Biocidal Products Committee (BPC)

Opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on

Eligibility of Powdered Corn Cob for Inclusion into Annex I to the BPR

ECHA/BPC/175/2017

Adopted

11 December 2017

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Opinion of the Biocidal Products Committee

on the eligibility of powdered corn cob for inclusion into Annex I to the BPR

In accordance with Article 75(1)(g) 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, the Biocidal Products Committee (BPC) has adopted this opinion on the eligibility of powdered corn cob for inclusion into Annex I to the BPR.

This document presents the opinion adopted by the BPC, having regard to the conclusions of the rapporteur.

Process for the adoption of the opinion

A request by Commission was received by ECHA on 26 April 2017. ECHA was appointed as the rapporteur at BPC-20. The rapporteur presented the draft opinion to the BPC at its meeting of 11-14 December 2017.

Adoption of the opinion

Rapporteur: European Chemicals Agency (ECHA)

The BPC opinion was reached on 11 December 2017.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority positions including their grounds are published on the ECHA webpage at:

https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-other-requests-under-the-biocidal-products-regulation

Further details of the opinion and background

1. Request for the opinion and background

Powdered corn cob has been assessed and included by Directive 2013/44/EU into Annex I and IA to the Directive 98/8/EC (BPD) for use in PT14 biocidal products. In particular, this substance was considered as eligible for use in low risk products under the BPD, and was therefore also included into Annex IA to the BPD. This substance is now considered approved pursuant to Article 86 of the BPR.

The decision-making process on this substance took place late 2012 / beginning of 2013, after the adoption of the new Regulation (EU) No 528/2012 (BPR) on May 2012 and was finalized before its entry into application on 1 September 2013. The BPC, which delivers opinions on the inclusion of active substances into Annex I to the BPR according to Article 75(1)(c), was not operating before 1 September 2013.

Due to this calendar, it was not discussed whether powdered corn cob could be listed or not into Annex I to the BPR. Consequently, it is currently not possible for companies to obtain an authorisation via the simplified authorisation procedure for products containing powdered corn cob, as such procedure is only possible when the active substance is listed in Annex I to the BPR.

As provided under Article 28(1) of the BPR, a new inclusion of an active substance into Annex I to the BPR has to be made by means of delegated acts on the basis of an ECHA opinion.

At the 70th meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 of March 2017, a discussion took place to define the best approach to take on this case. During that meeting, it was agreed that the Commission would request a formal opinion to ECHA, in order to be able to proceed with the inclusion of powdered corn cob into Annex I to the BPR in case it is eligible.

Pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012, ECHA was requested by the Commission to formulate an opinion addressing the following question:

> Does powdered corn cob give rise to concern in accordance with Article 28(2) of the BPR, and is it eligible for inclusion into Annex I to the BPR?

2. Summary and evaluation of information supporting the request for the opinion

2.1. Summary of the information supporting the opinion

The evaluation of powdered corn cob as PT 14 was carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of the BPD. ECHA has used all information available in the application submitted and the assessment report finalised in 2012 on this active substance, as well as other new information accessible to ECHA (see references). The list of end points of the assessment report is included in Appendix I of this opinion. The additional information was used to further support the characterisation of powdered corn cob as an active substance eligible for Annex I inclusion.

Powdered corn cob is made from animal grade stripped corn cobs. The stripped corn cobs are ground into powder to produce the active substance. Ground raw corn cob is a naturally occurring composite material and therefore it is difficult to assign one structure. Powdered corn cob is a very stable carbohydrate material, poorly soluble in water and all solvents. It is recommended to use corn cob only in the form of pellets in dry locations This was a specific provision for the inclusion into Annex IA under the BPD and indicated in the Annex of Directive 2013/44/EU.

2.2. Evaluation of information supporting the request for the opinion

Specific criteria are defined in the BPR concerning the properties that active substances shall not have to be listed in Annex I. According to Article 28(1) and (2), active substances can be included in Annex I if there is evidence that they do not give rise to concern.

A substance is considered to give rise to concern where:

(a) it meets the criteria for classification according to Regulation (EC) No 1272/2008 as:

- Explosive/highly flammable
- Organic peroxide
- Acute toxicity category 1, 2 or 3
- Corrosive category 1A, 1B or C
- Respiratory sensitizer
- Skin sensitiser
- Germ cell mutagen of cat 1 or 2
- Carcinogen of cat 1 or 2
- Human reproductive toxicant of category 1 or 2 with effects on or via lactation
- Specific target organ toxicant by single or repeated exposure
- Toxic to aquatic life of acute category 1

(b) it fulfils any of the substitution criteria set out in Article 10(1); or

(c) it has neurotoxic or immunotoxic properties.

