

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the single biocidal product:

EULA HYDRA-LIME 23

ECHA/BPC/341/2022

Adopted

14 June 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of single biocidal product EULA HYDRA-LIME 23

In accordance with Article 44(3) 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 Union authorisation of:

Name of the biocidal product:	EULA HYDRA-LIME 23
Authorisation holder:	European Lime Association aisbl
Active substance common name:	calcium dihydroxide (hydrated lime; CAS No: 1305-62-0)
Product types:	PT 2 and 3

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 29 March 2018, recorded in R4BP3 under case number BC-JR038510-32, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 13 December 2021. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-43) and its Working Groups (WG 1 2022). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the Union authorisation of the biocidal product was reached on 14 June 2022.

The BPC opinion was adopted by simple majority of the members present having the right to vote.

The opinion and the minority position including its grounds are published on the ECHA website at: <https://echa.europa.eu/opinions-on-union-authorisation/bpc>.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the single biocidal product is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012, as defined in Article 3(1)(r).

The single biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of EULA HYDRA-LIME 23 referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product EULA HYDRA-LIME 23.

General

France, as e-CA, received an application from European Lime Association aisbl for Union authorisation for the biocidal product EULA HYDRA-LIME 23.

The biocidal product EULA HYDRA-LIME 23, containing 100% calcium dihydroxide is intended to be used for disinfection of sewage sludge and manure, of bedding materials and of indoor and outdoor floor surfaces of animal accommodation walls by brush (product type 2 and 3). The biocidal product EULA HYDRA-LIME 23 is a dustable powder to be used by professional users.

Physico-chemical properties

The product is the same as the active substance. It is a white dusty solid of naturally occurring origin. The dusts are within the inhalable/respirable range fraction. The solid has an alkalinity of 0.24-0.26% w/w as NaOH.

A 6 month shelf-life was accepted in the CAR of the active substance but based on the new storage study provided by applicant, a 15 month shelf-life can be accepted as well for the product.

The product is not classified for any physical hazard properties.

The product is the same as the active substance, thus analytical methods or justification for non-submission of data, submitted in the frame of the active substance approval, are also applicable and relevant to the product.

Labelling:

- Protect from humidity.
- Do not store at a temperature above 30°C.

Efficacy

The product EULA HYDRA-LIME 23 has shown a sufficient efficacy:

- For the **disinfection of sewage sludge (PT 2) against bacteria and endoparasites (helminth eggs)**.

The effective final use concentration and contact time are variable. pH should be > 12 during the exposure time. The proper amount of active substance has to be added to the substrate in order to reach the required pH and should be calculated by the users based on the dry weight of the substrate.

No data has been provided for yeast and fungi for the disinfection of sewage sludge.

Regarding virus, for the disinfection of sewage sludge, the EFF WG (WG I 2022 meeting) concluded that efficacy data submitted for virus were not sufficiently robust, due to the lack of negative control in the first study. This target organism is therefore not proposed for authorisation on this use.

- For the **disinfection of manure (PT3), against bacteria, virus and endoparasite (helminth eggs)**.

The effective final use concentration and contact time are variable. pH should be > 12 during the exposure time. The proper amount of active substance has to be added to the substrate in order to reach the required pH and should be calculated by the users based on the dry weight of the substrate.

No data has been provided for yeast and fungi for the disinfection of manure.

- For the **disinfection of indoor floor surfaces of animal accommodations (including limewashing of walls) and transportation, floors of outdoor animal enclosures (PT3), against bacteria, yeast, fungi and virus**.

The effective application rate is of 800 g Ca(OH)₂/m²

- For the **disinfection of bedding materials against bacteria, yeast, fungi and virus**.

No specific efficacy data on bedding materials was presented to support this claim. A read-across with manure, considered as a worst case, was proposed but the EFF WG (WG I 2022 meeting) concluded that the demonstration of the efficacy is not acceptable. The efficacy is therefore not supported by the data presented in the dossier and the use is not proposed for authorisation.

Human health

The product EULA HYDRA-LIME 23 is classified as follow for human health:

- H315: Causes skin irritation;
- H318: Causes serious eye damage;
- H335: May cause respiratory irritation.

Systemic and local quantitative risk assessments have been performed in line with the CAR. No risk for operator is expected considering systemic effects, as intake of Ca^{2+} and Mg^{2+} during application combined with the dietary intake is still below the Upper Limit values set for Ca^{2+} and Mg^{2+} by EFSA. Regarding local effect by inhalation (respiratory irritation), the risk is deemed acceptable based on the experimental data provided in the dossier and a weight of evidence approach.

• Disinfection of sewage sludge and manure

The risk for human health is considered acceptable **only for the fully automated process** (including loading and disposal of empty bags) with the following PPE:

- gloves;
- protection coverall;
- respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter);
- goggles.

Moreover, it is likely that the addition of calcium dihydroxide to sewage or manure leads to the production of ammonia gas, which may be of concern. During the treatment of sewage sludge, wearing RPE specific for air fed ammonia gas or for canisters, is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m^3 for this gas.

In addition to above-mentioned PPE, the following RMMs are needed:

- The pouring of the hydrated lime into the treatment unit must be done fully automatically.
- Considering the use of big bags (500-1000 kg), the loading into the treatment unit and the disposal of empty bags must be performed using a telehandler (including a closed cabin).
- The cleaning of the treatment unit must be avoided or performed with an automated process with no exposure of the professional.
- Wear protective gloves and protection coverall during the manipulation of treated sewage sludge/manure.
- Do not let bystanders (including co-workers and children) and pets enter the treatment area during all the treatment duration (including loading, application, disposal of empty bags, the acting time and the following removal of the biocidal product and its residues from the ground).
- Use in a well ventilated area.

