Official Journal
of the European Union

EN
L series

2024/2423

16.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2423

of 13 September 2024

granting a Union authorisation for the single biocidal product 'Ca(OH)2 PT02' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 44(5), first subparagraph, thereof,

Whereas:

(1) On 12 April 2018, Lhoist submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ([2]) for Union authorisation of the same single biocidal product, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named 'Ca(OH)2 PT02', of product-type 2, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-YU038691-99 in the Register for Biocidal Products. The application also indicated the case number of the related reference single biocidal product 'EuLA hydra-lime 23' later authorised by Commission Implementing Regulation (EU) 2023/2701 ([3]), recorded in that register under case number BC-JR038510-32.

(2) The single biocidal product 'Ca(OH)2 PT02' contains calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 2.

(3) On 22 September 2022, the Agency submitted to the Commission its opinion ([4]) and the draft summary of the biocidal product characteristics ('SPC') of 'Ca(OH)2 PT02' in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.

(4) In its opinion, the Agency concludes that the proposed differences between the single biocidal product 'Ca(OH)2 PT02' and the related reference single biocidal product 'EuLA hydra-lime 23' are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ([5]), and that based on the assessment of the related reference single biocidal product 'EuLA hydra-lime 23' and subject to compliance with the draft SPC, the same single biocidal product 'Ca(OH)2 PT02' meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

([2]) Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/414/oj).

([3]) Commission Implementing Regulation (EU) 2023/2701 of 4 December 2023 granting a Union authorisation for the single biocidal product EuLA hydra-lime 23 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L, 2023/2701, 5.12.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2701/oj).

([4]) European Chemicals Agency opinion of 22 September 2022 on the Union authorisation of the same single biocidal product 'Ca(OH)2 PT02', https://echa.europa.eu/opinions-on-union-authorisation.

([5]) Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/354/oj).

(5) On 26 February 2024, the Agency transmitted to the Commission the revised SPC of 'Ca(OH)2 PT02' in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the same single biocidal product 'Ca(OH)2 PT02'.

(7) The expiry date of the authorisation should be aligned with the expiry date of the authorisation of the related reference single biocidal product 'EuLA hydra-lime 23'.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0029527-0000 is granted to Lhoist for the making available on the market and use of the same single biocidal product 'Ca(OH)2 PT02' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 6 October 2024 until 30 November 2033.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Ca(OH)2 PT02

Product type 2 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Authorisation number: EU-0029527-0000

R4BP asset number: EU-0029527-0000

1. **ADMINISTRATIVE INFORMATION**

1.1. **Trade name(s) of the product**

Trade name(s)	Neutralac® H UP Neutralac® CEC Neutralac® H LP Neutralac® H100 Neutralac® H200 Neutralac® H90 Neutralac® RH Eurolime Olimpic

1.2. **Authorisation holder**

Name and address of the authorisation holder	Name	Lhoist
	Address	Rue Charles Dubois, 28, 1342 Ottignies-Louvain-La-Neuve, Belgium
Authorisation number	EU-0029527-0000	
R4BP asset number	EU-0029527-0000	
Date of the authorisation	6 October 2024	
Expiry date of the authorisation	30 November 2033	

1.3. **Manufacturer(s) of the product**

Name of manufacturer	Cal Industrial SL
Address of manufacturer	Pedro I, 19-21, 31 007 Pamplona, Spain
Location of manufacturing sites	Pedro I, 19-21, 31 007 Pamplona, Spain

Name of manufacturer	CalGov
Address of manufacturer	Carretera Fuente, Apartado 2, 41 560 Estepa, Spain
Location of manufacturing sites	Carretera Fuente, Apartado 2, 41 560 Estepa, Spain

Name of manufacturer	Carrières et Chaux Balthazard et Cotte
Address of manufacturer	Rue du Pra Paris, 38 360 Sassenage, France
Location of manufacturing sites	Rue du Pra Paris, 38 360 Sassenage, France

Name of manufacturer	Carrières et fours à chaux de Dugny
Address of manufacturer	B.P.1, 55 100 Dugny-sur-Meuse, France
Location of manufacturing sites	B.P.1, 55 100 Dugny-sur-Meuse, France

