Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Hydrated lime

Product type: 2

ECHA/BPC/100/2016

Adopted

14 April 2016

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance hydrated lime for product type 2

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 2 of the following active substance:

Common name:	**Hydrated lime**
Chemical name:	**Calcium dihydroxide**
EC No.:	**215-137-3**
CAS No.:	**1305-62-0**

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 European Lime Association (EuLA) on 27 February 2006, the evaluating Competent Authority United Kingdom submitted an assessment report and the conclusions of its evaluation to the Commission on 19 September 2011. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-15) and its Working Groups (WG V 2015). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: United Kingdom

The BPC opinion on the approval of the active substance hydrated lime in product type 2 was adopted on 14 April 2016.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that hydrated lime in product type 2 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 hydrated lime in product type 2. Hydrated lime is an inorganic salt produced by the reaction of calcium oxide (burnt lime) with water. Hydrated lime acts by causing an increase in alkalinity and temperature, and a decrease in water availability, resulting in the denaturation of protein structures of microorganisms such as cell walls, capsid structures, enzymes and organelles. Specifications for the reference source are established.

The physico-chemical properties of the active substance, which is also the biocidal product, 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. Many different analytical methods for hydrated lime are presented in literature. These methods were developed not only for the analysis of hydrated lime, but also for other lime variants and the associated impurities. Analysis by any of these methods should be sufficient to characterise the active substance.

Relevant residues of hydrated lime are calcium and hydroxide ions. Validated analytical methods are available for soil. However, given that these ions will occur naturally in soil (and also from hydrated lime being used for agricultural liming) it would not be possible to determine the source of these ions as being from biocidal use. Whether or not measurement of the active/residues in air is required will depend on a combination of factors such as particle size, method of application and degree of enclosure. This should be determined at product authorisation. Specific methods for analysis of the active substance/residues in water have not been provided as for the analysis of the active can be used, as these require initial dissolution in water. However, given the nature of the active substance/residues these or any other methods would not be able to determine whether the source was natural or from biocidal use. Analytical methods for human body fluids and tissues are not required.

No harmonised classification for hydrated lime is available. A CLH dossier will be submitted for this active substance to ECHA by the evaluating Competent Authority. The proposed classification and labelling according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Skin Irrit. 2 Eye Dam. 1 STOT SE 3

Labelling	
Pictograms	GHS05
Signal Word	Danger
Hazard Statement Codes	H315: Causes skin irritation H318: Causes serious eye damage H335: May cause respiratory irritation

b) Intended use, target species and effectiveness

Products containing hydrated lime are used to treat sewage sludge to control bacteria, viruses and parasites (industrial and professional use only), prior to its use for agricultural purposes.

Hydrated lime acts by causing an increase in alkalinity and temperature, and a decrease in water availability, resulting in the denaturation of protein structures of microorganisms such as cell walls, capsid structures, enzymes and organelles.

The efficacy of hydrated lime is well established and acceptable studies have demonstrated sufficient efficacy against the target species.

Given the non-specific mode of action of hydrated lime, the development of resistance is unlikely to occur.

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

Human health

The toxicological properties of hydrated lime have been evaluated on the basis of human data and animal studies conducted with some of the four lime variants that are active substances in the biocides review programme (burnt lime, hydrated lime, hydrated dolomitic lime and burnt dolomitic lime) and with soluble calcium salts and with other hydroxides. Where data on hydrated lime were not available, read-across from data on the other lime variants and calcium salts or other hydroxides, has been performed.

The lead health effects of hydrated lime are the systemic repeated dose effects caused by excess calcium (hypercalciuria, kidney stones, hypercalcemia, renal insufficiency, lethargy, coma and death) in the body and the local irritative effects on the external surfaces of the body (skin, eye, respiratory tract and gastrointestinal tract) caused by the hydroxide ion. The available data do not support classification of hydrated lime as a mutagen, carcinogen or reproductive toxicant.

With regard to systemic effects, exposures have been compared to the tolerable Upper oral intake Level (UL) for calcium established by the European Scientific Committee on Food (SCF). If the exposure estimates give rise to calcium body burdens that are significantly lower than the UL, then the risk of systemic effects from exposure to hydrated lime are considered to be acceptable.

