Report and to further data is available.

As biocidal active substances are approved, there is an obligation on ECHA to make certain non-confidential data submitted as part of the process of obtaining the approval available. Please be aware that ECHA does not verify the information before dissemination.

The number of substances for which information is available and the data published per substance will increase over time as more substances are approved and as companies submit more data to ECHA.

Note that the active substance data linked below are the official data sets on which the approval reports are based. Third party active substance data is not yet published but is anticipated to be published in the future.

NB: Following Commission Implementing Decision 2014/397/EU of 25th June, the expiry date of approval of difethialone and difenacoum for use in biocidal products for product-type 14 is postponed to 30th June 2018.

Last updated 12 May 2014. List contains 64 approved active substances.

EC Number

CAS Number

Clicking on the link “Commission Implementing Decision 2014/397/EU” in the notation shows the document inside EUR-Lex database.

26.6.2014

EN

Official Journal of the European Union

L 186/111

COMMISSION IMPLEMENTING DECISION

of 25 June 2014

postponing the expiry date of approval of difethialone and difenacoum for use in biocidal products for product-type 14

(Text with EEA relevance)

(2014/397/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 14(5) thereof,

The initial approvals for these two active substances for use in PT14 (Rodenticides) were given a shorter than usual period of validity. One needs to go back to the initial decisions for inclusion on the Union list (formerly the Annex I, IA to the BPD) to find the reason(s) for this short period of approval. Through the Implementation Decision 2014/397/EU the period for both active substances has been extended for the reasons mentioned in the decision.

Example 3, Malathion as a PT18 (Insecticides) - Withdrawal

✓ Check status of the active substance in EU

Search for Malathion as an insecticide PT18 in the Union list of approved substances, following instructions in section 4.10 of this document.

Last updated 12 May 2014. List contains 64 approved active substances.

| | | | | |
|---|---|-------------------------------------|--------------------------------------|----------------------|
| 1 | EC Number | <input type="text"/> | CAS Number | <input type="text"/> |
| | Substance Name | malathion | Rapporteur Member State | <input type="text"/> |
| | Type | 18 - Insecticides, acaricides and p | Legislative act | <input type="text"/> |
| | Date of approval (min) | <input type="text"/> | Date of approval (max) | <input type="text"/> |
| | Expiry Date (min) | <input type="text"/> | Expiry Date (max) | <input type="text"/> |
| | 2 <input checked="" type="checkbox"/> I have read and I accept the legal notice | | | |
| | 3 <input type="button" value="Search"/> | | <input type="button" value="Reset"/> | |

1. Enter the name of the substance in the substance name box.
2. Check the box "I have read and I accept the legal notice"
3. Click on the "Search" button.

| | | | |
|---|-------------------------------------|--------------------------------------|----------------------|
| Substance Name | malathion | Rapporteur Member State | <input type="text"/> |
| Type | 18 - Insecticides, acaricides and p | Legislative act | <input type="text"/> |
| Date of approval (min) | <input type="text"/> | Date of approval (max) | <input type="text"/> |
| Expiry Date (min) | <input type="text"/> | Expiry Date (max) | <input type="text"/> |
| <input checked="" type="checkbox"/> I have read and I accept the legal notice | | | |
| <input type="button" value="Search"/> | | <input type="button" value="Reset"/> | |
| 💡 There are no Biocides | | | |

After clicking the "Search" button, the database will show a message that there are no biocides, meaning that Malathion is not in the Union list for PT18.

The next step is to check if the active substance is one of the listed low-concern substances. This list is available as the Annex I listing to the BP Regulation EU 528/2012.

1. Go to EUR-Lex database on the Internet: <http://eur-lex.europa.eu/search.html>
2. Type "528/2012" in the Search box and click "enter" (refine by choosing Year "2012")
3. You will see the following screen appear:

EUR-Lex
Access to European Union law

Search for: 528/2012, Search language: English, Exclude corrigenda: True

Sort by: Relevancy Descending

Results 1 – 10 of 95

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Text with EEA relevance)

Author: European Parliament, Council

4. Click on the link for the Biocidal Products Regulation and open the PDF-text for it.
5. Go to the page in the BPR with the Annex I. As below:

L 167/50 EN Official Journal of the European Union 27.6.2012

ANNEX I

LIST OF ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 25(a)

| EC number | Name/group | Restriction | Comment |
|---|-----------------|--|---------|
| Category 1 — Substances authorised as food additives according to Regulation (EC) No 1333/2008 | | | |
| 200-018-0 | Lactic acid | Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008 | E 270 |
| 204-823-8 | Sodium acetate | Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008 | E 262 |
| 208-534-8 | Sodium benzoate | Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008 | E 211 |

6. Check if the active substance Malathion is in the listing for the right product-type PT18.
7. It is not. Therefore, continue with the next step in Diagram A.

Check whether or not the active substance Malathion is listed in the consolidated non-inclusion table, available from the EU CIRCABC site.

