Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Carbendazim

Product type: 7

ECHA/BPC/234/2019

Adopted

10 December 2019

Opinion of the Biocidal Products Committee

on the application for approval of the active substance carbendazim for product type 7

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 7 of the following active substance:

Common name:	**carbendazim**
Chemical name:	**Methyl -benzimidazol-2-ylcarbamate**
EC No.:	**234-234-0**
CAS No.:	**10605-21-7**

Existing active substance

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Troy Chemical Company BV on 31 October 2008, the evaluating Competent Authority Germany submitted an assessment report and the conclusions of its evaluation to the Commission on 2 August 2013. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-25 and BPC-33) and its Working Groups (WG II 2015, WG IV 2017 and WG I 2017). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at https://www.echa.europa.eu/web/guest/potential-candidates-for-substitution-previous-consultations/-/substance-rev/11/term on 4 July 2014, in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 2 September 2014.

Adoption of the BPC opinion

Rapporteur: Germany

The BPC opinion on the application of approval of the active substance carbendazim in product type 7 was adopted on 25 April 2018. Due to the entry into force of Regulation (EU) 2017/2100[1] the Commission returned the BPC opinion to the Agency on 26 April 2018 with the request to revise the opinion already adopted by the Biocidal Products Committee (BPC), related to the application of the criteria for endocrine disrupting properties as laid down in this regulation. The BPC opinion was then finally adopted on 10 December 2019.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of BPR.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority position including its ground are published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

[1] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the carbendazim in product type 7 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of carbendazim in product type 7.

Specifications for the reference source are established.

The physico-chemical properties of the active substance have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities.

Validated analytical methods are required and available for determination of carbendazim in soil, drinking water, surface water, body fluids and tissues. Relevant exposure of plants and plant products, and animal products is unlikely from the intended uses. Therefore, analytical methods are not needed for these matrices.

The approval[2] of carbendazim under Regulation (EC) No 1107/2009 expired on 30 November 2014.

A harmonized classification according to Regulation (EC) No 1272/2008 is available for carbendazim. However, the eCA proposes to amend the classification and submitted a CLH dossier on 29 May 2017. The current classification and labelling for carbendazim according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Muta. 1B Repr. 1B Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictogram codes	GHS09 GHS08
Signal Word	Danger
Hazard Statement Codes	H340 H360FD H410

[2] Reg. (EU) No 542/2011

The proposed classification and labelling for carbendazim according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed Classification according to the CLP Regulation	
Hazard Class and Category Codes	Muta. 1B Repr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictogram codes	GHS09 GHS08 GHS07
Signal Word	Danger
Hazard Statement Codes	H340 H360FD H317 H 410
Specific Concentration limits, M-Factors	M = 10 (acute) M = 10 (chronic)
Justification for the proposal	
Carbendazim has a legal classification for Muta. 1B and Repr. 1B. Classification with Skin Sens. 1 is additionally proposed by the eCA based on results of a Magnusson & Kligman test.	

b) Intended use, target species and effectiveness

Carbendazim is used as a fungicide in biocidal film preservative products which are applied to, or incorporated into end-applications like paints. Products containing carbendazim will be used by industrial users, while the end-use treated items may be used by professionals and non-professionals.

Carbendazim acts as a systemic fungicide by inhibiting mitosis, thus preventing growth of the target organisms. Efficacy of carbendazim used as a film preservative against fungi has been sufficiently demonstrated by the submitted data.

Carbendazim has a single site mode of action, which causes an elevated potential for resistance. Therefore, monitoring of resistance development and resistance management strategies are required at renewal stage of the active substance approval.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