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**
Mixing and Loading – automated and manual handling	Primary dermal and inhalation exposure. Hydrated lime is either mechanically fed or directly fed into the dosing equipment	Industrial and professional user	Acceptable with RPE, coveralls, gloves
Application - automated	Primary exposure Hydrated lime dosed into sewage sludge and mixed by means of a blender and the resulting mixture transferred to a maturing container. Negligible operator exposure.	Industrial and professional user	Acceptable

Local effects

For the mixing and loading scenario, with regard to the local irritative effects, no threshold/NOAEC has been identified for the occurrence of such effects on the skin, eyes and gastrointestinal tract. Therefore, for these routes of exposure, as risks cannot be assessed, exposure needs to be prevented by the implementation of appropriate risk mitigation measures, such as automation. For inhalation, acceptable risk is identified when respiratory protective equipment (RPE) is worn (wpf 40[1]).

For the application scenario, negligible operator exposure is predicted as the process is fully automated, therefore risks are considered to be acceptable.

Overall, acceptable risks for professional users are identified for local effects when RPE, coveralls and gloves.

Systemic effects

Acceptable risks for systemic effects are identified for automated mixing and loading operations without PPE. However, for manual mixing and loading acceptable risks are only identified when appropriate RPE/PPE is worn to reduce dermal and inhalation exposure.

For the application scenario, negligible operator exposure is predicted as the process is fully automated, therefore risks are considered to be acceptable.

Note: No secondary exposure is predicted to occur as hydrated lime reacts significantly during the treatment process and is no longer considered to be the original substrate.

Environment

In general following exposure to the environment, hydrated lime will simply convert to its respective ion constituents where they would form part of existing chemical cycles in the natural environment.

The table below summarises the exposure scenarios assessed.

[1] The wpf of 40 is the maximum default value workplace or assigned protection factor recommended for estimating reduction in exposure in ECHA Biocides Human Health Exposure Methodology, October 2015 (see pages 154-5).

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Treatment of sewage sludge prior to application to the land.	Exposure to the terrestrial and aquatic compartments following application of treated sewage sludge to agricultural land and subsequent surface run-off.	Acceptable risks to sewage treatment plants and soil; risk to surface water.

During the EU Review it was noted that a standard quantitative environmental risk assessment may not be the most appropriate way to assess the risks posed by the lime variants. In addition to the standard quantitative assessment summarised above, a qualitative assessment was also performed. The qualitative assessment considered various mitigating factors including the likely higher environmental loading rates from the agricultural use of lime to amend soil pH (a use outside the scope of the BPR); information on background concentrations of the key constituents and the fact that the dissociation products of the lime variants will form parts of existing natural chemical cycles; and results of laboratory soil and water/sediment studies where application of lime or lime amended sludge did not result in long term pH changes outside the typical range for agricultural soils or natural surface water bodies. Overall, based on the quantitative and qualitative assessments, the biocidal uses of lime are not expected to have an adverse effect on environmental pH and no unacceptable impact on non-target organisms is predicted.

Overall conclusion

A safe use for both human health and the environment was identified for the treatment of sewage sludge by products containing hydrated lime (industrial and professional use only, provided appropriate risk mitigation measures are applied).

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.	Hydrated lime 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 applicable.	Hydrated lime does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not applicable.	

	Toxic (T)	Not applicable.	10(1)]
Endocrine disrupting properties	Hydrated lime is not considered to have endocrine disrupting properties.		
Respiratory sensitisation properties	No classification required. Hydrated lime does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	Hydrated lime does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Hydrated lime does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

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

Hydrated lime 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

Not applicable as hydrated lime is an inorganic compound.

2.3. BPC opinion on the application for approval of the active substance hydrated lime in product type 2

In view of the conclusions of the evaluation, it is proposed that hydrated lime 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: 800 g/kg (the value provides the content of Ca expressed as $Ca(OH)_2$).
2. The authorisations of biocidal products are subject to the following condition(s):
    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.

[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)

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

    i. Industrial and 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 there is a proposal to classify with STOT SE 3 (H335).

2.4. Elements to be taken into account when authorising products

1. 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 for professional users is identified for the product, 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. If an unacceptable risk is identified for mixing and loading by professionals then automated processes shall be used unless it can be demonstrated that the risk can be reduced to an acceptable level by other means.

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 hydrated lime.

However, members of the EuLA must all ensure that Certificates of Analysis for their active substances are submitted to the evaluating Competent Authority (UK) as soon as possible but no later than 6 months before the date of approval of the active substance.

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