

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Nordkalk QL 0-0,1

Product type(s)

PT02: Disinfectants and algaecides not intended for direct application to humans or animals

PT03: Veterinary hygiene

Authorisation number: EU-0029359-0000

R4BP asset number: EU-0029359-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Nordkalk QL 0-0,1
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Nordkalk AB
	Address	Kungsängsvägen 22 73129 Köping Sweden
Authorisation number		EU-0029359-0000
<i>R4BP asset number</i>		EU-0029359-0000
Date of the authorisation		19/06/2024
Expiry date of the authorisation		30/11/2033

1.3. Manufacturer(s) of the product

Name of manufacturer	Nordkalk AB
Address of manufacturer	Box 901 SE-731 29 Köping Sweden
Location of manufacturing sites	Nordkalk AB, Köping Nordkalk AB, Köping, Kungsängsvägen 22 SE-731 36 Köping Sweden

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

Active substance	Calcium oxide/lime/burnt lime/quicklime
Name of manufacturer	Nordkalk AB
Address of manufacturer	Box 901 SE-731 29 Köping Sweden
Location of manufacturing sites	Nordkalk AB, Köping Kungsängsvägen 22 SE-731 36 Köping Sweden Nordkalk AB, Lärbro Lärbro Storugns 2741 SE-624 53, Lärbro Sweden

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 oxide/ lime/burnt lime/ quicklime		active substance	1305-78-8	215-138-9	100

2.2. Type(s) of formulation

DP Dustable powder

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. EUH014: Reacts violently with water.
Precautionary statements	P261: Avoid breathing dust. P264: Wash hands thoroughly after handling. P271: Use only outdoors or in a well-ventilated area. P280: Wear protective gloves, protective clothing, eye protection and face protection. P302+P352: IF ON SKIN: Wash with plenty of water. P321: Specific treatment (see instructions on this label). P332+P313: If skin irritation occurs: Get medical advice. P362+P364: Take off contaminated clothing and wash it before reuse. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTRE or doctor/physician. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a poison center/doctor if you feel unwell. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P501: Dispose of container to accordance with local regulations. P405: Store locked up.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Disinfection of sewage sludge

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
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 use
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 should be loaded by fully automated processes.
Application rate(s) and frequency	Application rate: 0,15 - 1,5 kg product / kg dry weight of substance; typical dry solid content - 12-25 % in sewage sludge Dilution (%): - Ready to use (RTU) product Number and timing of application: The application rate must be sufficient to maintain a pH of > 12 and a temperature >50°C during the contact time. Contact time: 24 hours
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 - 1200 kg

4.1.1. Use-specific instructions

- The dose must be sufficient to maintain a pH of > 12 and a temperature >50°C during the 24 hour contact time.

- Application rate : 0,15 – 1,5 kg product / kg dry weight of substrate; typical dry solids content - 12-25% in sewage sludge.

- The ratio may vary between application and treatment plant designs. The user must ensure that the treatment is effective through preliminary laboratory test that guarantee efficacy according to the legislation applicable to each case.

4.1.2. Use-specific risk mitigation measures

4.1.3. 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 big bags or sacks (500 - 1200 kg) must be performed using a telehandler (including a closed cabin).
- During the loading of the product and the disposal of empty bags or sacks, wear:
 - a respiratory protective equipment (RPE) 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 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 absence of collective management measures to estimate and prevent an exposure greater than the EU occupational exposure limit value (OEL) of 14 mg/m³ for that gas.
- During the manual handling of treated sewage sludge wear protective gloves in accordance with EN 374 or equivalent and protection 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 treatment unit must be avoided or performed with an automated process with no exposure of the professional.