Name of manufacturer	Chaux de Boran
Address of manufacturer	Route de Boran, 60 640 Précy-Sur-Oise, France
Location of manufacturing sites	Route de Boran, 60 640 Précy-Sur-Oise, France

Name of manufacturer	Chaux de Bretagne
Address of manufacturer	-, 53600 Evron, France
Location of manufacturing sites	-, 53600 Evron, France

Name of manufacturer	Chaux de la Tour
Address of manufacturer	1 chemin des Chaux de la Tour, 13 820 Ensues La Redonne, France
Location of manufacturing sites	1 chemin des Chaux de la Tour, 13 820 Ensues La Redonne, France

Name of manufacturer	Carrières et Fours à Chaux Dumont Wautier
Address of manufacturer	Rue la Mallieue, 95, B-4470 Saint-Georges-sur-Meuse, Belgium
Location of manufacturing sites	Rue la Mallieue, 95, B-4470 Saint-Georges-sur-Meuse, Belgium

Name of manufacturer	Etablissement Leon Lhoist
Address of manufacturer	Usine de On-Jemelle, 6900 Marche-en-Famenne, Belgium
Location of manufacturing sites	Usine de On-Jemelle, 6900 Marche-en-Famenne, Belgium

Name of manufacturer	Vápenka Čertovy schody a.s
Address of manufacturer	Tmaň 200, 267 21 Tmaň, Czech Republic
Location of manufacturing sites	Tmaň 200, 267 21 Tmaň, Czech Republic

Name of manufacturer	Faxe Kalk
Address of manufacturer	Hovedgaden 13, 4654 Faxe Ladeplads, Denmark
Location of manufacturing sites	Gl. Strandvej 14, 4640 Faxe, Denmark

Name of manufacturer	Lhoist France Ouest
Address of manufacturer	15 rue Henri Dagallier, 38 100 Grenoble, France
Location of manufacturing sites	15 rue Henri Dagallier, 38 100 Grenoble, France

Name of manufacturer	Lusical
Address of manufacturer	Valverde, 2025-201 Alcanede, Portugal
Location of manufacturing sites	Valverde, 2025-201 Alcanede, Portugal

Name of manufacturer	Zakłady Wapiennicze Lhoist S.A.
Address of manufacturer	ul. Wapiennicza 7, 46-050 Tarnów Opolski, Poland
Location of manufacturing sites	ul. Fabryczna 22, 47-316 Górażdże, Poland ul. Bolesława Chrobrego 77B, 59-550 Wojcieszów, Poland ul. Wapiennicza 7, 46-050 Tarnów Opolski, Poland

Name of manufacturer	Lhoist Bukowa Sp. z o.o.
Address of manufacturer	Bukowa, ul. Osiedlowa 10, 29-105 Krasocin, Poland
Location of manufacturing sites	Bukowa, ul. Osiedlowa 10, 29-105 Krasocin, Poland

1.4. **Manufacturer(s) of the active substance(s)**

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime
Name of manufacturer	Cal Industrial SL
Address of manufacturer	Pedro I 19-21, 31 007 Pamplona, Spain
Location of manufacturing sites	Pedro I 19-21, 31 007 Pamplona, Spain

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime
Name of manufacturer	CalGov
Address of manufacturer	Carretera Fuente, Apartado 2, 41 560 Estepa, Spain
Location of manufacturing sites	Carretera Fuente, Apartado 2, 41 560 Estepa, Spain

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/ slaked lime
Name of manufacturer	Carrières et Chaux Balthazard et Cotte
Address of manufacturer	Rue du Pra Paris, 38 360 Sassenage, France
Location of manufacturing sites	Rue du Pra Paris, 38 360 Sassenage, France

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/ slaked lime
Name of manufacturer	Carrières et fours à chaux de Dugny
Address of manufacturer	B.P.1, 55 100 Dugny-sur-Meuse, France
Location of manufacturing sites	B.P.1, 55 100 Dugny-sur-Meuse, France