An active substance also gives rise to concern, even if none of the specific criteria in points (a) to (c) are met, where a level of concern equivalent to that arising from points (a) to (c) can be reasonably demonstrated based on reliable information.

Most of these criteria were already specified criteria for Annex IA and IB inclusion[1] under the BPD and were described in Article 10(2). Accordingly, an active substance could not be included in Annex IA if it was classified according to Directive 67/548/EEC (replaced currently by the CLP Regulation) as:

- carcinogenic,
- mutagenic,
- toxic for reproduction,
- sensitising, or
- is bioaccumulating and does not readily biodegrade.

[1] TNsG on Annex I inclusion. Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market.

The assessment report submitted by the designated Rapporteur Member State under the BPD Greece concluded that biocidal products used as rodenticides and containing powdered corn cob were expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, and therefore, recommended the inclusion of powdered corn cob for use in product type 14 in Annex I to that Directive.

The assessment report also concluded that biocidal products used as rodenticides and containing powdered corn cob was expected to present ony low risk to humans, non-target animals and the enivonment in particular with regard to the use which was examined and detailed in the assessment report. The report therefore recommended the inclusion of powdered corn cob for the use in Annex IA to the BPD. Consequently, powdered corn cob was included in Annex IA in Directive 2013/44/EU. To the inclusion a specific provision was added: Member States shall ensure that registrations are subject to the following condition: - Only for use in the form of pellets in dry locations.

The available data on powdered corn cob were evaluated using the newly defined criteria of the BPR. The table below summarises the relevant information to define if powdered corn cob gives rise to concern in accordance with Article 28(2):

<table>
<tr><th colspan="2">Property</th><th colspan="2">Conclusions</th></tr>
<tr><td rowspan="2">Physical hazards</td><td>Explosive/highly flammable</td><td>No classification required</td><td rowspan="2">Powdered corn cob does not fulfil criterion (a), of Article 28(2)</td></tr>
<tr><td>Organic peroxide</td><td>No classification required</td></tr>
<tr><td>Acute toxicity category 1, 2 or 3</td><td colspan="3">No classification required. Powdered corn cob does not fulfil criteria (a) of Article 28(2).</td></tr>
<tr><td>Corrosive category 1A, 1B or C</td><td colspan="3">No classification required. Powdered corn cob does not fulfil criteria (a) of Article 28(2).</td></tr>
<tr><td>Respiratory sensitisation properties</td><td colspan="3">No classification required. Powdered corn cob does not fulfil criteria (b) of Article 10(1) and (a) of Article 28(2).</td></tr>
<tr><td>Skin sensitiser</td><td colspan="3">No classification required. Powdered corn cob does not fulfil criteria (a) of Article 28(2).</td></tr>
<tr><td rowspan="3">CMR properties</td><td>Carcinogenicity (C)</td><td>No classification required</td><td rowspan="3">Powdered corn cob does not fulfil criterion (a), (b) and (c) of Article 5(1) and (a) of Article 28(2)</td></tr>
<tr><td>Mutagenicity (M)</td><td>No classification required</td></tr>
<tr><td>Toxic for reproduction (R)</td><td>No classification required</td></tr>
<tr><td>Specific target organ toxicant by single or repeated exposure</td><td colspan="3">No classification required. Powdered corn cob does not fulfil criteria (a) of Article 28(2).</td></tr>
</table>

<table>
<tr><td>Toxic to aquatic life of acute category 1</td><td colspan="3">No classification required. Powdered corn cob does not fulfil criteria (a) of Article 28(2).</td></tr>
<tr><td rowspan="3">PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td>Not P or vP</td><td rowspan="3">Powdered corn cob does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)</td></tr>
<tr><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td><td>not B or vB</td></tr>
<tr><td>Toxic (T)</td><td>not T</td></tr>
<tr><td>Endocrine disrupting properties</td><td colspan="3">Powdered corn cob is not considered to have endocrine disrupting properties</td></tr>
<tr><td>Neurotoxic or immunotoxic properties</td><td colspan="3">Powedered corn cob is not considered to have neurotoxic or immunotoxic properties.</td></tr>
</table>

Based on the available data, no classification is currently used or proposed for powdered corn cob concerning its physico-chemical, toxicological, environmental and ecotoxicological properties in accordance with Annex I of Council Directive 67/548/EEC and the CLP Regulation (EU) No 1272/2008 (criteria (a) Article 28(2)).

