Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Folpet

Product type: 09

ECHA/BPC/012/2014

Adopted

17 June 2014

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Opinion of the Biocidal Products Committee

on the application for approval of the biocidal active substance Folpet for product type 09

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, the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 09 of the following active substance:

Common name:	**Folpet**
Chemical name(s):	**N-(trichloromethylthio) phthalimide**
EC No.:	**205-088-6**
CAS No.:	**133-07-3**

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 and conclusions, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of opinions

Following the submission of an application by Makhteshim Agan Holding (currently: ADAMA Agriculture B.V.) on 13 July 2009, the evaluating Competent Authority Italy submitted an assessment repor and the conclusions of its evaluation to the Commission on June 2011. In order to review the assessment report and the conclusions of the evaluating Competent Authority the Agency organised consultations via the BPC and the Commission via the biocides Technical Meeting. Folpet was discussed at the BPC Environment Working Group during WG-I-2014. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the opinion

Rapporteur: BPC member for Italy

The BPC opinion on the approval of the active substance Folpet in product-type 09 was reached on 17 June 2014.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The minority position including its grounds is published on ECHA webpage :

http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval

Detailed opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the active substance folpet in product type 09 may be approved. The assessment report contains the detailed grounds for the overall conclusion.

2. Opinion

2.1. Conclusions of the evaluation

a) Presentation of the active substance and representative biocidal product including classification of the active substance

This evaluation covers the use of folpet in product type 09. Folpet is a general thiol reactant, the mechanism of action against target organisms is non-specific and is not the result of a single interaction at a specific site. Folpet acts by entering the conidia of the target organisms and inhibiting oxidative enzymes, carboxylases and enzymes involved in phosphate metabolism and citrate synthesis.Folpet reacts with the sulphhydryl groups of the nuclear proteins, which causes the inhibition of cell division. Spore germination is hindered as a result.The reaction of folpet and the reaction of thiophosgene, one of its decomposition products, with thiols and other groupings may be a means of metabolic inhibition.Specifications for the reference source are established.

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

Validated analytical methods are available for the determination of the active substance as manufactured and for the analyisis of impurities. Validated analytical methods are available for the technical active substance and in soil, water and air. Analytical methods are provided for water including determination of several metabolites because the targeted analyte (folpet) does not exist in water.

Folpet is listed in Annex VI table 3.1 and 3.2 of Regulation (EC) No 1272/2008 (CLP Regulation) and is presented in the table below. On basis of the information presented in the dossier, the evaluating Competent Authority (Italy) is proposing not to change the current classification and labelling.

Classification according to the CLP Regulation	
Hazard Class and Category Codes Hazard Statement Code(s)	Acute Tox. 4; H332 Eye Irrit. 2; H319 Skin Sens. 1; H317 Carc. 2; H351 Aquatic Acute 1; H400
Labelling	
Pictograms	GHS07 GHS08 GHS09
Signal Word	Warning

Hazard Statement Codes	H332 Harmful if inhaled H319 Causes serious eye irritation H317 May cause an allergic skin reaction H351 Suspected of causing cancer H400 Very toxic to aquatic life
Specific Concentration limits, M-Factors	M = 10 for Aquatic Acute 1

The representative biocidal product is similar to the active substance: folpet technical. Folpet technical is a solid in the form of powder/crystals. It is not formulated as a preparation for biocide use.

b) Intended use, target species and effectiveness: containing a description of the use(s) evaluated in the assessment report

Folpet is used as a preservative in plastics (PT 9). Products containing folpet may be used by professionals (decorators and builders) and non-professionals. The function is as a fungicide and the maximum end use concentration of folpet in the final end use products is 2,000 to 7,500 ppm. Organisms to be controlled are fungal species (*Candida albicans).* The data on the active substance and the representative product have demonstrated sufficient efficacy against the target organisms for approval to be recommended.

The biocidal product is added to plastic pellets prior to extrusion or film formation; alternatively the product is added directly to the plastisol.