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/ slaked lime
Name of manufacturer	Chaux de Boran
Address of manufacturer	Route de Boran, 60 640 Précy-Sur-Oise, France
Location of manufacturing sites	Route de Boran, 60 640 Précy-Sur-Oise, France

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/ slaked lime
Name of manufacturer	Chaux de Bretagne
Address of manufacturer	-, 53 600 Evron, France
Location of manufacturing sites	-, 53 600 Evron, France

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/ slaked lime
Name of manufacturer	Chaux de la Tour
Address of manufacturer	1 chemin des Chaux de la Tour, 13 820 Ensues La Redonne, France
Location of manufacturing sites	1 chemin des Chaux de la Tour, 13 820 Ensues La Redonne, France

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/ slaked lime
Name of manufacturer	Carrières et Fours à Chaux Dumont Wautier
Address of manufacturer	Rue la Mallieue, 95, B-4470 Saint-Georges-sur-Meuse, Belgium
Location of manufacturing sites	Rue la Mallieue, 95, B-4470 Saint-Georges-sur-Meuse, Belgium

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/ slaked lime
Name of manufacturer	Etablissement Leon Lhoist
Address of manufacturer	Usine de On-Jemelle, 6900 Marche-en-Famenne, Belgium
Location of manufacturing sites	Usine de On-Jemelle, 6900 Marche-en-Famenne, Belgium

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/ slaked lime
Name of manufacturer	Lhoist France Ouest
Address of manufacturer	15 rue Henri Dagallier, 38 100 Grenoble, France
Location of manufacturing sites	15 rue Henri Dagallier, 38 100 Grenoble, France

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/ slaked lime
Name of manufacturer	Lusical
Address of manufacturer	Valverde, 2025-201 Alcanede, Portugal
Location of manufacturing sites	Valverde, 2025-201 Alcanede, Portugal

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/ slaked lime
Name of manufacturer	Zakłady Wapiennicze Lhoist S.A.
Address of manufacturer	ul. Wapiennicza 7, 46-050 Tarnów Opolski, Poland
Location of manufacturing sites	ul. Fabryczna 22, 47-316 Górażdże, Poland ul. Bolesława Chrobrego 77B, 59-550 Wojcieszów, Poland

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/ slaked lime
Name of manufacturer	Faxe Kalk
Address of manufacturer	Hovedgaden 13, 4654 Faxe Ladeplads, Denmark
Location of manufacturing sites	Gl. Strandvej 14, 4640 Faxe, Denmark

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/ slaked lime
Name of manufacturer	Lhoist Bukowa Sp. z o.o.
Address of manufacturer	Bukowa, ul. Osiedlowa 10, 29-105 Krasocin, Poland
Location of manufacturing sites	Bukowa, ul. Osiedlowa 10, 29-105 Krasocin, Poland

Active substance	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/ slaked lime
Name of manufacturer	Vápenka Čertovy schody a.s
Address of manufacturer	Tmaň 200, 267 21 Tmaň, Czech Republic
Location of manufacturing sites	Tmaň 200, 267 21 Tmaň, Czech Republic

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime		Active Substance	1305-62-0	215-137-3	100,0

2.2. Type of formulation

DP - Dustable powder WP - Wettable powder (only for use for disinfection of animal accommodations; limewashing of walls)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Causes skin irritation. Causes serious eye damage. May cause respiratory irritation.
Precautionary statements	Avoid breathing dust. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves, protective clothing, eye protection and face protection. IF ON SKIN:Wash with plenty of water. Specific treatment (see instructions on this label). If skin irritation occurs:Get medical advice. Take off contaminated clothing.And wash it before reuse. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/physician. IF INHALED:Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell. Store in a well-ventilated place.Keep container tightly closed. Store locked up. Dispose of container to accordance with local regulations.

