



2024/267

18.1.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/267

of 17 January 2024

granting a Union authorisation for the single biocidal product 'DEC-SPORE 200 Plus' 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 28 September 2017, Veltek Associates Inc. Europe submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a single biocidal product named 'DEC-SPORE 200 Plus' of product-type 2, as described in Annex V to that Regulation, providing written confirmation that the competent authority of [the] Netherlands had agreed to evaluate the application. The application was recorded under case number BC-WV034235-09 in the Register for Biocidal Products.
- (2) 'DEC-SPORE 200 Plus' contains peracetic acid 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 30 August 2022, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 23 March 2023, the Agency submitted to the Commission its opinion ⁽²⁾, the draft summary of the biocidal product characteristics ('SPC') of 'DEC-SPORE 200 Plus' and the final assessment report on the single biocidal product, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that 'DEC-SPORE 200 Plus' is a single biocidal product within the meaning of Article 3(1), point (r), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) of that Regulation.
- (6) On 14 April 2023, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'DEC-SPORE 200 Plus'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 2 March 2023 on the Union authorisation of the single biocidal product 'DEC-SPORE 200 Plus' (ECHA/BPC/374/2023), <https://echa.europa.eu/opinions-on-union-authorisation>

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0030727-0000 is granted to Veltek Associates Inc. Europe for the making available on the market and use of the single biocidal product 'DEC-SPORE 200 Plus' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 7 February 2024 to 31 January 2034.

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, 17 January 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

DEC-SPORE 200 Plus

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

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

Authorisation number:

R4BP asset number:

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	DEC-SPORE 200 Plus DEC-SPORE 300 Plus
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	
	Address	
Authorisation number		
R4BP asset number		
Date of the authorisation		
Expiry date of the authorisation		

1.3. Manufacturer(s) of the product

Name of manufacturer	Evonik Operations GmbH (Acting for Evonik Active Oxygens, LLC (US))
Address of manufacturer	One Commerce Square, 2005 Market Street, Suite 3200, 19103 Philadelphia PA United States
Location of manufacturing sites	Tonawanda Plant, 35 Sawyer Avenue, 14150 Tonawanda, NY United States

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

Active substance	Peracetic acid
Name of manufacturer	Evonik Operations GmbH (Acting for Evonik Active Oxygens, LLC (US))

Address of manufacturer	One Commerce Square, 2005 Market Street, Suite 3200, 19103 Philadelphia, PA United States
Location of manufacturing sites	Tonawanda Plant, 35 Sawyer Avenue, 14150 Tonawanda, NY United States

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 (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	5,13
Acetic acid (glacial)	Acetic acid	Non-active substance	64-19-7	200-580-7	10,4
Hydrogen peroxide	Hydrogen peroxide	Non-active substance	7722-84-1	231-765-0	21,7

2.2. Type of formulation

SL – Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Heating may cause a fire. May be corrosive to metals. Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled. Corrosive to the respiratory tract. Very toxic to aquatic life with long lasting effects. Causes severe skin burns and eye damage.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. – No smoking. Keep only in original packaging. Do not breathe vapours. Do no eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water. IF SWALLOWED:Rinse mouth.Do NOT induce vomiting. 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. Take off contaminated clothing.And wash it before reuse. Dispose of contents to in accordance with local/national regulations. Dispose of container to in accordance with local/national regulations. IF INHALED:Remove person to fresh air and keep comfortable for breathing. Store locked up.
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4. **AUTHORISED USE(S)**

4.1. **Use description**

Table 1

Use # 1 – Use #1 Surface disinfectant use – Indoors

Product type	PT02 – Disinfectants and algacides 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: Bacterial cells Scientific name: Yeast species Common name: Yeasts Development stage: Cellular yeasts
Field(s) of use	Indoor Disinfectant for industrial use only. For indoor use on floors, walls and other hard non-porous surfaces such as, but not limited to, general surfaces, tools, tables, shelves, etc. in clean rooms of manufacturing facilities for pharmaceutical, biopharmaceutical, medical device, healthcare and diagnostic products.
Application method(s)	Method: Surface disinfection by soaking or trigger spraying, to distribute the product mop, cloth or wipe can be used Detailed description: -
Application rate(s) and frequency	Application Rate: 100 ml/m ² Dilution (%): 0,5 % v/v Dilute product 1:200 in water (for example 5 ml product into 995 ml water) by manual dilution or use the SimpleMix system Number and timing of application:

	Typical application frequency of 1 application per day Contact time: 5 minutes for bactericidal and yeasticidal treatment,
Category(ies) of users	Industrial
Pack sizes and packaging material	75 ml high density polyethylene (HDPE) bottles (opaque) 473 ml HDPE bottles (opaque) – SimpleMix package 503 ml HDPE bottles (opaque) 3.79 litre HDPE bottles (opaque) – SimpleMix package Each bottle at least double bagged (more bags upon request of customer) in clear low density polyethylene (LDPE) bags heat sealed shut, contained in cardboard shipping cases. Not offered as single bottles. Only sold in full sealed boxes.

