

Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Potassium sorbate

Product type: 8

ECHA/BPC/37/2014

Adopted

4 December 2014

Opinion of the Biocidal Products Committee

on the approval of the active substance potassium sorbate for product type 8

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 8 of the following active substance:

Common name:	Potassium sorbate
Chemical name(s):	2, 4-Hexadienoic acid, potassium salt (1:1), (2E, 4E)
EC No.:	246-376-1
CAS No.:	24634-61-5

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 Sorbic Acid Task Force on 28 March 2004, the evaluating Competent Authority Germany submitted an assessment report and the conclusions of its evaluation to the Commission on 20 October 2010. 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 Meetings. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: BPC Member for Germany.

The BPC opinion on the approval of the active substance potassium sorbate in product type 8 was adopted on 4 December 2014.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the potassium sorbate in product type 8 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 potassium sorbate in product type 8. Potassium sorbate acts as fungicide / fungistatic agent.

The antimicrobial effect of sorbates rests on a wide spectrum of different and relatively unspecific mechanisms, including enzyme inhibition and membrane destruction.

Specifications for the reference source are established.

The physico-chemical properties of the active substance and 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 active substance as manufactured. Validated analytical methods are required and available for the relevant matrices soil, water, air and plant materials.

The proposed classification and labelling for potassium sorbate according to Regulation (EC) No 1272/2008 (CLP Regulation) according to the opinion adopted by the Committee for Risk Assessment on 6 March 2013 is:

Classification according to the CLP Regulation		
Hazard Class and Category Codes	Eye Irrit. 2	H319
Labelling		
Pictograms	GHS07	
Signal Word	Warning	
Hazard Statement Codes	H319 Causes serious eye irritation	

b) Intended use, target species and effectiveness

Potassium sorbate is used by professionals as a wood preservative for freshly cut wood. Target organisms are staining fungi, mould and storage rot. The treated wood is predominantly intended to be used for the construction of pallets for the transportation and storage of goods (industrial indoor use) where uninvolved people (non professionals or the general public) or food will not get into direct contact with.

The antimicrobial effect of sorbates rests on a wide spectrum of different and relatively unspecific mechanisms. To cause its biocidal effect, sorbate respectively sorbic acid must penetrate the cell wall, which is only possible in its undissociated form as free acid. Due

to the equilibrium between the sorbate and the free acid, both substances are available within the solution depending on the pH - independent of the nature of the compound applied (in the present case potassium sorbate). With respect to wood protection, the slightly acidic matrix that wood represents ensures the presence of free acid in sufficient amounts.

Sorbic acid forms covalent bonds with SH groups, thereby inactivating a broad range of enzymes, such as enolases or lactate dehydrogenases involved in the carbohydrate metabolism, catalases and peroxidases, and interferes with several enzymes of the citrate cycle. Sorbic acid also inhibits absorption of amino acids and may partially destruct the cell membrane, thus leading to osmotic disturbance.

The antimicrobial action of sorbic acid probably is a consequence of a combination of the above factors which may differ among various types of microorganisms, with some details remaining unexplained.

An efficacy test, which had been performed with a 5 to 10% aqueous solution of the active substance, showed effective protection of freshly cut wood for 2-4 weeks against staining fungi.

Its detrimental effect on the metabolism of fungi in general has been described in the literature. From the test results it cannot be differentiated whether there is a fungicidal and/or fungistatic effect.

Overall, the test results support fungicidal/fungistatic activity of potassium sorbate against staining fungi and surface moulds. A literature research conducted in order to retrieve corresponding information on resistance gave no evidence for resistance.

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

Human health

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios		
Scenario	Primary or secondary exposure and description of scenario, Exposed group	Acceptable/ Unacceptable
Automated bathing and dipping (application of biocidal product)	Primary exposure, dermal and inhalation exposure Exposed group: Professionals 5 cycles per day (30 min per cycle), for application the biocidal product is diluted to an aqueous solution containing 10 % of the active substance	Acceptable with protective gloves (90% protection factor) ,work clothing (70% protection factor) ¹
Mechanical processing of treated wood: Sawing of treated wood or piling of pallets	Secondary exposure, dermal and inhalation exposure Exposed group: Professionals	Acceptable without PPE

The evaluation of potassium sorbate has indicated that it has no carcinogenic or mutagenic potential, is not toxic for reproduction and is not sensitising.

The representative product has only been assessed for professional use, because non-professional use is not intended. During automated bathing and dipping dermal exposure is mainly expected to appear during all phases of the process. Primary exposure of professionals is considered acceptable taking into account protective gloves and a coated coverall. Secondary (indirect) exposure of professionals during mechanical processing of treated wood is considered acceptable without further risk mitigation measures.

Secondary exposure of non-professionals or the general public can be excluded since the treated wood is predominantly intended to be used as pallets for the transportation of goods where uninvolved people or food will not get into direct contact with.