Carbendazim is rapidly absorbed up to estimated 80 % from the gastrointestinal tract, extensively metabolised and rapidly excreted. Carbendazim proved to be neither acutely toxic after oral, dermal, inhalation, or intraperitoneal administration, nor irritating to skin or eyes. Carbendazim is however considered to be skin sensitising based on results of a Magnusson & Kligman test. Target organs after repeated dose and chronic exposure are liver and testes. Testis toxicity was also observed in reproduction toxicity studies which revealed seminiferous tubular atrophy and depression of spermatogenesis in rats. Developmental toxicity (increased resorptions, decreased litter size, decreased birth weight) and teratogenicity (malformations) was observed in rats and rabbits. Liver tumours were observed after chronic exposure to carbendazim in two related mouse strains (CD-1 and Swiss, strains known to have a high spontaneous incidence of liver tumours) but not in rats or NMRKf mice. Since there was no increase in tumour incidence in any other organ system examined or in rats or in NMRKf mice these findings were not considered to indicate a specific carcinogenic hazard for humans. Carbendazim is considered to have aneugenic properties not damaging the DNA directly but interacting with a non-DNA target (tubulin) and thus affecting the spindle apparatus during mitosis. A threshold for aneuploidy induction was observed after gavage administration in sperm and bone marrow of rats. This effect is likely to be responsible also for the embryo-/foetotoxicity in rabbits and rats.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Production of end-products	Primary inhalation and dermal exposure during connecting transfer lines. The mixing of the biocidal product, i.e. of the film preservative into the end-use products is done in industrial scale. Closed conditions: Connecting lines – liquid automated transfer (considering only incidental hand contamination and no body exposure) – concentrate ≤10 % a.s.	Industrial user	**Acceptable** without PPE
Application of film-preserved paints	Secondary inhalation and dermal exposure during application of ready to use products, containing 0.1 % carbendazim as film preservative, by brushing and cleaning of brushes	Professional user	**Acceptable** without PPE
Application of film-preserved paints	Secondary inhalation and dermal exposure after painting of surfaces with ready to use products containing 0.1% carbendazim as film preservative	Professional bystander	**Acceptable** without PPE
Application of film-preserved paints	Secondary exposure, acute inhalation and dermal exposure during application of ready to use products, containing 0.1 % carbendazim as film preservative, by brushing sheds and fences and during cleaning of brushes	non-professional user[3]	**Acceptable**
Freshly painted rooms	Secondary exposure; toddlers staying in freshly painted rooms and contact to wet surfaces after application of ready to use products, containing 0.1 % carbendazim as film preservative; acute oral, dermal and inhalation exposure	toddlers, general public	**Acceptable**
Painted rooms	Secondary exposure; toddlers staying in painted rooms and contact to dried surfaces after application of ready to use products, containing 0.1 % carbendazim as film preservative; medium- and long-term oral, dermal and inhalation exposure	toddlers, general public	**Acceptable**

Professional user:

The occupational risk assessment for carbendazim takes into account systemic effects. Primary and secondary exposure of professional user is considered acceptable. The ratio of estimated uptake and reference value is below 100 % for all professional exposure scenarios, resulting in no concern. Based on this analysis, there is no need for further refinement of this risk assessment.

[3] Carbendazim is listed in Annex XVII of the Reach Regulation (EC) No 1907/2006 in entry 29-30. Consequently, end-products which are mixtures and contain 0.1% or more carbendazim cannot be supplied to the general public.

Regarding the dermal local effects of carbendazim a qualitative risk assessment was carried out based on the classification and labelling.

For the production of end-products (scenario 1) a dermal contact with the 10% carbendazim biocidal product is possible. As the biocidal product is classified with H 317 (May cause an allergic skin reaction), protective gloves are recommended for the opening of the closed system (e.g. during connection/disconnection of containers and handling of empty drums).

Non-professional user and the general public:

Secondary exposure of the non-professional user and the general public is considered acceptable. Specific measures for non-professionals and the general public are not required. Residues in food are not expected from the intended use.

Environment

Carbendazim is not readily biodegradable, hydrolytically stable at pH 5 and 7, and photolytically stable. Carbendazim is a persistent substance regarding the results of degradation studies in water/sediment systems (worst case DT_{50} value of 145.6 days at 12°C). In soil, carbendazim is not persistent by definition (DT50 < 120 d) but it tends to the formation of high amounts of non-extractable residues (36-81%) along with low mineralization rates (<14%). The substance has moderately adsorption properties. Data on bioconcentration indicate that carbendazim neither bioconcentrate in aquatic biota nor bioaccumulates in the food chain of terrestrial organisms. Based on short-term and long-term aquatic studies with fish, daphnia and algae it can be concluded that carbendazim is very toxic to fish and crustacea (acute and chronic). For the terrestrial compartment high acute and chronic toxicity to earthworm was found. Carbendazim is classified as very toxic to aquatic life and can cause long lasting effects.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments***	**Conclusion**
Formulation of film-preserved paints	Formulation of the water-based suspension of carbendazim into the end-use-product (paint) is processed at industrial scale under insulated/closed conditions. Exposure to the environment is considered negligible.	**Acceptable**
OUTDOOR		
CITY-outdoor		

