Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate)

or

KMPS

Product type: 3

ECHA/BPC/378/2023

Adopted

6 June 2023

Opinion of the Biocidal Products Committee

on the application for approval of the active substance trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) or KMPS for product type 3

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 3 of the following active substance:

Common name:	**Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate)**
Chemical name:	**Pentapotassium bis((hydroperoxysulfonyl)oxidanide) hydrogen sulfate sulfate**
EC No.:	**274-778-7**
CAS No.:	**70693-62-8**
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 the BPC opinion

Following the submission of an application by KMPS Registration Group on 31 July 2007, the evaluating Competent Authority Slovenia submitted an assessment report and the conclusions of its evaluation to the ECHA on 23 September 2022. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via BPC (BPC-47) and its Working Groups (WG I 2023). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Slovenia

The BPC opinion on the application for approval of the active substance trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) in product type 3 was adopted on 6 June 2023.

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 trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) in product type 3 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

Initially, pentapotassium bis(peroxymonosulphate) bis(sulphate)[1] was a notified name for the active substance. It was established that the name is incorrect, primarily due to a violation considering a charge balance. Consequently, the active substance has been renamed to trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) where the positions of the protons are not specified.

This evaluation covers the use of trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate)in product type 3. The acronym KMPS stands for potassium monopersulfate, which is the common name for trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate). Specifications for the reference source are established. Dipotassium peroxydisulphate is regarded as a relevant impurity with a max level of 20 g/kg.

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 and for the relevant impurity. Analytical methods for determination of the active substance in water, soil, body fluids and tissues, food and feed stuffs are not considered necessary because the active substance is unstable (reactive) inorganic salt of which the decomposition products (potassium and sulphate ions) are innocuous. For air an analytical method for dusts is available and for aerosols is missing and therefore required at product authorisation (see the section 2.5.).

A harmonised classification and labelling according to Regulation (EC) No 1272/2008 (CLP Regulation) is not available for the active substance. A CLH dossier has been resubmitted to ECHA in January 2023.

The proposed classification and labelling for trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4, H302 Skin Corr. 1, H314 Eye Dam. 1, H318 STOT RE 1, H372 (eyes) Aquat. Acute 1, H400 Aquat. Chronic 3, H412
Labelling	
Pictogram codes	GHS07, GHS05, GHS09

[1] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.067.959

Signal Word	Danger
Hazard Statement Codes	H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage. H372: Causes damage to organs (eyes) through prolonged or repeated exposure. H410: Very toxic to aquatic life with long-lasting effects.
Suppl. Hazard Statement Code	EUH071: Corrosive to the respiratory tract. EUH208: Contains dipotassium peroxodisulphate (CAS 7727-21-1). May produce an allergic reaction.
Specific Concentration limits, M-Factors	M=1 (Aquatic Acute 1)

b) Intended use, target species and effectiveness

Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) is intended to be used by professional users in the veterinary hygiene (PT 3) for foot dips and for terminal disinfection of animal houses with a low-pressure sprayer. KMPS shows a broad spectrum of antimicrobial activity and functions as a bactericide, yeasticide, fungicide and virucide.

Mode of action of KMPS is based on releasing reactive oxygen, which oxidises macromolecules of the cell wall, membranes and virus capsids in an unspecific manner leading to the cell wall disruption, loss of membrane integrity and disintegration of virus capsids. In addition, after penetration into cells or viruses, intracellular molecules such as amino acids, polypeptides, RNA and DNA are also oxidised leading to the disruption of protein synthesis and cell death.

The data on KMPS and the representative biocidal product have demonstrated sufficient efficacy against target species for the active substance approval. Considering that only innate efficacy of KMPS was demonstrated, additional data to support all intended uses against all claimed target organisms need to be provided during the biocidal product authorisation.

No resistance phenomenon has been reported with KMPS in the scientific literature for the time being. KMPS is an inorganic substance with an unspecific mode of action, hence the development of resistance to KMPS is a highly unlikely event.