1. Go to the site: (see section 4.13 for this)

2. Type "Consolidated list of non-inclusion decisions" in the Search box and click "Search"
3. Then you will see the following link on the screen:

Biocides - Regulation
528/2012 - Public

Library > Review programme
Review programme
The Library is the space where contents are stored, managed and shared.

This sections contains items relating to the review programme of existing active substances used in biocidal products.
3 folders and 1 files in this space.

Spaces

| Title | Modified Date | Actions |
|-----------------------------------|------------------------|---------|
| Draft competent authority reports | 4 September 2013 17:42 | [Icons] |
| Essential use derogations | 3 February 2014 14:26 | [Icons] |
| Withdrawal notices | 14 January 2014 17:25 | [Icons] |

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Content

| Name | Size | Modified Date | Actions |
|--|-----------|-------------------------|---------|
| Consolidated list of non-inclusion decisions.pdf | 355.44 KB | 23 September 2013 14:31 | [Icons] |

Page 1 of 1

CIRABC is Open Source

4. Click the download button (at the red arrow above) and open/save the PDF-file.
5. Check if Malathion is in the listing for product type 18.

Find
malathion
Previous Next

Existing active substances for which a decision of non-inclusion into Annex I or Ia of Directive 98/8/EC has been adopted
In accordance with Article 4(2) of Regulation (EC) No 2032/2003, biocidal products containing active substances for which a non-inclusion decision was taken
removed from the market within 12 months of the entering into force of such decision; unless otherwise stipulated in that non-inclusion decision

Dates by which products containing these active substances shall no longer be placed on the market for the relevant product-types

PT 18
Insecticides, acaricides and products to control other arthropods

| Name (EINECS and/or others) | EC number | CAS number | Products to be phased-out by | Decision reference |
|--|-----------|-------------|------------------------------|--|
| Silica, amorphous, crystalline-free | | 112945-52-5 | 03/01/2008 | Commission Regulation (EC) 1849/2006 |
| Formaldehyde | 200-001-8 | 50-00-0 | 03/01/2008 | Commission Regulation (EC) 1849/2006 |
| Dimethoate | 200-480-3 | 60-51-5 | 01/09/2006 | Commission Regulation (EC) 1048/2005 |
| Dichlorvos | 200-547-7 | 62-73-7 | 01/11/2012 | |
| Ethanol | 200-578-6 | 64-17-5 | 01/09/2006 | Commission Regulation (EC) 1048/2005 |
| Formic acid | 200-579-1 | 64-18-6 | 22/08/2008 | Commission Decision 2007/565/EC |
| Propan-2-ol | 200-661-7 | 67-63-0 | 22/08/2008 | Commission Decision 2007/565/EC |
| 1,4-dichlorobenzene | 203-400-5 | 106-46-7 | 22/08/2008 | Commission Decision 2007/565/EC |
| N-(2-ethylhexyl)-8,9,10-trinorborn-5-ene-2,3-dicarboximide | 204-029-1 | 113-48-4 | 22/08/2008 | Commission Decision 2007/565/EC |
| Propoxur | 204-043-8 | 114-26-1 | 31/05/2010 | Commission Decision 2009/324/EC |
| Benzyl benzoate | 204-402-9 | 120-51-4 | 21/08/2009 | Commission Decision 2008/681/EC |
| Malathion | 204-497-7 | 121-75-5 | 22/08/2008 | Commission Decision 2007/565/EC |
| Fenitrothion | 204-524-2 | 122-14-5 | 31/05/2010 | Commission Decision 2009/324/EC |
| Sodium hydrogencarbonate | 205-633-8 | 144-55-8 | 03/01/2008 | Commission Regulation (EC) 1849/2006 |
| Naled | 206-098-3 | 300-76-5 | 01/11/2012 | |

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This document is intended for use as a documentation tool and the Commission services do not assume any liability for its content.

Yes, a non-inclusion decision is available for Malathion as a PT18. This decision is from 2007, and therefore it is wise to check whether Malathion was added to the review programme for

biocides at a later date. This is done by checking in the text of Directive EU 613/2013 listing the latest additions to the review programme.

L 173/34

EN

Official Journal of the European Union

26.6.2013

COMMISSION REGULATION (EU) No 613/2013

of 25 June 2013

amending Regulation (EC) No 1451/2007 as regards additional active substances of biocidal products to be examined under the review programme

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽¹⁾, and in particular Article 16(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 1451/2007 of

clarified that the concept of 'biocidal products' must be interpreted as including certain products which act only by indirect means on the target harmful organisms.

- (4) Persons relying on guidance notes published, or written advice given, by the Commission or by a competent authority designated in accordance with Article 26 of Directive 98/8/EC may therefore have failed to notify the existing active substance/product-type combination in a product placed on the market, or to take over the role of participant, in the objectively justified belief that the product is excluded from the scope of Directive 98/8/EC or that it falls under a different product-type.