4.1.1. Use-specific instructions for use

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection, if appropriate. Prepare a disinfectant dilution (1:200). Apply thoroughly as directed in directions for use: wet the surface thoroughly and allow to air dry. No rinsing is necessary but may be done if desired.

Preparation of dilution manually

Mix a use dilution of 1:200.

1. Measure 995 ml of water into a clean or sterilized container.
2. Add 5 ml product.
3. Close container securely. Swirl the closed container to mix well.
4. Proportional dilutions can be made for other quantities, if desired.

Preparation of dilution by using the SimpleMix package. (See cap on bottle or SimpleMix Instruction brochure for written directions)

The SimpleMix container (473 ml or 3,79 litres) is pre-dosed with water and product concentrate that results in a 1:200 use dilution.

1. Open the large cap of the SimpleMix System.
2. Push down on the inner small bottle to release the concentrate portion inside the package into the water inside the package.
3. Reattach and close the large cap.
4. If the container is a 3,79 litre bottle, also ensure the pour opening cap on the main bottle is closed tight. 473 ml bottles have only one large cap and a trigger sprayer.
5. Swirl the closed container for 15 seconds.
6. Pour from the large bottle into mechanical spray device or use the attached trigger spray of the 473 ml bottle.

Use a mechanical spray device for application of the product or apply the product onto the surface by other means and then use a cloth, mop or wipe for distribution. Make sure to wet the surfaces completely, allow to take effect for at least 5 minutes.

For use on walls, multiple applications might be necessary to wet the surface completely.
No rinsing is necessary but may be done, if desired.

4.1.2. *Use-specific risk mitigation measures*

For the undiluted product:

Provide adequate ventilation with a minimum of 10 air changes per hour (ACH). The length of stay in the treated area should be minimised.

Use of respiratory protective equipment (RPE) in accordance with European Standard EN 14387 or equivalent providing a protection factor of 4 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type AB1, brown/grey filter type).

Wear protective chemical-resistant gloves (classified under European Standard EN 374 or equivalent) glove material to be specified by the authorisation holder within product information and a protective coverall (at least Type 6 EN 13034 or equivalent) which is impermeable for the biocidal product during product handling.

The use of eye or face protection in accordance with EN 16321 or equivalent during handling of the product is mandatory.

Dispose of protective gloves after use.

This is without prejudice to the application by employers 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.

For diluted product (0,5 % v/v):

No risk mitigation measures required for the diluted product.

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*

See general directions for use

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

See general directions for use

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

See general directions for use

4.2. **Use description**

Table 2

Use # 2 – Use # 2 Surface disinfectant Indoors, Sporicidal use

Product type	PT02 – Disinfectants and algacides 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: Bacterial spores Common name: Bacterial spores Development stage: Bacterial spores

	Scientific name: Bacteria Common name: Bacteria Development stage: Bacteria cells Scientific name: Yeast species Common name: Yeasts Development stage: Cellular yeasts Scientific name: Fungi Common name: Fungi Development stage: Fungi
Field(s) of use	Indoor Disinfectant for industrial use only. For indoor use on floors, walls and other hard non-porous surfaces such as, but not limited to, general surfaces, tools, tables, shelves, etc. in clean rooms of manufacturing facilities for pharmaceutical, biopharmaceutical, medical device, healthcare and diagnostic products.
Application method(s)	Method: Surface disinfection by soaking or trigger spraying, to distribute the product mop, cloth or wipe can be used Detailed description: -
Application rate(s) and frequency	Application Rate: 100 ml/m² Dilution (%): 6,7 % v/v Dilute product 1:15 in water or (for example 67 ml into 933 ml water)by manual dilution or use the SimpleMix System Number and timing of application: Typical application frequency of 1 application per day Contact time: 5 minutes for bactericidal, yeasticidal and fungicidal treatment 15 minutes for sporicidal treatment
Category(ies) of users	Industrial
Pack sizes and packaging material	75 ml high density polyethylene (HDPE) bottles (opaque) 473 ml HDPE bottles (opaque) – SimpleMix package 503 ml HDPE bottles (opaque) 3,79 litre HDPE bottles (opaque) – SimpleMix package Each bottle at least double bagged (more bags upon request of customer) in clear low density polyethylene (LDPE) bags heat sealed shut, contained in cardboard shipping cases. Not offered as single bottles. Only sold in full sealed boxes.