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

Human health

The mode of action of trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) is based on its oxidative reactivity. It reacts rapidly with available organic material at the site of first contact, leading to local corrosion/irritation. KMPS is corrosive to the skin, eyes, and mucous membranes (gastrointestinal and respiratory tracts). It causes damage to the eyes through repeated exposure, even at low doses.

KMPS dissociates at the first contact site in the organism into potassium and sulphate ions. Both breakdown products are the only species that can become systemically available. They constitute physiologically essential metabolites in the human body which are efficiently excreted and are not toxic *per se*.

Due to rapid dissociation of KMPS at first contact site in organism into potassium and sulphate ions and the lack of primary systemically toxic effects after exposure to KMPS, no systemic reference values were derived for KMPS. Only local risk assessment was considered necessary for the use of KMPS. Oral and dermal NOAEC values were considered unnecessary due to the risk management measures that are to be applied due to the KMPS classification for corrosive properties. Therefore, only $AEC_{inhalation}$ of 0.175 mg/m^3 has been derived.

The risk assessment for the relevant impurity dipotassium peroxodisulphate (CAS 7727-21-1) is covered by the risk assessment for KMPS for the relevant impurity content ≤ 2%.

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**
Terminal disinfection of animal houses using a low-pressure sprayer			
Mixing & loading of granules – manual dosing	**Primary exposure** during manual dosing and dissolving of KMPS granules (50 % KMPS). PPE: gloves, goggles, protective coveralls, RPE RMM for high hazard class chemicals[2]	Professionals	Acceptable with PPE and RMM
Application - Spraying	**Primary exposure** during manual spraying of animal houses at low pressure. PPE: goggles, RPE	Professionals	Acceptable with PPE
Post-application – Handling empty containers and disposal of treatment solution	**Primary exposure** during handling of empty containers and disposal of treatment solution (emptying of spray equipment).	Professionals	Acceptable
Secondary exposure: Bystander during spraying	**Secondary inhalation** exposure of bystanders during terminal disinfection of animal houses using a low pressure sprayer. PPE: goggles, RPE	Professional bystanders	Acceptable with PPE
Foot dips			
Mixing & loading of granules – manual dosing	**Primary exposure** during manual dosing and dissolving of KMPS granules (50 % KMPS). PPE: gloves, goggles, body protection, RPE RMM for high hazard class chemicals[2]	Professionals	Acceptable with PPE and RMM
Application – Foot dips	**Primary exposure** during disinfection of boots in foot dips.	Professionals	Acceptable
Post-application – Handling empty containers and disposal of treatment solution	**Primary exposure** during handling of empty containers and disposal of treatment solution (foot dip).	Professionals	Acceptable

<u>Conclusion on risk assessment for the professional user</u>

The exposure of a professional user and bystander during the use of KMPS for terminal disinfection of animal houses using a low-pressure sprayer and foot dips is considered acceptable assuming the use of suitable PPE where relevant.

In-use concentrations do not trigger any classification for local effects, so no qualitative local risk assessment has been performed for the inhalation and dermal routes. Nevertheless, for primary inhalation exposure, a semi-quantitative local risk assessment has been conducted.

[2] Guidance on the BPR: Volume III Human Health, Assessment + Evaluation (Parts B+C)

Where it was concluded that due to an exceedance of the $AEC_{inhalation}$ RPE is needed for in-use concentrations, goggles should also be used due to observed eye effects in the study used for AEC-derivation. A professional user and bystander must wear goggles and RPE during spraying.

Indirect exposure via food

Breakdown products, potassium and sulphate ions are the only species that can become systemically available. As both breakdown products constitute physiologically essential metabolites in the human body that are efficiently excreted via the urine after oral uptake, no risk assessment for dietary exposure is deemed necessary for the intended uses in PT3.

Disinfection by-products

Using KMPS for disinfection in the presence of chloride or bromide can lead to the formation of potentially hazardous disinfection by-products (DBPs). The assessment of DBPs is necessary at product authorisation (on provision of suitable guidance).