- **Disinfection of indoor and outdoor floor surfaces, transportation and bedding materials**

The risk for human health is considered acceptable for loading, application and the disposal of empty bags considering the following PPE:

- gloves;
- protective coverall;
- respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter).

In addition to above-mentioned PPE, the following RMM are needed:

- Considering the use of big bags (500-1000 kg), the loading of the product and the disposal of empty bags must be performed fully automatically using a telehandler (including a closed cabin).
- During the loading of small bags (25 kg) thoroughly empty out the bags in order to minimise the remaining powder;
- For the disposal of small empty bags, moisten the bag and fold it carefully in order to avoid any spills.
- Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration (including the loading, the application, the disposal of empty bags, the acting time and the following removal of the biocidal product and its residues from the ground).
- Use in a well ventilated area.

- **Disinfection of animal accommodation walls by brush**

The risk for human health is considered acceptable for the loading and the disposal of empty bags considering the following PPE:

- gloves;
- protective coverall;
- respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter).

During the application of water suspended lime on the walls, the risk is considered acceptable taking into account the following PPE:

- gloves;
- protective coverall;
- respiratory protective equipment at least APF 4 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P1 filter).

Moreover, the following RMMs are needed:

- Considering the use of big bags (500-1000 kg), the loading of the product and the disposal of empty bags must be performed fully automatically using a telehandler (including a closed cabin);

- Minimisation of splash and spills during application of water suspended lime.
- Do not let bystanders (including co-workers and children) touch the treated surfaces until complete drying.
- Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration (including the loading, the application, the disposal of empty bags, the acting time and the following removal of the biocidal product and its residues from the ground).
- Use in a well ventilated area.

Animal Health

The risk for animal health is considered acceptable if the following RMMs are applied:

- Animals should not be present during all the treatment duration;
- Remove residues of the biocidal product on the ground by thorough sweeping before re-entry of animals. Collect the resulting dry waste and recycle them as agricultural liming material or dispose the dry waste according to local requirements.
- For animal transportation use only: after brushing, rinse and clean the vehicle.
- Do not let animal re-enter the accommodations before complete drying of surfaces;
- Feed and drinking water must be carefully covered or removed during the application of the product.

Consumers via residues in food

Regarding the natural exposure and the toxicological properties of Ca^{2+} the dietary risk for consumer related to the intended uses is negligible.

Environment

The product EULA HYDRA-LIME 23 is not classified for the environment.

The risks are considered acceptable for the environment for the uses:

In PT2:

- disinfection of sewage sludge,

In PT3:

Consider the following RMM "Do not apply the product if releases from animal housings, manure/slurry storage areas, or animal transportation disinfection areas can be directed to a sewage treatment plant or directly to surface water." for:

- disinfection of manure,
- disinfection of animal bedding material,
- disinfection of indoor walls of animal accommodations,
- disinfection of indoor floor of animal accommodations and transportation.

This RMM is necessary for these uses as the risk assessment is conducted for the release to the STP and risks are expected for the STP microorganisms.

In PT3:

And consider the following RMM: "Do not exceed two applications per year." for:

- disinfection of floors of outdoor animal enclosures.

b) Presentation of the biocidal product including classification and labelling

The description of the biocidal product is available in the SPC.

The hazard and precautionary statements of the biocidal product according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance calcium dihydroxide contained in the biocidal product does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product was not performed in accordance with Article 23(1) of Regulation (EU) No 528/2012.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The conformity to the uniform principles, as defined in Regulation (EU) No 528/2012, for the product is reported in the table below for each use.

Uses	Target	Conditions of use	Conclusions
Disinfection of sewage sludge	Bacteria, yeast, fungi, viruses, Endoparasites: helminth eggs	Indoor Professional The product is mixed with the sewage sludge in an open mixer.	Acceptable, except for yeast, fungi and virus
Disinfection of manure	Bacteria, yeast, fungi, viruses, Endoparasites: helminth eggs	Indoor Professional The product is mixed with the manure	Acceptable except for yeast and fungi
Disinfection of indoor floor surfaces of animal accommodations and transportation	Bacteria, yeast, fungi, viruses	Indoor Professional Direct application	Acceptable

Uses	Target	Conditions of use	Conclusions
Disinfection of animal bedding materials	Bacteria, yeast, fungi, viruses	Indoor Professional Direct application	Not Acceptable No efficacy studies submitted
Disinfection of animal accommodations; limewashing of walls	Bacteria, yeast, fungi, viruses	Indoor Professional The product is suspended in water prior its application by brushing on the walls	Acceptable
Disinfection of floors of outdoor animal enclosures	Bacteria, yeast, fungi, viruses	Outdoor Professional Direct application	Acceptable

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the biocidal product have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product are met.

The physico-chemical properties of the biocidal product are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised uses, according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product is sufficiently effective;
2. the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
 - the fate and distribution of the biocidal product in the environment,
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
 - the impact of the biocidal product on non-target organisms,
 - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product

As the conditions of Article 19(1) are met it is proposed that the single biocidal product shall be authorised¹ for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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¹ This is without prejudice of any specific conditions that might apply in the territory of Member State(s) in accordance with Article 44(5) of the BPR.