No, Malathion is not listed in 613/2013. Then look into the reason for non-inclusion in the decision for the non-inclusion listed in the PDF-file with the consolidated list of non-inclusion decisions. It can either be due to a withdrawal of the notification by industry, or due to the inability of industry to complete a dossier for the active substance in due time. No clues are given about the exact reason. Nevertheless, this substance is not allowed to be used in product type 18 (Insecticides) within the EU. Looking in CIRCABC (see section 4.13) for a CAR on Malathion for PT18 was unsuccessful, which indicates that the substance was initially notified to the review programme, and withdrawn later. This resulted in the 2007 decision for non-inclusion of the substance.

Example 4, Naled as a PT18 (Insecticides) – Non-inclusion decision

Naled has been part of the review programme for PT18, but it was found to not fulfil the requirements set by the BPR, and thus a non-inclusion decision has recently been made by the Commission. Here is how you can find out.

✓ Check status of the active substance in EU

Search for Naled as an insecticide PT18 in the Union list of approved substances, following instructions in section 4.10 of this document.

The screenshot shows a search form with the following fields and annotations:

- Substance Name:** "Naled" (circled in red, labeled 1)
- Type:** "18 - Insecticides, acaricides and p..." (circled in red)
- Legislative act:** (empty)
- Date of approval (min):** (empty, marked with a red X)
- Date of approval (max):** (empty, marked with a red X)
- Expiry Date (min):** (empty, marked with a red X)
- Expiry Date (max):** (empty, marked with a red X)
- Checkboxes:** "I have read and I accept the legal notice" (checked, circled in red, labeled 2)
- Buttons:** "Search" and "Reset" (labeled 3 with a red arrow pointing to "Search")

1. Enter the name of the substance in the substance name box.
2. Check the box "I have read and I accept the legal notice"
3. Click on the "Search" button.

The screenshot shows the search results page with the following fields and annotations:

- Substance Name:** "Naled"
- Type:** "18 - Insecticides, acaricides and p..."
- Legislative act:** (empty)
- Date of approval (min):** (empty, marked with a red X)
- Date of approval (max):** (empty, marked with a red X)
- Expiry Date (min):** (empty, marked with a red X)
- Expiry Date (max):** (empty, marked with a red X)
- Checkboxes:** "I have read and I accept the legal notice" (checked)
- Buttons:** "Search" and "Reset"
- Message:** "There are no Biocides" (highlighted with a red arrow)

After clicking the "Search" button, the database will show a message that there are no biocides (see at the red arrow above), meaning that Naled is not in the Union list for PT18.

The next step is to check if the active substance is one of the listed low-concern substances. This list is available as the ANNEX 1 listing to the BP Regulation EU 528/2012.

8. Go to EUR-Lex database on the Internet: <http://eur-lex.europa.eu/search.html>
9. Type "528/2012" in the Search box and click "enter" (refine by choosing Year "2012")
10. You will see the following screen appear:

EUR-Lex
Access to European Union law

Search for: 528/2012, Search language: English, Exclude corrigenda: True

Sort by: Relevancy Descending

Results 1 – 10 of 95

02012R0528–20130923: Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Text with EEA relevance)

Author: European Parliament, Council

11. Click on the link for the Biocidal Products Regulation and open the PDF-text for it.

12. Go to the page in the BPR with the Annex I. As below:

L 167/50 EN Official Journal of the European Union 27.6.2012

ANNEX I

LIST OF ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 25(a)

| EC number | Name/group | Restriction | Comment |
|---|-----------------|--|---------|
| Category 1 — Substances authorised as food additives according to Regulation (EC) No 1333/2008 | | | |
| 200-018-0 | Lactic acid | Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008 | E 270 |
| 204-823-8 | Sodium acetate | Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008 | E 262 |
| 208-534-8 | Sodium benzoate | Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008 | E 211 |

13. Check if the active substance Naled is in the listing for the right product-type PT18.

14. It is not. Thus, continue with the next step.

Check whether or not the active substance Naled is listed in the consolidated non-inclusion table, available from the EU CIRCABC site.

4. Go to the site: (see section 4.13 for this)

5. Type "Consolidated list of non-inclusion decisions" in the Search box and click "Search"

6. Then you will see the following link on the screen:

Biocides - Regulation 528/2012 - Public

Library > Review programme

Review programme
The Library is the space where **contents** are stored, managed and shared.

This sections contains items relating to the review programme of existing active substances used in biocidal products.
3 folders and 1 files in this space.