Powdered corn cob does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Powdered corn cob does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not 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 (EU) No 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).

It is concluded that powdered corn cob does not give rise to concern according to Article 28(2) of the BPR.

[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)

3. Overall conclusions

It is concluded that powdered corn cob does not give rise to concern according to Article 28 and therefore is eligible for inclusion in Annex I of Regulation (EU) No 528/2012 with the following substance identifiers:

Common name:	Powdered corn cob
Chemical name:	None
EC No:	None
CAS No:	None

It is proposed to include the following restriction in Annex I: “Only for use in the form of pellets in dry locations”.

4. Reference list

Pointner, M., Kuttner, P., Obrlik, T., Jäger, A. and Kahr, H. (2014). Composition of corn cobs as a substrate for fermentation of biofuels. Agronomy Research 12(2), 391–396.

Schmolz, E. (2010). Efficacy of anticoagulant-free alternative bait products against house mice (Mus musculus) and brown rats (Rattus norvegicus). Integrative Zoology, 1, 44-52.

Assessment Report Powdered corn cob, product-type PT 14. (2012) (Published on ECHA web-site at: http://dissemination.echa.europa.eu/Biocides/factsheet?id=1278-14).

Appendix I: List of end points

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	Powdered corn cob
Product-type	14

Identity

Chemical name (IUPAC)	None
Chemical name (CA)	None
CAS No	None
EC No	None
Other substance No	None
Minimum purity of the active substance as manufactured (g/kg or g/l)	1000g/kg (Due to the nature of the active substance as corn cob we can consider the core of a maize.)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	No substances of concern
Molecular formula	Powdered corn cob is a naturally occurring composite material and thus does not have a molecular formula
Molecular mass	Powdered corn cob is a naturally occurring composite material and thus does not have molecular mass.
Structural formula	Powdered corn cob is a naturally occurring composite material and thus does not have a structural formula.

Physical and chemical properties

Melting point (state purity)	100% natural corn cob fractions have a melting point of 1204-1325°C.
Boiling point (state purity)	n.a.
Temperature of decomposition	Due to the nature of the active substance it is expected to be stable
Appearance (state purity)	Solid tan powder
Relative density (state purity)	0.288 – 0.416g/cm3 (woody portion of the corn cob) (Bulk density)
Surface tension	n.a.
Vapour pressure (in Pa, state temperature)	n.a.
Henry's law constant (Pa m^3 mol^{-1})	n.a.
Solubility in water (g/l or mg/l, state temperature)	Due to the nature of the active substance it is expected to have poor solubility in water
Solubility in organic solvents (in g/l or mg/l, state temperature)	Due to the nature of the active substance it is expected to have poor solubility in all solvents.
Stability in organic solvents used in biocidal products including relevant breakdown products	Due to the nature of the active substance it is expected to have poor solubility in all solvents
Partition coefficient (log P_{OW}) (state temperature)	n.a.
Hydrolytic stability (DT_{50}) (state pH and temperature)	n.a.
Dissociation constant	n.a.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	n.a.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	n.a.
Quantum yield of direct phototransformation in water at Σ > 290 nm	n.a.
Flammability	Non highly flammable.
Explosive properties	No explosive properties based on the structure of the compound and the percentage oxygen balance.

Classification and proposed labelling

with regard to physical/chemical data	None
with regard to toxicological data	None
with regard to fate and behaviour data	None
with regard to ecotoxicological data	None

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	An analytical method for identification is not identifiable.
Impurities in technical active substance (principle of method)	-

Analytical methods for residues

Soil (principle of method and LOQ) Air (principle of method and LOQ) Water (principle of method and LOQ) Body fluids and tissues (principle of method and LOQ) Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Corn cobs decompose mainly to sugars which are readily incorporated into intermediary metabolism in the environment. Thus there are no residues which pose a treat to human or animal health or the environment. Furthermore an analytical method is not identifiable.