Summary table: environment scenarios			
Scenario		**Description of scenario including environmental compartments***	**Conclusion**
Application of film-preserved paint	SPRAY-via STP	Assessment of losses from treatment of city house façades by spraying due to run off and spray drift. Losses are flushed with rainwater via sewer system to STP and affect indirectly the environmental compartments surface water, sediment, soil and groundwater.	**Acceptable** but only with the RMM of covering the paved soil (to prevent emission to the STP) during application of carbedanzim containing paints and only if the carbendazim concentration in paints is restricted to 0.025 %
	SPRAY-direct rainwater discharge	In separate sewer systems rainwater and wastewater are separately collected in different sewers. Assessment of losses from treatment of city house façades by spraying due to run off and spray drift. Losses are flushed with rainwater into the rainwater sewer. The rainwater is (commonly) not treated and will be discharged directly to surface water bodies. Subsequently, the sediment is affected.	**Not acceptable** because of unacceptable risks in the surface water and sediment compartment (despite the recommended RMM of covering the paved soil (to prevent emission to rainwater sewer) during application of carbedanzim containing paints and an additionally restriction of a carbendazim concentration in paints to 0.025 %)
	BRUSH-via STP	Assessment of losses from treatment of city house façades by rolling/ brushing due to dripping. Losses are flushed with rainwater via sewer system to STP and affect indirectly the environmental compartments surface water, sediment, soil and groundwater.	**Acceptable** but only with the RMM of covering the paved soil (to prevent emission to the STP) during application of carbedanzim containing paints
	BRUSH-direct rainwater discharge	In separate sewer systems rainwater and wastewater are separately collected in different sewers. Assessment of losses from treatment of city house façades by rolling/ brushing due to dripping. Losses are flushed with rainwater into the rain water sewer. The rainwater is (commonly) not treated and will be discharged directly to surface water bodies. Subsequently, the sediment is affected.	**Acceptable** but only with the RMM of covering the paved soil (to prevent emission to rainwater sewer) in the city during application to protect
Service life	via STP	Leachates of treated city house façades are flushed with rainwater via sewer system to STP and affect indirectly the environmental compartments surface water, sediment, soil and groundwater.	**Not acceptable** because of unacceptable risks in the surface water and sediment compartment; no adequate RMM is available to avoid releases in the sewer

Summary table: environment scenarios			
Scenario		**Description of scenario including environmental compartments***	**Conclusion**
	STP bypass	Leachates of treated city house façades are flushed with rainwater into the sewer system. In case a storm water event takes place, wastewater plus rainwater from mixed sewer systems may be discharged directly to surface water bodies. Subsequently, the sediment is affected.	**Not acceptable** because of unacceptable risks in the surface water and sediment compartment; no adequate RMM is available to avoid releases in the sewer
	direct rainwater discharge	In separate sewer systems rainwater and wastewater are separately collected in different sewers. Leachates of treated city house façades are flushed with rainwater into the rainwater sewer. The rainwater is (commonly) not treated and will be discharged directly to surface water bodies. Subsequently, the sediment is affected.	**Not acceptable** because of unacceptable risks in the surface water and sediment compartment; no adequate RMM is available to avoid releases in the sewer
COUNTRYSIDE-House			
Application of film-preserved paint	SPRAY	Assessment of losses from treatment of countryside house façades by spraying due to run off and spray drift. Losses end up in an adjacent and distant soil compartment and are, subsequently, transferred to groundwater	**Acceptable** but only with the RMM of covering the adjacent ground/soil during application of carbedanzim containing paints
	BRUSH	Assessment of losses from treatment of countryside house façades by rolling/ brushing due to dripping. Losses end up in an adjacent soil compartment and are, subsequently, transferred to groundwater.	**Acceptable** but only with the RMM of covering the adjacent ground/soil during application of carbedanzim containing paints
Service life		Leachates of treated countryside house façades are flushed with rainwater into an adjacent soil compartment and are, subsequently, transferred to groundwater.	**Acceptable**
COUNTRYSIDE-Bridge over pond			
Application of film-preserved paint	BRUSH	Assessment of losses from treatment of a wooden bridge by rolling/ brushing due to dripping. Losses end up directly to a surface water body. Subsequently, the sediment is affected	**Acceptable** but only if the carbendazim concentration in paints is restricted to 0.025 %

Summary table: environment scenarios			
Scenario		**Description of scenario including environmental compartments***	**Conclusion**
Service life		Leachates of a treated wooden bridge end up directly to a surface water body. Subsequently, the sediment is affected.	**Acceptable**
INDOOR			
CITYindoor			
Application of film-preserved paint	BRUSH-via STP	The brush or roller from the treatment of rooms is washed and rinsed with water. Losses of a.s. end up via sewer system into STP and affect indirectly the environmental compartments surface water, sediment, soil and groundwater.	**Acceptable**
	BRUSH-STP bypass	The brush or roller from the treatment of rooms is washed and rinsed with water. Losses of a.s. end up in the sewer system. In case a storm water event takes place, wastewater plus rainwater from mixed sewer systems may be discharged directly to surface water bodies. Subsequently, the sediment is affected.	**Acceptable**
Service life		No emission scenario is available to cover the indoor use of carbendazim containing paints. Negligible exposure of the environment is assumed.	**Acceptable**