The envisaged uses are:

- Flexible PVC (plastisol, coated fabrics); potential applications are in roof membranes, vinyl flooring, windows and refrigerator gaskets, swimming pool liners etc.
- Rigid PVC; potential applications include pipes, siding, window frames furniture etc.
- Non-PVC polymers; polyurethane, melamine resins, acrylonitrile butadiene styrene (ABS), polypropylene, polyethylene, thermoplastic elastomer (TPE) plastics and acrylics.

c) Overall conclusion on the risks for human health and environment including the need for risk management measures

Human health

Folpet is classified according to the CLP as acute toxic (harmful by inhalation), eye irritant, skin sensitiser and carcinogenic category 2.

The table below summarises the exposure scenarios assessed.

Summary table: scenarios		
Scenario	**Primary or secondary exposure Description of scenario**	**Exposed group**
Mixing & Loading	Secondary exposure: Mixing and loading of product during polymerised material manufacture. Loading 125 kg as/day equivalent to 5 drums /day	Professionals (industrial users)
Installation of vinyl flooring	Secondary exposure: installing 100 m^2 vinyl flooring on a daily basis	Professionals
Installation of vinyl flooring	Secondary exposure: installing 20 m^2 vinyl flooring on an occasional basis	Non-professionals
Exposure from vinyl flooring	Secondary exposure: infant crawling and playing on treated PVC flooring	General public
Inhalation exposure	Secondary exposure: Inhalation exposure from vinyl flooring by child /adult	General public
Use of folpet in swimming pool liners	Secondary exposure: dermal exposure to swimming pool liner	General public
Dermal contact with dust (child)	Secondary exposure: Dermal contact with dust by child	General public (children)
Oral ingestion of dust (child)	Secondary exposure: Oral ingestion of dust by child	General public (children)

Local effects

According to CLP folpet is classified as skin sensitiser cat 1. The levels of folpet achieved in the end-use product of 7.5 g/kg (0.75 %) are lower than the concentrations eliciting positive responses in the maximisation study. Considering the CLP sub-categories (Skin Sens. 1A and 1B), folpet would not be classified as a strong sensitiser based on the results of the maximisation study and is therefore considered to have low to moderate potency as a sensitiser. Additionally, the concentrations of folpet are below the threshold for classification of the product according to Directive 99/45/EEC. Consequently, risks as a result of local toxicity are considered to be acceptable for professionals and non-professionals.

Systemic effects

The potential exposure of professional industrial users during the production of polymerised materials containing the preservative folpet was assessed. Safe use was identified where engineering controls (local exhaust ventilation) and/or personal protective equipment such as gloves and facemask (suitable also for eyes protection) are assumed.

Acceptable risks were identified for professionals and non-professionals exposed to folpet through the installation of vinyl flooring in the absence of PPE.

Secondary exposure may occur through contact with dust from treated materials such as PVC flooring. No unacceptable risks were identified for the general public.

Professional and non-professional users are potentially at risk of exposure from several sources during or after use of products containing folpet. However, the exposure estimates are based on daily work rates and, therefore, the combination of any individual tasks is not applicable.

Environment

Hydrolysis is the primary route of degradation for folpet in the environment. The major metabolites are phthalimide and phthalic acid. As the hydrolysis is rapid, in the order of hours, the risks of these two metabolites were also assessed for all environmental compartments.

One of the other metabolites formed in the breakdown of folpet is thiophosgene, however its tendency to hydrolyse rapidly and its high reactivity with other substances likely to be present in wash-waters, leachates, drains and sewers mean that it is unstable and that exposure of biota in aquatic and terrestrial compartments of the environment to thiophosgene will not occur. Thiophosgene is therefore not considered to be an environmentally relevant metabolite of folpet.

Given the exposure considerations that are outlined above, the environmental risk assessment for folpet needs to take account of the facts that:

a) the exposure arising from the various PT 9 biocidal uses of folpet is continuous and therefore chronic in character, and;

b) the exposure will be to folpet's hydrolysis metabolites rather than the intact parent active substance.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Applying folpet to the polymer which is used to produce a plastic material	air, sewage treatment plant (STP), surface water, sediment, soil and groundwater
In-service life of the treated polymer	Leaching from the treated polymer using the scenarios used in the assessment of wood preservation as surrogate exposure models: fence, noise barrier, house, transmission pole and fence post (air, sewage treatment plant (STP), surface water, sediment, soil and groundwater)
Aggregated exposure	Release to the environment from the use of folpet in product types 6, 7 and 9 using the tonnage approach

Application to the polymer

No significant releases occur to the environment during formulation of polymers containing folpet. Waste resulting from the formulation process is treated as trade waste and its treatment is controlled and governed by industrial legislation. There is no release to public drain and STP and no release to the soil environment. Release to air will be negligible because of the low vapour pressure of folpet and its hydrolysis metabolites (ca 1×10^{-5} Pa).