Spaces

| Title | Modified Date | Actions |
|-----------------------------------|------------------------|---------|
| Draft competent authority reports | 4 September 2013 17:42 | [Icons] |
| Essential use derogations | 3 February 2014 14:26 | [Icons] |
| Withdrawal notices | 14 January 2014 17:25 | [Icons] |

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Content

| Name | Size | Modified Date | Actions |
|--|-----------|-------------------------|---------|
| Consolidated list of non-inclusion decisions.pdf | 355.44 KB | 23 September 2013 14:31 | [Icons] |

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Top of the page

W3C WAI-A WCAG 1.0

CIRCABC is Open Source

7. Click the download button (at the red arrow above) and open/save the PDF-file.

8. Check if Naled is in the listing for the product type 18.

Find: Previous Next

Existing active substances for which a decision of non-inclusion into Annex I or Ia of Directive 98/8/EC has been adopted in accordance with Article 4(2) of Regulation (EC) No 2032/2003, biocidal products containing active substances for which a non-inclusion decision was taken, shall be removed from the market within 12 months of the entering into force of such decision; unless otherwise stipulated in that non-inclusion decision

Dates by which products containing these active substances shall no longer be placed on the market for the relevant product-types:

PT 18
Insecticides, acaricides and products to control other arthropods:

| Name (EINECS and/or others) | EC number | CAS number | Products to be phased-out by | Decision reference |
|--|-----------|-------------|------------------------------|--|
| Silica, amorphous, crystalline-free | | 112945-52-5 | 03/01/2008 | Commission Regulation (EC) 1849/2006 |
| Formaldehyde | 200-001-8 | 50-00-0 | 03/01/2008 | Commission Regulation (EC) 1849/2006 |
| Dimethoate | 200-480-3 | 60-51-5 | 01/09/2006 | Commission Regulation (EC) 1048/2005 |
| Dichlorvos | 200-547-7 | 62-73-7 | 01/11/2012 | |
| Ethanol | 200-578-6 | 64-17-5 | 01/09/2006 | Commission Regulation (EC) 1048/2005 |
| Formic acid | 200-579-1 | 64-18-6 | 22/08/2008 | Commission Decision 2007/565/EC |
| Propan-2-ol | 200-661-7 | 67-63-0 | 22/08/2008 | Commission Decision 2007/565/EC |
| 1,4-dichlorobenzene | 203-400-5 | 106-46-7 | 22/08/2008 | Commission Decision 2007/565/EC |
| N-(2-ethylhexyl)-8,9,10-trinorborn-5-ene-2,3-dicarboximide | 204-029-1 | 113-48-4 | 22/08/2008 | Commission Decision 2007/565/EC |
| Propoxur | 204-043-8 | 114-26-1 | 31/05/2010 | Commission Decision 2009/324/EC |
| Benzyl benzoate | 204-402-9 | 120-51-4 | 21/08/2009 | Commission Decision 2008/681/EC |
| Malathion | 204-497-7 | 121-75-5 | 22/08/2008 | Commission Decision 2007/565/EC |
| Fenitrothion | 204-524-2 | 122-14-5 | 31/05/2010 | Commission Decision 2009/324/EC |
| Permethrin | 205-633-8 | 144-55-8 | 03/01/2008 | Commission Regulation (EC) 1849/2006 |
| Naled | 206-098-3 | 300-76-5 | 01/11/2012 | |

Page 85 of 101

This document is intended for use as a documentation tool and the Commission services do not assume any liability for its content.

Yes, a non-inclusion decision is available for Naled as a PT18. This decision is from 2012, and therefore it is possible to check why Naled was not approved as an active substance for PT18. In this case, this can be done by reading the non-inclusion decision by the European Commission. Since no decision reference is listed as a link for Naled, you must go to EUR-Lex directly (see section 4.12) and find documents by typing "**Naled non-inclusion**" in the "Search"

box. Then you will find the Decision 2012/257/EU for non-inclusion. The text in the document reveals the following reasons:

(box excerpt from the decision)

...The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 9 December 2011, in an assessment report.

The assessment has demonstrated that biocidal products used as insecticides, acaricides and products to control other arthropods and containing Naled **cannot be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. The scenarios evaluated in the human health risk assessment as well as in the environmental risk assessment showed a potential and unacceptable risk.**

Furthermore, **the evaluation has not demonstrated sufficient efficacy**. It is therefore not appropriate to include Naled for use in product type 18 in Annex I, IA or IB to Directive 98/8/EC.

In the interest of legal certainty, the date as of which biocidal products of product type 18 containing Naled should no longer be placed on the market should be specified, taking into account both the unacceptable effects of those products and the legitimate expectations of manufacturers of those products.

The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products.

Thus, it is not possible to have biocidal products with a product type 18 specified activity containing the active substance Naled within the EU.

Note the short phase-out time of only 6 months, allowed by the decision.

Example 5, Camphor as a PT18 (Insecticides) or PT19 (Repellents) – Not found

Camphor is known to have a repelling effect on insects. For biocidal products containing Camphor (also called formosa, EC number 200-945-0) the following search is performed.

✓ **Check status of the active substance in EU**

Search for Camphor as an insecticide PT18 or repellent PT19 in the Union list of approved substances, following instructions in section 4.10 of this document.