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption	No data, not required
Rate and extent of dermal absorption	No data, not required
Distribution	No data, not required
Potential for accumulation	No data, not required
Rate and extent of excretion	No data, not required
Toxicologically significant metabolite(s)	None

Acute toxicity

Rat LD_{50} oral	>15 g/kg b.w.
Rat LD_{50} dermal	No data, not required
Rat LC_{50} inhalation	No data, not required
Skin irritation	Not irritating
Eye irritation	Not irritating
Skin sensitization (test method used and result)	Not sensitising

Repeated dose toxicity

Species/ target / critical effect	None
Lowest relevant oral NOAEL / LOAEL	Not established, not required
Lowest relevant dermal NOAEL / LOAEL	No data, not required
Lowest relevant inhalation NOAEL / LOAEL	No data, not required

Genotoxicity	No genotoxic potential

Carcinogenicity

Species/type of tumour	No carcinogenic potential
lowest dose with tumours	Not relevant

Reproductive toxicity

Species/ Reproduction target / critical effect	None
Lowest relevant reproductive NOAEL / LOAEL	Not established, not required
Species/Developmental target / critical effect	None
Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	Not established, not required

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	No data, not required
Lowest relevant developmental NOAEL / LOAEL.	No data, not required

Other toxicological studies

.....	No data, not required

Medical data

.....	No data, not required

Reference values	Value	Study	Assessment factor
Non-professional user			
ADI (acceptable daily intake, external long-term reference dose)	-	-	-
DWL (Drinking water limit	-	-	-
AELs (Acceptable Exposure Limits. Internal reference dose):	-	-	-
AEL short term	-	-	-
AEL medium-term	-	-	-
AEL long-term	-	-	-
ARfD (acute reference dose)	-	-	-

Reference value for inhalation (proposed OEL)	-	-	-
Reference value for dermal absorption	-	-	-

Acceptable exposure scenarios (including method of calculation)

Production of active substance:	Not under the scope of the BPD
Professional and non professional users	No unacceptable exposure is foreseen

Chapter 4: Fate and Behaviour in the Environment

Corn cobs decompose mainly to sugars which are readily incorporated into intermediary metabolism in the environment. No further data were submitted by the applicant and thus no arithmetic end-points could be derived.

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH_____: No data available
	pH_____: No data available
	pH_____: No data available
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	No data available
Readily biodegradable (yes/no)	No data available
Biodegradation in seawater	No data available
Non-extractable residues	No data available
Distribution in water / sediment systems (active substance)	No data available
Distribution in water / sediment systems (metabolites)	No data available

Route and rate of degradation in soil

Mineralization (aerobic)	
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): No data available
	DT_{90lab} (20°C, aerobic): No data available
	DT_{50lab} (10°C, aerobic): No data available
	DT_{50lab} (20°C, anaerobic): No data available
	degradation in the saturated zone: No data available
Field studies (state location, range or median with number of measurements)	DT_{50f}: No data available
	DT_{90f}: No data available
Anaerobic degradation	No data available
Soil photolysis	No data available
Non-extractable residues	No data available
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	No data available
Soil accumulation and plateau concentration	No data available

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	No data available

Fate and behaviour in air

Direct photolysis in air	No data available
Quantum yield of direct photolysis	No data available
Photo-oxidative degradation in air	Latitude: . No data available Season: ..... DT_{50} .....
Volatilization	No data available

Monitoring data, if available

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	No data available

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
		No data available	
Invertebrates			
		No data available	
Algae			
		No data available	
Microorganisms			
		No data available	

Effects on earthworms or other soil non-target organisms

Acute toxicity to ……..	Not applicable
Reproductive toxicity to ……	Not applicable

Effects on soil micro-organisms

Nitrogen mineralization	Not applicable
Carbon mineralization	Not applicable

Effects on terrestrial vertebrates

Acute toxicity to mammals	No data available
Acute toxicity to birds	No data available
Dietary toxicity to birds	No data available
Reproductive toxicity to birds	No data available

Effects on honeybees

Acute oral toxicity	Not applicable
Acute contact toxicity	Not applicable

Effects on other beneficial arthropods

Acute oral toxicity	Not applicable
Acute contact toxicity	Not applicable
Acute toxicity to ……..	Not applicable

Bioconcentration

Bioconcentration factor (BCF)	No data available
Depration time (DT_{50}) (DT_{90})	No data available
Level of metabolites (%) in organisms accounting for > 10 % of residues	No data available

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