*only non-professionals evaluated, considered as worst case

The risk assessment reveals that overall the outdoor use of carbendazim containing paints pose an unacceptable risk to the environment since no adequate risk mitigation measure is available to avoid releases in the sewer over a period of 5 years (service life).

The indoor use of carbendazim containing paints does not pose an unacceptable risk to the environment.

Referring to secondary poisoning of non-target animals, carbendazim has only a very low potential for a concern.

Overall conclusion

The risk assessment reveals that the outdoor use of carbendazim containing paints pose an unacceptable risk to the environment.

The indoor use of carbendazim containing paints does not pose an unacceptable risk to human health and the environment.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	no classification required	Carbendazim does fulfil criterion (b) and (c) of Article 5(1)
	Mutagenicity (M)	Cat 1B	
	Toxic for reproduction (R)	Cat 1B	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Carbendazim: P Metabolite 2-Aminobenzimidazole: Potentially P (not P in soil)	Carbendazim does not fulfil criterion (e) of Article 5(1) but does fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Carbendazim: not B Metabolite 2-Aminobenzimidazole: not B	
	Toxic (T)	Carbendazim: T Metabolite 2-Aminobenzimidazole: Potentially T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No conclusion can be drawn based on the available data	No conclusion can be drawn whether carbendazim fulfils criterion (d) of Article 5(1) and/or criterion (e) of Article 10(1)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No conclusion can be drawn based on the available data	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s)	No	
Respiratory sensitisation properties	No classification required. Hence, carbendazim does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	For classification no concerns regarding critical effects according to Article 10(1)(e) are identified.		
Proportion of non-active isomers or impurities	Carbendazim is not considered to have a significant proportion of non-active impurities. That means carbendazim does not fulfil criterion (f) of Article 10(1).		

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[4], with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[5] and with "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment"[6] agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

Consequently, the following is concluded:

Carbendazim does meet the exclusion criteria laid down in Article 5(1)(b) and (c) of Regulation (EU) No 528/2012. For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100, no conclusion can be drawn on the available data. For reports submitted before 1 September 2013, it is mentioned in the CA meeting note mentioned above that the evaluating Competent Authority has to conclude based on the already available data and/or the data provided by the applicant and, in case the data is insufficient to reach a conclusion, the BPC may conclude in its opinion that no conclusion could be drawn. It is noted that the evaluation of carbendazim for PT 7 was submitted before 1 September 2013.

Carbendazim does meet the conditions laid down in Article 10(1)(a) and (d) of Regulation (EU) No 528/2012, and is therefore considered as a candidate for substitution.

According to the "Note on the principles for taking decisions on the approval of active substances under the BPR"[4] for draft assessment report and the conclusions of its evaluation submitted by the evaluating Competent Authorities before 1 September 2013, the exclusion and substitution criteria as defined in the BPR have to be assessed, but the principles of the Biocidal Products Directive will apply for the decision-making. This means that though carbendazim fullfills Article 5(1)(b) and (c) of Regulation (EU) No 528/2012, Article 5(2) of Regulation (EU) No 528/2012 is not of relevance for the approval decision.

2.2.2. POP criteria

Carbenazim does not fulfil the POP criteria.

2.2.3. Identification of potential alternatives substances or technologies, including the results of the public consultation for potential candidates for substitution

As carbendazim is considered a candidate for substitution ECHA launched the public consultation in accordance with Article 10(3) of Regulation (EU) No 528/2012. The public consultation took place from July to September 2014.

[4] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)

[5] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

[6] See document: Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment (available from https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/48320db7-fc33-4a91-beec-3d93044190cc/details).

Eleven non-confidential contributions were received from third parties, all of them companies or industrial associations. Most of the contributions did not differentiate between the uses of carbendazim in PT 7, 9 and 10.

According to the received documents, carbendazim is used against fungi, mould, algae and bacteria. It is said that carbendazim provides a long-term protection and a long-term efficacy and can offer high-quality water based paints. Based on the information available from the received documents, it is stable at high pH and compatible with building products. The water solubility is very low. This property reduces the leaching potential and so the effectiveness of the fungicidal protection over a longer period of time could be ensured.