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

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

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

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4.2. Use description

Table 2. Disinfection of manure

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage: -</p> <p>Scientific name: Viruses Common name: Viruses Development stage: -</p> <p>Scientific name: Endoparasites Common name: Helminth eggs Development stage: -</p>
Field(s) of use	indoor use
Application method(s)	<p>Method: Automatic direct application</p> <p>Detailed description: The product is mixed with the manure. The product is dosed into the manure and mixed by means of a blender. The product shall be loaded by fully automated processes.</p>
Application rate(s) and frequency	<p>Application rate: -</p> <p>Dilution (%): - RTU product</p> <p>Number and timing of application:</p> <p>The application rate must be sufficient to maintain a pH of > 12 and a temperature > 60°C during the contact time.</p> <p>Contact time: 24 hours</p>
Category(ies) of users	professional

Pack sizes and packaging material	Bulk powder Big bags or sacks (with PP or PE inner layer): 500 - 1200 kg
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4.2.1. Use-specific instructions

- The application rate must be sufficient to maintain a pH of > 12 and a temperature > 60°C during the 24 hour contact time.
- Do not apply more than 100 kg product /m³ of manure.
- The mixture should be moistened and any self-ignition that might occur should be extinguished with water.
- After the necessary contact time, remove the treated manure from the animal house. Use of the treated manure according to local legislation.

4.2.2. Use-specific risk mitigation measures

4.2.3. 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 or sacks must be performed using a telehandler (including a closed cabin).
- During the loading of the product and the disposal of empty bags or sacks, wear:
 - RPE of at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to EN 149 with a P3 filter or equivalent);
 - chemical resistant gloves in accordance with 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 the manure, the wearing of air-fed or canister RPE specific for ammonia gas in accordance with EN 374 or equivalent, is recommended in the absence of collective management measures to estimate and prevent an exposure greater than the EU OEL of 14 mg/m³ for that gas.
- During the manual handling of treated manure wear protective gloves in accordance with EN 374 or equivalent and protection coverall in accordance with EN 14126 or equivalent protecting against the intrinsic properties of the manure.
- 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 legislations.
- The cleaning of the treatment unit must be avoided or performed with an automated process with no exposure of the professional.
- Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant or directly to surface water.

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

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

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

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4.3. Use description

Table 3. Disinfection of indoor floor surfaces of animal accommodations and transportation

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage: -</p> <p>Scientific name: Yeast Common name: Yeasts Development stage: -</p> <p>Scientific name: Fungi Common name: fungi Development stage: -</p> <p>Scientific name: viruses Common name: Viruses Development stage: -</p>
Field(s) of use	indoor use
Application method(s)	<p>Method: Direct application</p> <p>Detailed description: The product is spread directly onto the floors of animal accommodations using manual or automated techniques. Manual spreading using a shovel or semi-automated using a low-impact spreader.</p>
Application rate(s) and frequency	<p>Application rate: 800 g product / m²</p> <p>Dilution (%): - RTU product</p> <p>Number and timing of application: Frequency in animal housing: before each production cycle. Frequency in animal transportation: after each animal transport.</p> <p>Contact time: 48 hours</p>

Category(ies) of users	professional
Pack sizes and packaging material	Bulk powder Big bags or sacks (with PP or PE inner layer): 500 - 1200 kg Paper sacks (with PP or PE inner layer): 25 kg

4.3.1. Use-specific instructions

- The product is spread onto the floors of animal accommodations and transportation using manual or automated techniques. Manual spreading using a shovel or semi-automated using a low-impact spreader.
- A long-handled shovel must be used for the manual spreading application.

A. On concrete floors:

1. Wash the surface with running water;
2. Sprinkle approximatively 800 g of product / m² to cover the damp ground and add 0,9 litre/m² of water;
3. Leave to act for at least 48 hours.

B. On beaten-earth floor:

1. Brush and wet the surface;
2. Sprinkle approx. 800 g of product / m² on the damp ground and add 0,9 litre/m² of water;
3. Leave to act for at least 48 hours.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

- During the loading, the application of the product and the disposal of empty bags or sacks, wear:

- RPE of at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to EN 149 with a P3 filter or equivalent);
- chemical resistant gloves in accordance with EN 374 or equivalent (glove material to be specified by the authorisation holder within the product information);
- a protective coverall in accordance with EN 13982 or equivalent (coverall material to be specified by the authorisation holder within the product information).