EC Number **1** 200-945-0 CAS Number
Substance Name camphor Rapporteur Member State
Type
Date of approval (min) Date of approval (max)
Expiry Date (min) Expiry Date (max)
2 ☒ I have read and I accept the legal notice
3 Search Reset
There are no Biocides

1. Enter the name of the substance in the substance name box, and the EC number in the box above that.
2. Check the box “I have read and I accept the legal notice”
3. Click on the “Search” button.

After clicking the “Search” button, the database will show a message that there are no biocides, meaning that Camphor is not in the Union list for any product types (since you did not specify a product-type).

The next step is to check if the active substance is one of the listed low-concern substances. This list is available as the Annex 1 listing to the BP Regulation EU 528/2012.

1. Go to EUR-Lex database on the Internet: <http://eur-lex.europa.eu/search.html>
2. Type “528/2012” in the Search box and click “enter”
3. You will see the following screen appear:

EUR-Lex
Access to European Union law

Search for: 528/2012, Search language: English, Exclude corrigenda: True

Sort by: Relevancy Descending

Results 1 – 10 of 95

02012R0528-20130923: Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Text with EEA relevance)

Direct text access: [PDF](#) [HTML](#) Author: European Parliament, Council

4. Click on the link for the Biocidal Products Regulation and open the PDF-text for it.
5. Go to the page in the BPR with the Annex I. As below:

L 167/50 EN Official Journal of the European Union 27.6.2012

ANNEX I

LIST OF ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 25(a)

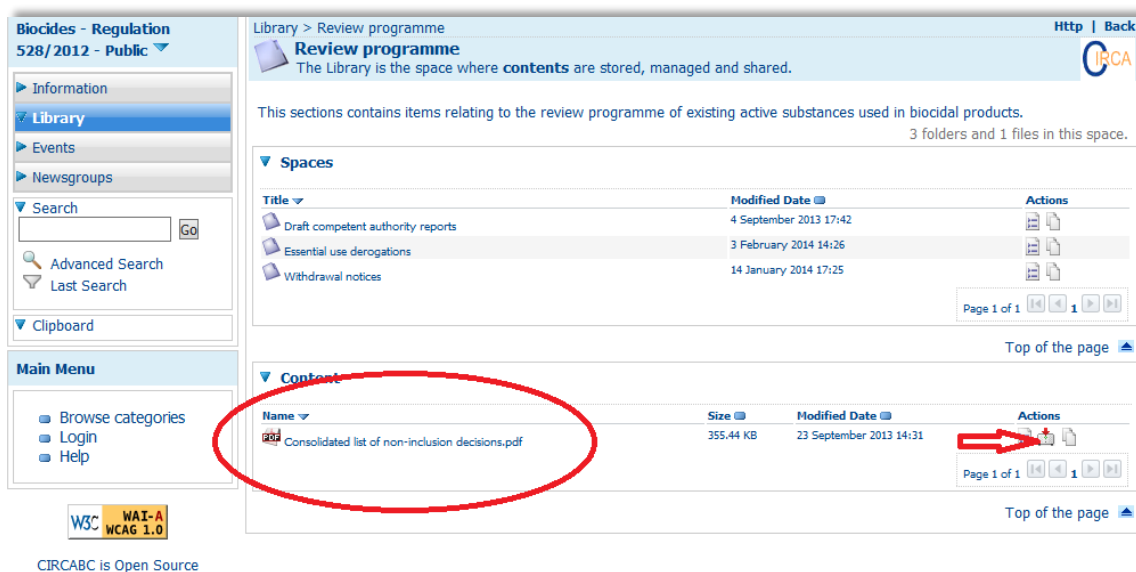
| EC number | Name/group | Restriction | Comment |
|--|-----------------|--|---------|
| Category 1 — Substances authorised as food additives according to Regulation (EC) No 1333/2008 | | | |
| 200-018-0 | Lactic acid | Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008 | E 270 |
| 204-823-8 | Sodium acetate | Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008 | E 262 |
| 208-534-8 | Sodium benzoate | Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008 | E 211 |

6. Check if the active substance Camphor is in the listing for the right product-type PT18 or PT19.
7. It is not. Thus, continue with the next step.

Check whether or not the active substance Camphor is listed in the consolidated non-inclusion table, available from the EU CIRCABC site.