Environment

The fate of KMPS in the environment is determined by its oxidative reactivity. Upon contact with oxidizable organic substrate, KMPS decomposes either by hydrolysis or disproportionation to potassium ions, hydrogen sulphate and oxygen. Due to the high concentration of oxidizable organic substrate in sewage sludge and soil, decomposition in these compartments is very rapid. Leaching of KMPS in the soil profile to groundwater can therefore be excluded. In water, the rate of decomposition is dependent on the presence of oxidizable organic substrate as well as on the presence of sodium chloride. The higher the concentration of oxidizable organic substrate is in water, the faster KMPS will be degraded. Compared to freshwater degradation in seawater is faster due to the oxidation of sodium chloride leading to the formation of hypochlorous acid. KMPS is neither volatile nor is it expected to be present in air. The potential for bioaccumulation is low.

The available data demonstrate a higher toxicity to marine species compared to freshwater species. Chronic data for marine species were relied upon to derive the PNEC for freshwater in the absence of chronic data for freshwater species. The sensitivity ranking of aquatic pelagic organisms based on chronic toxicity is fish >≈ invertebrates >≈ algae. For organisms in the terrestrial compartment, the PNEC derived with the EPM method is used in the risk assessment, as being more conservative than that derived experimentally.

For the product uses in PT3 KMPS is ultimately discharged to either drains and STP or to manure. Environmental exposure via emission to either drains and STP or manure after use is taken to represent a worst-case in terms of exposure to the environment.

Disinfection by-products

KMPS can in the presence of chlorine or bromine lead to the formation of potentially hazardous disinfection by-products (DBPs), e.g., chlorate and bromate. The risk to the environment from exposure to disinfection by-products was not evaluated due to the absence of guidance.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Disinfectant for animal housing	Terminal disinfection of animal housing with emission *via* wastewater to Sewage Treatment Plant (STP) and to manure. Compartments assessed: STP, air, surface water, sediment, soil and groundwater	Acceptable
Disinfectant for footware	Disinfection of footwear and animal feet with emission *via* wastewater to Sewage Treatment Plant (STP) and to manure. Compartments assessed: STP, air, surface water, sediment, soil and groundwater	Acceptable

PEC/PNEC ratios for STP and surface water and terrestrial PEC/PNEC ratios for the product uses in PT3 are less than one, demonstrating that the risks to STP, aquatic organisms and soil organisms are acceptable.

Overall conclusion

In conclusion, safe uses covering both the human health and the environment have been identified for PT 3. An acceptable risk has been identified for a terminal disinfection of animal houses using a low-pressure sprayer and for foot dips when appropriate RMMs are in place for the mixing and loading phase and PPE where required.

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	KMPS does not fulfil criterion (a), (b) and (c) of Article 5(1).
	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	KMPS does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1).
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B or vB	
	Toxic (T)	Not T	

Property		Conclusions	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No	KMPS does not fulfil Article 5(1)(d) and does not fulfil criterion (e) of Article 10(1).
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No	
	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. KMPS does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	KMPS does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	KMPS does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) 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", "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR" and "Implementation of scientific criteria to determine the endocrine – disrupting properties of active substances currently under assessment" 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).

2.2.2. POP criteria

POP criteria are not applicable to inorganic substances such as trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate).

2.3. BPC opinion on the application for approval of the active trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) in product type 3

In view of the conclusions of the evaluation, it is proposed that trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) 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: ≥ 890 g/kg (≥ 89 w/w), dipotassium peroxydisulphate (relevant impurity): ≤ 20 g/kg (≤ 2 % w/w).

2. The authorisations of biocidal products are subject to the following conditions:

    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. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

        i. Professional users.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012 as the active substance is proposed to be classified as Skin Corr. 1 (H314), STOT RE 1 (H372 (eyes)) and Aquat. Acute 1 (H400).

2.4. Elements to be taken into account when authorising products

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 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. Disinfectant by-products may be formed because of the use of KMPS in the presence of chloride or bromide. Further information on formation of DBPs is necessary at product authorisation on provision of suitable guidance.

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 trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate). However, the validated analytical method for the determination of the active substance (aerosols) in air has to be provided to the Competent Authority Slovenia as soon as possible but not later than 6 months before the date of approval of the active substance.