4. **AUTHORISED USE(S)**

4.1. **Use description**

Table

Use # 1 – Disinfection of sewage sludge

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: - Scientific name: Endoparasites Common name: Helminth eggs Development stage: -
Field(s) of use	Indoor
Application method(s)	Method: Automatic direct application Detailed description: The product is dosed into the sewage sludge and mixed by means of a blender. The dry product is mixed with the sewage sludge in an open mixer. The product shall be loaded by fully automated processes.
Application rate(s) and frequency	Application Rate: 0,2-2 kg product/kg dry weight of substrate; typical dry solids content - 12-25 % in sewage sludge. The application rate must be sufficient to maintain a pH > 12 during the contact time. Dilution (%): - Ready-to-use (RTU) product Number and timing of application: Contact time: 24 hours to 90 days for endoparasites (helminth eggs) - the specific contact time depends on several parameters (e.g. temperature, content of dry matter, etc.). Preliminary laboratory tests must be performed to guarantee efficacy.
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk powder Big bags or sacks (with Polypropylene (PP) or polyethylene (PE) inner layer): 500-1 000 kg

4.1.1. *Use-specific instructions for use*

— The dose must be sufficient to maintain a pH > 12 during the contact time.

— Application rate: 0,2-2 kg product/kg dry weight of substrate; typical dry solids content - 12-25 % in sewage sludge.

The ratios may vary between applications and treatment plant designs. The user should ensure that the treatment is effective through preliminary laboratory tests that guarantee efficacy according to the legislation applicable to each case.

4.1.2. *Use-specific risk mitigation measures*

— The loading of the product into the treatment unit and the application must be done fully automatically. The loading into the treatment unit and the disposal of empty bags and sacs must be performed using a telehandler (including a closed cabin).

— During the loading of the product and the disposal of empty bags, wear:

  — respiratory protective equipment (RPE) of at least assigned protection factor (APF) 40 (airtight face piece covering eyes, nose, mouth and chin according to European Standard (EN) 149 with a P3 filter or equivalent);

  — chemical resistant gloves classified under EN 374 or equivalent (glove material to be specified by the authorisation holder within the product information);

  — protective coverall in accordance with EN 13982 or equivalent (coverall material to be specified by the authorisation holder within the product information).

— During the treatment of sewage sludge, the wearing of air-fed or canister RPE specific for ammonia gas in accordance with EN 14387 or equivalent, is recommended in the absence of collective management measures to estimate and prevent an exposure greater than the EU occupational exposure limit value (OEL) of 14 mg/m^3 for that gas.

— During the manual handling of treated sewage sludge wear protective gloves in accordance with EN 374 or equivalent and protective coverall in accordance with EN 14126 or equivalent protecting against the intrinsic properties of the sewage sludge.

— The provisions on personal protective equipment are without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

— See section 6 for the full titles of the EN standards and legislation

— The cleaning of the unit treatment must be avoided or performed with an automated process with no exposure of the professional.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

-

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

-

5. **GENERAL DIRECTIONS FOR USE** ([1])

5.1. **Instructions for use**

— Comply with the instructions for use.

— Respect the conditions of use of the product.

— Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved.

— For outdoor use of the product, do not apply in the case of wind or rain.

([1]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

5.2. **Risk mitigation measures**

— Do not let bystanders (including co-workers and children) and pets enter the treatment area during the entire treatment duration (including the loading, the application of the product, the disposal of empty bags and sacs, the agreed contact time and the subsequent removal of the product and its residues from the ground).

— Use only in a well-ventilated area.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

— IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

— IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

— IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTER or a doctor.

— IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and ease to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. Information to healthcare personnel/doctor: the eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemical (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

5.4. **Instructions for safe disposal of the product and its packaging**

— Do not discharge unused product on the ground, into water courses, into pipes (e.g. of sinks, toilets) or down the drains.

— Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

— Do not store at a temperature above 30°C.

— Protect from humidity.

— Shelf-life: 15 months.

6. **OTHER INFORMATION**

Full titles of EN standards and legislation referred to in section 4.1.2:

EN 149 - Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking;

EN 374 - EN ISO 374-1: 2018: Protective gloves against dangerous chemicals and micro-organisms. Part 1: terminology and performance requirements for chemical risks;

EN 13982 - Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates;

EN 14387 - EN 14387:2021: Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, marking;

EN 14126 - BS EN 14126: 2003 - Protective clothing. Performance requirements and tests methods for protective clothing against infective agent;

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11.)