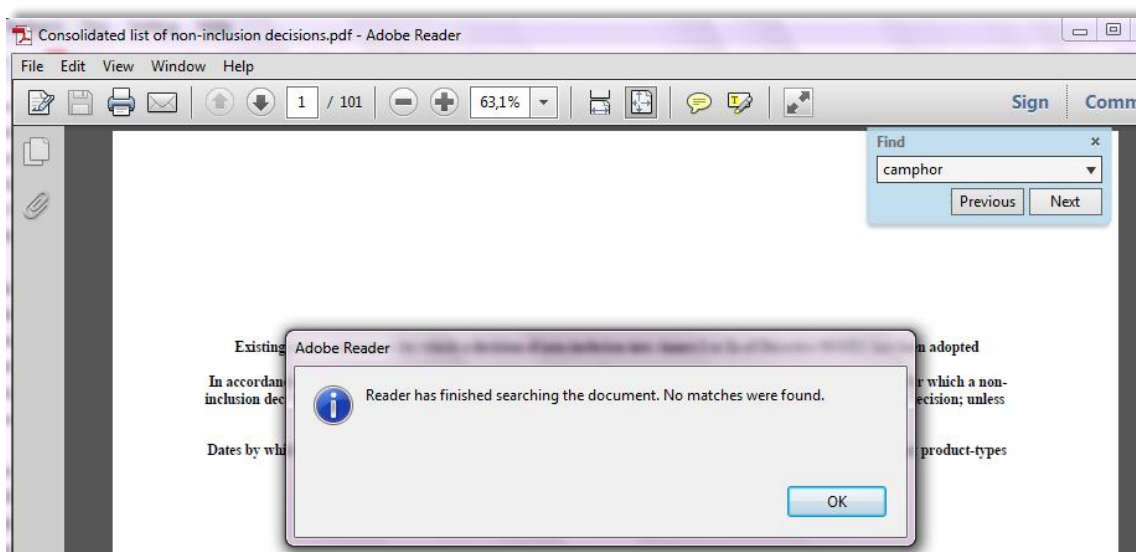
8. Go to the site: (see section 4.13 for this)
9. Type “Consolidated list of non-inclusion decisions” in the Search box and click “Search”

10. Then you will see the following link on the screen:



11. Click the download button and open the PDF-file.

12. Check if Camphor is in the listing for the product type 18 or 19.



No, a non-inclusion decision is not found for Camphor as a PT18 or PT19 (or any other product-type).

The next step is to see whether or not Camphor is part of the review programme for biocidal active substances. This is done by going to the EUR-Lex database (see section 4.12) and searching for the consolidated listing of the review programme as Commission Regulation EC/1451/2007.

Choosing to open the PDF-file for the regulation 1451/2007 results in the following view:

► B COMMISSION REGULATION (EC) No 1451/2007
of 4 December 2007
on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market
(Text with EEA relevance)
(OJ L 325, 11.12.2007, p. 3)

Amended by:

| | | Official Journal | | |
|-------------|--|------------------|------|-----------|
| | | No | page | date |
| ► <u>M1</u> | Commission Regulation (EU) No 298/2010 of 9 April 2010 | L 90 | 4 | 10.4.2010 |
| ► <u>M2</u> | Commission Regulation (EU) No 613/2013 of 25 June 2013 | L 173 | 34 | 26.6.2013 |

And when searching this document for Camphor, no results are obtained.

► B COMMISSION REGULATION (EC) No 1451/2007
of 4 December 2007
on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market
(Text with EEA relevance)

Amended by:

Find
camphor
Previous Next

Adobe Reader
Reader has finished searching the document. No matches were found.
OK

No page date

As the document shows on the first page, the Regulation (EC) No 1451/2007 has since been amended by Regulations 298/2010 and 613/2013. It is best to check these two regulations as well for the active substance Camphor. With the same results, no matches were found. All of this indicates that Camphor has not previously been notified to the Commission as a possible active substance to be used in biocides. Thus, it is **not possible** to market biocidal products with a product type 18 or 19 specified activity containing the active substance Camphor within the EU.

Example 6, Propiconazole as a PT8 (wood protection products) – Substitution candidate

✓ Check status of the active substance in EU

In the EU Union list of approved substances it is possible to see that propiconazole was approved in April 2010 as active substance in product-type 8 biocides in the EU. Search for all Product-type 8 active substances (red circle below), following the instructions in section 4.10 of this document.

Biocidal Active Substances

The list contains those substances approved in accordance with Directive 98/8/EC (The Biocidal Products Directive) and Regulation (EU) No 528/2012 (The Biocidal Products Regulation). For each substance a brief summary and links to the Assessment Report and to further data is available.

As biocidal active substances are approved, there is an obligation on ECHA to make certain non-confidential data submitted as part of the process of obtaining the approval available. Please be aware that ECHA does not verify the information before dissemination.

The number of substances for which information is available and the data published per substance will increase over time as more substances are approved and as companies submit more data to ECHA.

Note that the active substance data linked below are the official data sets on which the approval reports are based. Third party active substance data is not yet published but is anticipated to be published in the future.

Last updated 12 May 2014. List contains 64 approved active substances.

Search filters:

- EC Number:
- Substance Name:
- Type: **8 - Wood preservatives** (highlighted with a red circle)
- Rapporteur Member State:
- Legislative act:
- Date of approval (min):
- Date of approval (max):

Note that the box “I have read and I accept the legal notice” must be ticked.

Choose “Search” and find propiconazole in the listing.