The authors of the documents describe that there is only a limited selection of active substances for this application and so there are less alternatives. A replacement of carbendazim in paints is technically possible. However, according to the information received the substitution of the active ingredient in the paint system is a very complex exercise given that it would be necessary to test the chemical compatibility of a new formulation with other ingredients which would be associated with very high costs. It is claimed that it would also be too costly for biocides companies to develop a new substance and it would take years before such new substance is discovered.

With regard to this last comment, it has to be highlighted that in the meantime, two new active substance, fludioxonil and azoxystrobin, has been approved for PT 7.

One contribution declares that only very few effective dry-film biocide active substances are left and that active substances are normally not replaceable one by one and that several parameters have to be considered, like chemical and physical compatibility, stability in the wet stage and in the dry stage (such as pH on masonry), rate of degradation, leaching behaviour, intrinsic toxicity for human health and for the environment etc..This author also proposes that, for those biocides showing a safe use, before taking any regulatory measure, Competent Authorities should first get a proper overview of the impact on the dry-film preservation sector as safety in use is demonstrated by a risk based approach and not by a hazard based approach.

One contribution highlights the fact that carbendazim is preferably used in southern European countries with several different climate regions. Furthermore, the authors pointed out that it is difficult to assess the availability of alternatives given that many of them still have to be reviewed under the BPR.

Another contribution claims that manufacturers of preserved paints and coatings are not in charge of developing alternative biocidal active substances.

Several contributions highlight the fact that carbendazim is characterized by its stability at very high pH values and that they are not aware of any other fungicide with the same property. With regard to this comment, due to the very low number of approved active substances for this PT, information available for the BPC is currently not sufficient to decide whether there is any other active substance which could be any alternative for carbendazim being used as preservative in plasters characterised by a high pH value.

According to one contribution, most of the biocidal products used in PT 7 contain more than one fungicide. Carbendazim for example is often used in combination with IBPC or OIT and with algaecides. This has also to be taken into account when thinking on possible alternatives for carbendazim.

Alternative active substances approved for PT 7:

At the moment there are 4 existing active substances approved for product type 7 (tebuconazole, propiconazole, folpet and tolylfluanid), as well as two new active substances, fludioxonil and azoxystrobin. The evaluation of folpet, propiconazole and tolylfluanid covers the use in film-preserved paints for outdoor use, whereas tebuconazole was only assessed with regard to its use indoors in seal joints. With its opinion RAC considers propiconazole as being a reproductive toxicant category 1B what makes propiconazole fulfil the exclusion criteria according to Art. 5 of the BPR as well. For the approval of azoxystrobin in PT 7, only the use as film-preservative in paints for indoor use was assessed. The same applies for fludioxonil.

The BPC could not further assess potential alternative substances, due to lack of information received during the public consultation.

2.3. BPC opinion on the application for approval of the active substance carbendazim in product type 7

In view of the conclusions of the evaluation, it is proposed that carbendazim shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: ≥99.0% w/w
2. Relevant impurities: 2,3-diaminophenazine: ≤0.00023% w/w
   3-amino-2-hydroxyphenazine: ≤0.00003% w/w
3. Carbendazim is considered a candidate of substitution in accordance with Article 10(1)(a) and (d) of Regulation (EU) No 528/2012.
4. The authorisations of biocidal products are subject to the following condition(s):
   a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
   b. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.
   c. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:
      i. Surface water, sediment, soil and groundwater for products used in paints which are intended to be used outdoors.
5. The placing on the market of treated articles is subject to the following condition(s):
   a. The person responsible for the placing on the market of a treated article treated with or incorporating the active substance carbendazim shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012. Carbendazim gives rise to concern for human health and the environment, i.e. it is classified as Muta. 1B, as Repr. 1B and as Aquatic acute 1. In addition, it is proposed to be classified as Skin Sens. 1.

2.4. Elements to be taken into account when authorising products

1. The active substance carbendazim is considered as a candidate for substitution, and consequently the competent authority shall perform a comparative assessment as part of the evaluation of an application for national authorisation.
2. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:
    a. If an unacceptable risk is identified for industrial and/or professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.
    b. Unacceptable risks for surface water, sediment, soil and groundwater are identified for outdoor uses of paints containing carbendazim. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, products used in treated articles which are intended to be used outdoors should not be authorised.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of carbendazim.

However, for renewal of the approval, available monitoring data on resistance should be submitted to the eCA in addition to an updated systematic literature review concerning carbendazim resistance.

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