- For the use of big bags or sacks (500-1200 kg), the loading of the product and the disposal of empty bags or sacks must be performed fully automatically using a telehandler (including a closed cabin).

- During the loading of small sacks (25 kg), thoroughly empty out the sacks in order to minimise the remaining powder.

- Fold carefully the small bag in order to avoid any spills.

- During the disposal of any residues of the product after the application, wear:

- RPE of at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to EN 149 with a P3 filter or equivalent);
- chemical resistant gloves in accordance with 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).

- 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.
- Animals must not be present during the entire treatment duration.
- Remove residues of the product on the ground by sweeping before re-entry of animals.
- Feed and drinking water must be carefully covered or removed during the application of the product.
- 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.

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

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

- After treatment, remove the product by brushing. Collect the resulting dry waste and recycle it as agricultural liming material or dispose of the dry waste according to local requirements.
- For animal transportation use only: after brushing, rinse and clean the vehicle.

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

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4.4. Use description

Table 4. Disinfection of floors of outdoor animal enclosures

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage: -</p> <p>Scientific name: Yeast Common name: Yeasts Development stage: -</p> <p>Scientific name: other fungi Common name: fungi Development stage: -</p>

	Scientific name: Virus Common name: Virus Development stage: -
Field(s) of use	outdoor use
Application method(s)	Method: Direct application Detailed description: The product is spread directly onto the surfaces (floors) of animal enclosures using manual or automated techniques. Manual spreading using a shovel or semi-automated using a low-impact spreader.
Application rate(s) and frequency	Application rate: 600 - 800 g product/m ² Dilution (%): - RTU product Number and timing of application: Contact time 48 hours Frequency: maximum two applications per year.
Category(ies) of users	professional
Pack sizes and packaging material	Bulk powder Big bags or sacks (with PP or PE inner layer): 500 - 1200 kg Paper sacks (with PP or PE inner layer): 25 kg

4.4.1. Use-specific instructions

Before the introduction of new animals:

- Brush and wet the floor.

- spread 600 - 800 g product/m² onto the ground then add 0,9 litre/m² of water.

- leave to act for at least 48 hours.

Do not apply in the case of wind or rain.

4.4.2. Use-specific risk mitigation measures

4.4.3. Use-specific risk mitigation measures

- During the loading, the application of the product on the floor and the disposal of empty bags, wear:

- RPE of at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to EN 149 with a P3 filter or equivalent);
- chemical resistant gloves in accordance with EN 374 or equivalent (glove material to be specified by the authorisation holder within the product information);
- a protective coverall in accordance with EN 13982 or equivalent (coverall material to be specified by the authorisation holder within the product information).

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- For the use of big bags or sacks (500-1200 kg), the loading of the product and the disposal of empty bags or sacks must be performed fully automatically using a telehandler (including a closed cabin).
 - During the loading of small sacks (25 kg), thoroughly empty out the sacks to minimise the remaining powder.
 - Fold carefully the small bag in order to avoid any spills.
 - During the disposal of the product after the application, wear:

- RPE of at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter or equivalent);
- chemical resistant gloves in accordance with 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).

- 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.

- Do not exceed two applications per year.
- Animals must not be present during the entire treatment duration.
- Remove the residues of the product on the ground by thorough sweeping before allowing re-entry of animals.
- Feed and drinking water must be carefully covered or removed during the application of the product.

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

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

- After treatment, remove the product by brushing. Collect the resulting dry waste and recycle it as agricultural liming material or dispose of the dry waste according to local requirements.

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

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5. GENERAL DIRECTIONS FOR USE¹

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 uses, do not apply in the case of rain or wind

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 or sacks, the required 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 easy 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 chemicals (pH > 11), amines and acids like acetic 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. sink, 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.

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

6. OTHER INFORMATION

Full titles of EN standards and legislation referred to in sections 4.1.2 - 4.4.2:

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.