☒ I have read and I accept the legal notice

[Search](#) [Reset](#)

| Substance Name | EC Number | CAS Number | Type | Legislative act | Date of approval | Expiry date | Rapporteur Member State | Data | Related authorised products |
|----------------------|------------------|-------------------|-------------------------------|-------------------|-------------------|-------------------|-------------------------|------|-----------------------------|
| K-HDO | | 66603-10-9 | 8 - Wood preservatives | 2008/80/EC | 01/07/2010 | 30/06/2020 | AT | | |
| propiconazole | 262-104-4 | 60207-90-1 | 8 - Wood preservatives | 2008/78/EC | 01/04/2010 | 31/03/2020 | FI | | |
| sulfuryl fluoride | 220-281-5 | 2699-79-8 | 8 - Wood preservatives | 2006/140/EC | 01/01/2009 | 31/12/2018 | SE | | |
| tebuconazole | 403-640-2 | 107534-96-3 | 8 - Wood preservatives | 2008/86/EC | 01/04/2010 | 31/03/2020 | DK | | |

The substances are listed in alphabetical order. Go to P, and find propiconazole. Here you can find the dates of approval and expiration of the approval, the ECA (Finland) EC and CAS numbers, and the linked legislative act of the approval decision (see below).



✓ **Check comparability (e.g. use, identity) in EU to the actual use or identity in your region or country**

Go to the CIRCABC homepage (see section 4.13, and download the Propiconazole PT8 assessment report. Notice that other product types are available for this substance! It will look like this.

| | | | |
|---|---|-----------|------------------------|
| finalised on 27.09.13) | | | |
| Octanoic acid - PT18 (assessment report as finalised on 13.12.13) | Octanoic acid - PT18 (assessment report as finalised on 13.12.13).pdf | 952.84 KB | 10 February 2014 13:50 |
| Octanoic acid - PT4 (assessment report as finalised on 13.12.13) | Octanoic acid - PT4 (assessment report as finalised on 13.12.13).pdf | 1 MB | 10 February 2014 13:45 |
| Propiconazole (assessment report as finalised on 29.11.07) | Final Assessment Report Propiconazole 29.11.2007.pdf | 367.88 KB | 26 August 2008 16:20 |
| Propiconazole - PT9 (assessment report as finalised on 12.07.13) | Propiconazole (assessment report as finalised on 12.07.13).pdf | 277.65 KB | 22 October 2013 10:18 |
| Pyriproxyfen (assessment report as finalised on 21.09.12) | Assessment_Report_Pyriproxyfen_September_2012.pdf | 381.49 KB | 28 January 2014 09:55 |
| S-Methoprene (assessment report as finalised on 13.12.13) | SCBP37 s-Methoprene PT18 Final AR - Clean - 2013-12-17.pdf | 850.57 KB | 6 February 2014 14:55 |
| Spinosad (assessment report as finalised on 27.05.10) | Spinosad Assessment Report post SCclean0211.pdf | 343.07 KB | 8 February 2011 09:39 |

Click on the PDF-link (see the red arrow) to download/open the PDF-document. After download of the assessment report, the first page will look like below.

Assessment Report



Propiconazole

Product-type 8

(Wood preservatives)

In this assessment report a listing of various important topics can be found under the heading “**Chapter 3. Decision**” specifically for the following points (see red box below).

| | | |
|-----------|---|-----------|
| 2.2.2.2. | Evaluation of emission due to leaching from treated wood..... | 16 |
| 2.2.2.3. | Risk characterization for the environment..... | 16 |
| 2.2.2.4. | Risk characterization for groundwater used as drinking water..... | 17 |
| 2.2.2.5. | Atmosphere..... | 18 |
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| 3. | DECISION | 18 |
| 3.1. | BACKGROUND TO THE DECISION..... | 18 |
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| 3.3. | ELEMENTS TO BE TAKEN INTO ACCOUNT BY MEMBER STATES WHEN AUTHORISING PRODUCTS..... | 20 |
| 3.4. | REQUIREMENT FOR FURTHER INFORMATION..... | 21 |
| 3.5. | UPDATING THIS ASSESSMENT REPORT..... | 21 |
| | APPENDIX I: LIST OF END POINTS..... | 22 |
| | CHAPTER 1: IDENTITY, PHYSICAL AND CHEMICAL PROPERTIES, CLASSIFICATION AND | |

✓ Check areas of concern and classification

Information on which areas need to be considered in particular for the national authorisation of products with this active substance, i.e. areas for which risk mitigation measures might be needed, can be found in chapter 3 of the assessment report. The European Commission gives the following message to the member states in the assessment report under the heading “**3.3 Elements to be taken into account by Member States when authorising products**”:

(box excerpt from the assessment report)