Environment

The table below summarises the exposure scenarios assessed.

¹ Old assessment: According to HEEG opinion 9 the protection factor of a coated coverall with 80% protection is meant here. However since there is no risk identified with the lower protection factor, no recalculation is performed.

Summary table: environment scenarios	
Scenario	Description of scenario including environmental compartments
Industrial use: application and post-treatment conditioning/storage	<p>Application by dipping/immersion. Two storage scenarios (storage after dipping) were assessed:</p> <ul style="list-style-type: none"> • 50 % direct emission to surface water, 50 % direct emission to soil (acoring to OECD ESD for Wood Preservation (2003)) • 100 % emission to surface water via STP <p>Emission to aquatic compartment (sediment included), STP, soil and groundwater were evaluated.</p>
Service life: use of treated wood for pallets	<p>Releases to the environment caused by weathering and leaching.</p> <p>Emission to aquatic compartment (sediment included), STP, soil and groundwater were evaluated.</p>

For the aquatic compartment, incl. sediment there is no unacceptable risk within the different life cycle stages. For production, formulation, industrial application and storage as well as wood in service all estimated PEC/PNEC ratios are lower than 1. For the sewage treatment plant the PEC/PNEC ratios also are lower than 1.

For the industrial application process (dipping/immersion) unacceptable risks were identified for groundwater. Therefore, adequate risk mitigation measures must be applied. .

The environmental risk assessment indicates that the storage of wood treated with a wood preservative containing potassium sorbate results in unacceptable risks for the terrestrial compartment including groundwater. As a consequence, appropriate risk mitigation measures shall be applied. After application of potassium sorbate, treated timber has to be stored under roof and on impermeable hard standing to avoid run off from the treated wood and, by this, any release of potassium sorbate into the environment.

For this intended application (pallets made of the treated wood exclusively used for food transportation and storage, stored protected from weathering) no unacceptable risks were observed in the environmental risk assessment. Furthermore, the estimated PEC/PNEC ratios for the life cycle stage "Wood in service" do not result in a risk for both the soil as well as the groundwater compartment assuming the storage of 1% of treated pallets outside the intended use of food transportation and storage.

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
	Mutagenicity (M)	No classification required
	Toxic for reproduction (R)	No classification required
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P and not vP
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B and not vB
	Toxic (T)	not T
Endocrine disrupting properties	Potassium sorbate is not considered to have endocrine disrupting properties.	

Consequently, the following is concluded:

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

Potassium sorbate 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 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).

2.2.2. POP criteria

As potassium sorbate is not P, B or vB, it does not meet the criteria for being a persistent organic pollutant

2.3. BPC opinion on the application for approval of the active substance potassium sorbate in product type 8

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

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](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))

1. Specification: minimum purity of the active substance evaluated: 990 g/kg.
2. 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.
3. For industrial or professional 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. Appropriate risk mitigation measures shall be taken to protect the groundwater, in particular: labels and, where provided, safety data sheets of products authorised shall indicate that
 - a) industrial application shall be conducted within a contained area on impermeable hard standing with bunding;
 - b) freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water;
 - c) any losses from the application of the product shall be collected for reuse or disposal;
unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means.
5. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council or Regulation (EC) No 396/2005 of the European Parliament and of the Council shall be verified, and any appropriate risk mitigation measures shall be taken into account to ensure that the applicable MRLs are not exceeded.

The active substance fulfills the criteria according to Article 28 (1) to enable inclusion in Annex I of Regulation (EU) No 528/2012.

2.4. Elements to be taken into account when authorising products

1. Dietary risk assessment has been performed for treated wood intended for pallets used for food transportation and storage without any direct contact with food. At product authorisation level an estimation of biocide residue transfer into food has to be performed if food contact is possible.
2. In case of leaving the food storage and transportation cycle to a general use of pallets, pallets are exposed to weathering, whereby the leachate run-off of potassium sorbate may pose a risk to the environment. Currently, an extension of the intended application "pallets for food transportation and storage" towards a more general use of pallets is not covered by the risk assessment.
3. The restrictions according to 2.3.4 for the use of wood preservatives containing potassium sorbate may be removed if the applicant for product authorisation submits the studies specified below to improve the data basis for the risk assessment also for any other uses than the one supported:

- A further leaching test for the active substance potassium sorbate
- Long-term ecotoxicity tests with terrestrial organisms
- Submission of a soil simulation test with three different soil types (e.g. OECD 307)

The additional ecotoxicity tests are only necessary if the applicant intends to use potassium sorbate also for other applications in which storage under roof cannot be guaranteed (lowering of the assessment factor for the PNEC derivation). If a simulation study on transformation in soil according to OECD 307 would be presented, the PEC value may decrease due to a potentially lower resulting DT₅₀ instead of the default value of 30 days.

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 potassium sorbate.