Service life of treated polymer

For the aquatic compartment (surface water, sediment and STP) no unacceptable risks were identified for in-service life of the treated polymer with folpet as a PT 9 polymer preservative demonstrating that the risks to aquatic organisms from folpet and its hydrolysis products, phthalimide and phthalic acid, are acceptable.

In the case of the terrestrial compartment, risks due to the direct release of folpet to soil were identified for areas immediately adjacent to outdoor polymer surfaces. No unacceptable risks were identified when a service life (time 2) of 10 to 20 years is considered for fence, transmission pole and fence post scenario. PEC/PNEC ratios above one were identified for the house scenario when the treatment of both roof and façade was considered. The refinement of this assumption (e.g. assumption of treatment of the roof membranes only) results in no risk for the terrestrial compartment for the service life (Time 2).

Folpet rapidly hydrolyses in phthalimide and phthalic acid, therefore, the assessment of exposure (and risk) for the hydrolysis product is relevant. No unacceptable risks were identified for fence, transmission pole, fence post and house scenarios at time 1 and 2 for the two main hydrolysis products (phthalimide and phthalic acid).

Mitigation measures are not required for environmental exposure.

Aggregated exposure

An aggregated exposure assessment for folpet by the tonnage based calculations was also performed. The calculation considers wider environmental exposure application of the preservative containing folpet to the material and due to in-service life of the treated material, and uses the total EU folpet tonnage across the relevant product types for folpet (PT 6, PT 7 and PT 9). The resulting Prediced Environmental Concentrations (PEC) values represent a collective estimation for folpet and the hydrolysis products, phthalimide and phthalic acid, respectively. No unacceptable risk was identified for non-target organisms resulting from simultaneous use of folpet in PT 6, PT 7 and PT 9.

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		Conclusion
CMR properties	Carcinogenicity (C)	Carc. 2
	Mutagenicity (M)	no classification required
	Toxic for reproduction (R)	no classification required
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P or vP
	Bioaccumualtive (B) or very Bioaccumulative (vB)	not B or vB
	Toxic (T)	T
Endocrine disrupting properties	active substance is considered not to have endocrine disrupting properties	

Consequently, the following is concluded:

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

Folpet 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" agreed at the 54th meeting 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 (CA-March14-Doc.4.1 - Final - Principles for the approval of AS.doc). This implies that the assessment of the exclusion criteria is based on Article 5(1) using the temporary criteria for the determination of endocrine-disrupting properties in Article 5(3) and the assessment of substitution criteria is based on Article 10(1)(a, b and d).

2.2.2. POP criteria

Folpet is a solid with a relatively high melting point and low vapour pressure and can therefore be considered as non-volatile. Folpet degrades rapidly in air due to reaction with hydroxyl radicals with a half-life of equal or less than one day. Based on this information folpet is not considered to be a persistent organic pollutant.

2.3. BPC opinion on the application for approval of the active substance folpet in product type 09

In view of the conclusions of the evaluation, it is proposed that folpet 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: 940 g/kg.
2. The biocidal 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.
3. For industrial users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
4. Where a treated article has been treated with or intentionally incorporates one or more biocidal products containing folpet, and where necessary due to the possibility of skin contact as well as the release of folpet under normal conditions of use of the article, the person responsible for placing the article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

Folpet cannot be included in Annex I of Regulation (EU) No 528/2012 because it meets the following criteria of Article 28(2): i) skin sensitiser; ii) carcinogen of category 2; and iii) toxic to aquatic life of acute category 1.

2.4. Elements to be taken into account when authorising products

Whilst the efficacy data provided is sufficient to recommend approval of the substance, data demonstrating the efficacy of the product at the minimum application rate against the range of proposed target organisms using the recommended application equipment must be provided at the product authorisation stage.

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 folpet.

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