Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Carbendazim

Product type: 9

ECHA/BPC/218/2019

Adopted

27 February 2019

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance carbendazim for product type 9

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 non-approval in product type 9 of the following active substance:

Common name:	**Carbendazim**
Chemical name:	**Methyl -benzimidazol-2-ylcarbamate**
EC No.:	**234-232-0**
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-29) and its Working Groups (WG II 2015, WG IV 2017, 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 non-approval of the active substance carbendazim in product type 9 was adopted on 27 February 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 consensus. The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the carbendazim in product type 9 may not 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 9.

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

The approval[1] 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 German MSCA submitted a CLH dossier to amend the classification in November 2018. 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 H400 H410

[1] 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 (may cause genetic defects) H360FD (may damage fertility. May damage the unborn child) H317 (may cause an allergic skin reaction) H410 (very toxic to aquatic life with long lasting effects)
Specific Concentration limits, M-Factors	M = 10 (acute) M = 10 (chronic)
Justification for the proposal	
Classification with Skin Sens. 1 is proposed based on the results of a Magnusson & Kligman test.	

b) Intended use, target species and effectiveness

Carbendazim is used as a fungicide for preservation of polymerised materials (e.g. plastic) (PT9). The use of carbendazim for preservation of roof membranes has been assessed. The biocidal product is only used by professionals and the end-product (e.g. roof membranes) can be used by either professionals or by non-professionals.

Carbendazim acts as a systemic fungicide by inhibiting mitosis, thus preventing growth of the target organisms.

The data on carbendazim showed innate efficacy against fungi when used for the preservation of plastics, which is sufficient for active substance approval.

Carbendazim has a single site mode of action, which causes an elevated potential for resistance.

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 (treated article)	Primary inhalation and dermal exposure during opening and handling of bags containing the biocidal product (100% carbendazim powder). ; PPE: coated coverall, protective gloves, respiratory protective equipment	industrial user	acceptable with PPE
Application of plastic materials	Primary inhalation and dermal exposure during application of ready to use products (plastic materials, e.g. roof membranes) in building trade, containing 0.35 % carbendazim.	professional user	acceptable without PPE
Application of plastic materials	Primary inhalation and dermal exposure during restauration work using plastic materials such as roof membranes	professional user	acceptable without PPE
Roof membranes	Primary inhalation/dermal exposure, while laying roof membranes	non-professional	acceptable
Roof membranes	Secondary acute exposure via the inhalation/dermal/oral routes, toddler getting in contact with roof membranes	general public: toddler	acceptable
Roof membranes	Secondary long-term exposure, inhalation of vapours from roof membranes in house attics for permanent use	general public: adult and toddler	acceptable

Professional user:

The occupational risk assessment for carbendazim takes into account systemic effects.

As risks are identified for opening of carbendazim bags (biocidal product, 100% carbendazim powder) and dis-/connecting to industrial automatic systems risk mitigation measures have to be applied (coated coverall, protective gloves, respiratory protective equipment).

For application of plastic materials (e.g. roof membranes) exposure of professional user is considered acceptable. The ratio of estimated uptake and reference value is below 100% for all professional scenarios, resulting in no concern and no PPE is necessary.

Non-professional user and the general public:

Primary exposure of the non-professional user and secondary exposure of the general public is considered acceptable. Specific measures for non-professionals and the general public are not required. Residues in food and feed 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 bioconcentrates 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**
Manufacture of plastic materials		Assessment of emissions from manufacture of plastics (used for production of roof membranes). Emissions to wastewater reach via sewer system the STP and affect indirectly the environmental compartments surface water, sediment, soil and groundwater. Emissions to air due to volatilisation reach the environmental compartments soil and groundwater via deposition.	**Acceptable**
OUTDOOR, SERVICE LIFE OF ROOF MEMBRANES			
CITY house:			
Use based approach (city)	via STP	Leachates of roof membranes, manufactured from carbendazim containing plastics, 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 to the sewer
	STP bypass	Leachates of roof membranes, manufactured from carbendazim containing plastics, 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 to the sewer
	direct rainwater discharge	In separate sewer systems rainwater and wastewater are separately collected in different sewers. Leachates of roof membranes, manufactured from carbendazim containing plastics, are flushed with rainwater into the rainwater sewer. The rainwater is 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 to the sewer

COUNTRYSIDE house:			
Use based approach (soil)		Leachates of roof membranes, manufactured from carbendazim containing plastics, are flushed with rainwater on an adjacent soil compartment and are, subsequently, transferred to groundwater.	**Not acceptable** because of unacceptable risks in the soil compartment; no adequate RMM is available.

*for roof membranes manufactured from plastics with a carbendazim concentration of 0.35 %

The production of the plastic materials does not pose any unacceptable risk to the environment. In contrast, the service life of roof membranes containing the active substance results in unacceptable risks, which cannot be mitigated by adequate risk mitigation measures. In the city scenario, unacceptable risks are identified for surface water and sediment due to releases to the sewer. Unacceptable risks are also identified for the countryside scenario, where rainwater leachates from roof membranes reaching the adjacent soil lead to unacceptable risks in this compartment.

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 assessed representative use of the biocidal product in plastic materials (e.g. roof membranes) poses an unacceptable risk to 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	

<table>
<tr><td rowspan="4">Endocrine disrupting properties</td><td>Section A of Regulation (EU) 2017/2100: ED properties with respect to humans</td><td rowspan="4">An assessment of the endocrine disrupting properties according to Regulation (EU) 2017/2100 was not conducted. Consequently, no conclusion can be drawn whether carbendazim fulfils criterion (d) of Article 5(1) for human health or criterion (e) of Article 10(1) for the environment.</td></tr>
<tr><td>Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms</td></tr>
<tr><td>Article 57(f) and 59(1) of REACH</td></tr>
<tr><td>Intended mode of action that consists of controlling target organisms via their endocrine system(s).</td></tr>
<tr><td>Respiratory sensitisation properties</td><td colspan="2">No classification required. Hence, carbendazim does not fulfil criterion (b) of Article 10(1).</td></tr>
<tr><td>Concerns linked to critical effects</td><td colspan="2">For classification no concerns regarding critical effects according to Article 10(1)(e) are identified.</td></tr>
<tr><td>Proportion of non-active isomers or impurities</td><td colspan="2">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).</td></tr>
</table>

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. However the endocrine disruptor properties have not been assessed as defined in Regulation (EU) No 2017/2100 and it is not possible to finally conclude on the exclusion criteria related to Article 5(1)(d).

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.

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”[2] and in line with “Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR”[3] agreed at the 54th and 58th 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).

[2] 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)

[3] 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)

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.

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. None of the information received was specific for PT 9.

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 can 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 not that many alternatives.

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.

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.

<u>Alternative active substances approved for PT 9:</u>

Propiconazole, Folpet, Chlorocresol, Fludioxonil and Azoxystrobin are active substances which have already been approved for PT 9. Although all of them are fungicides, only folpet has been evaluated with respect to its use in plastic pellets used for production of roof membranes.

2.3. BPC opinion on the application for approval of the active substance carbendazim in product type 9

In view of the evaluation, it is concluded that biocidal products containing carbendazim as an active substance used for preservation of polymerised materials may not be expected to meet the criteria laid down in points (b)(iv) of Article 19(1) of Regulation (EU) 528/2012. Consequently, it is proposed that carbendazim shall not be approved and included in the Union list of approved active substances.