1. In the review program propiconazole has been evaluated as a fungicide in wood preservatives (Product Type 8) for wood above ground exposed to occasional wetting and above ground not covered (Hazard Class 2 and 3). Extension of the use pattern beyond those reviewed will require a re-evaluation of the acceptance of propiconazole in order to establish whether the proposed extensions of use can satisfy the requirements of Article 10(1) and 5(1).
2. In the dossier submitted for the review program the minimum purity of 93 % w/w was supported. The FAO specification (AGP: CP/330, 1995) is min. 88 % w/w.
3. Products containing propiconazole may be used in the preventive treatment of wood by vacuum-pressure, double-vacuum, spraying, brushing and industrial dipping for constructions outdoors. Wood indoors may be treated by brushing, spraying and professional injection.
4. Protective clothing, gloves and footwear are required in industrial/professional use.
5. According to the EU waste legislation waste from wood preservative products and application solutions are considered hazardous waste. Therefore, application solutions must be collected and reused or disposed of as hazardous waste and they must not be released to soil, surface water or any kind of sewers.
6. Soil in the vicinity of the object to be treated in-situ has to be mechanically protected during the treatment (e.g. with a tarpaulin or plastic sheeting) and subsequent waste management has to be sorted out in an appropriate way.
7. In-situ application by brush or spray in the vicinity of water courses must not be conducted where direct losses to the aquatic compartment cannot be prevented.
8. Member States shall ensure that authorisations of propiconazole containing products are subject to the restrictions and conditions specified by number 5., 6. and 7. above. These requirements shall be given in labels/accompanying leaflets integral to the packaging and safety-data sheets of products authorised.
9. Complete data package on the identity and physico-chemical properties of products should be available at the product authorisation stage.
10. The efficacy of the individual products shall be demonstrated prior to product authorisation at the Member State level.
11. Specific dermal absorption data of the products and information on the duration of exposure shall be demonstrated at the product authorisation stage.
12. Based on the directive 1999/45/EEC preparations not classified as sensitising but containing at least one sensitising substance in a concentration $\geq 0.1\%$ must bear the inscription 'Contains (name of sensitising substance). May produce an allergic reaction.'
13. If indoor use for non-professionals is intended in the product authorisation applications, it has to be demonstrated that the exposure is acceptable.
14. When Member States are authorising products containing propiconazole the potential of propiconazole to cause endocrine disruption must be considered. This is because propiconazole may

have the potential to cause endocrine disruption based on suspected properties for the azole group and that there is not sufficient data. However, in the submitted studies there were no effects in the test animals which could be related to possible endocrine disruption.

15. The effects of possible re-applications on risk need to be evaluated at product authorisation stage. Re-applications in-situ (remedial treatment) are only possible according to conditions to be set in the product authorisation procedure.

16. In the product authorisation applications it has to be demonstrated that treated wood in service does not pose unacceptable risk to the environment. This is because in the dossier submitted for the review program environmentally safe use of propiconazole as a wood preservative in wood for Hazard Class 3 as required in Article 5(1)(b)(iv) of Directive 98/8/EC has not been demonstrated. E.g. additional treatment with a propiconazole-free coating or fixative may be considered to reduce the leaching of propiconazole from treated wood in wood Hazard Class 3.

17. In the evaluation of the active substance in the review program it was not possible to confirm the data protection claims of individual studies in accordance with Article 12.1(c) (i) or (ii) of Directive 98/8/EC.

The current harmonized classification from 2007 is found below. This example shows that the classification was made according to the old system of classification given in Annex I of Directive 67/548/EEC.

| Propiconazole | Product-type 8 | 29 November 2007 |
|--|---|------------------|
| 2.1.6. Classification and Labelling | | |
| Propiconazole is classified as follows: | | |
| Classification | In accordance with Annex I of Directive 67/548/EEC | |
| Class of danger | Xn (Harmful); N (Dangerous for the environment) | |
| R phrases | 22-43-50/53 (Harmful if swallowed. May cause sensitization by skin contact. Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.) | |
| S phrases | (2)-36/37-46-60-61 [(Keep out of the reach of children.*) Wear suitable protective clothing and gloves. If swallowed, seek medical advice immediately and show this container or label. This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions/Safety data sheets.] | |
| *) For preparations sold to general public | | |

✓ Check data gaps

No data gaps have been identified for the evaluated uses, this information can be inferred from the assessment report under the heading “**3.4 Requirements for further information**”

(box excerpt from the assessment report)

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of propiconazole in Annex I to Directive 98/8/EC.

✓ **Check risk mitigation measures**

For the uses evaluated in the EU the risk mitigation measures listed above (under heading “**3.3 Elements to be taken into account by Member States when authorising products**”) were considered essential. For national authorization other risk mitigation measure might however be needed depending on national conditions and the specific product use.

It is also a good practice to read through the summary document to get an understanding of the major risks associated with the use of this active substance in biocidal products aimed to treat wood.

Note about propiconazole on the EU list for substitution!

Since the data on propiconazole as an endocrine disrupting agent is incomplete, and some data suggest that the substance might be acting as an endocrine disruptor, the agent has been put on the EU list for substances that are considered for substitution. Also, the property of the substance as a known skin-sensitizer, make it a candidate for the substitution list. The final decision about this is yet to be made by the Commission. Before that, the risk mitigating measures listed above are to be followed by involved parties, in order to minimize the risks during use of products containing this active substance.