4.2.1. Use-specific instructions for use

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection, if appropriate. Prepare a disinfectant dilution (1:15). Apply thoroughly as directed in directions for use: wet the surface thoroughly and allow to air dry. No rinsing is necessary but may be done if desired.

Preparation of dilution manually:

Mix a use dilution of 1:15.

1. Measure 3,75 litre water into a clean or sterilized container.
2. Add 250 ml product.
3. Close container securely. Swirl the closed container to mix well.
4. Proportional dilutions can be made for other quantities, if desired.

Preparation of dilution by using the SimpleMix package (473 ml or 3,79 litre). (See cap on bottle or SimpleMix Instruction brochure for written directions).

[Note: The SimpleMix container labelled "Sporicide" results in a 1:15 use dilution.]

1. Open the large cap of the SimpleMix System.
2. Push down on the inner small bottle to release the concentrate from portion inside the package into the water inside the package.
3. Reattach and close the large cap.
4. If the container is a 3,79 litre bottle, also ensure the pour opening cap on the main bottle is closed tight. 473 ml bottles have only one large cap and a trigger sprayer.
5. Swirl the closed container for 15 seconds.
6. Pour from the large bottle into a mechanical spray device or use the attached trigger spray of the 473 ml bottle.

(See cap on bottle or SM-01-E SimpleMix Instructions brochure for written directions.)

Use a mechanical spray device for application of the product or apply the product onto the surface by other means and then use a cloth, mop or wipe for distribution. Make sure to wet the surfaces completely, allow to take effect for at least 5 minutes for bactericidal, yeasticidal and fungicidal treatment, 15 minutes for sporicidal treatment.

For use on walls, multiple applications might be necessary to wet the surface completely.

No rinsing is necessary but may be done, if desired.

4.2.2. Use-specific risk mitigation measures

For the undiluted product:

Provide adequate ventilation with a minimum of 10 air changes per hour (ACH). The length of stay in the treated area should be minimised.

Use of respiratory protective equipment (RPE) in accordance with European Standard EN 14387 or equivalent providing a protection factor of 4 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type AB1, brown/grey filter type).

Wear protective chemical resistant gloves (in accordance with EN 374 or equivalent)- glove material to be specified by the authorisation holder within product information and a protective coverall (at least Type 6 EN13034 or equivalent) which is impermeable for the biocidal product during product handling.

The use of eye or face protection in accordance with EN 16321 or equivalent during handling of the product is mandatory.

Dispose of protective gloves after use.

This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

For the diluted product (6,7 % v/v):

Provide adequate ventilation with a minimum of 10 ACH. The length of stay in the treated area should be minimised.

Wear protective chemical resistant gloves in accordance with EN 374 or equivalent -glove material to be specified by the authorisation holder within product information-and a protective coverall (at least Type 6 EN 13034 or equivalent) which is impermeable for the biocidal product.

Use of respiratory protective equipment (RPE) in accordance with EN 14387 or equivalent providing a protection factor of 4 for wiping is mandatory and a factor 10 for trigger spraying and mopping. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type AB1, brown/grey filter type).

In case of a ventilation rate of 30 ACH:

Wear protective chemical resistant gloves in accordance with EN 374 or equivalent – glove material to be specified by the authorisation holder within the product information and a protective coverall (at least Type 6 EN13034 or equivalent) which is impermeable for the biocidal product during product handling.

The use of eye or face protection during handling of the product is mandatory.

Dispose of protective gloves after use.

This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

Unprotected persons should be kept away from treated areas until surfaces are dry.

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

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

See general directions for use.

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

See general directions for use

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

See general directions for use

5. **GENERAL DIRECTIONS FOR USE ⁽¹⁾**

5.1. **Instructions for use**

See use-specific directions for use

5.2. **Risk mitigation measures**

Unprotected individuals must be excluded from treated areas where in-air hydrogen peroxide and/or peracetic acid concentrations exceed the respective in-air AEC values (1,25 mg/m³ or hydrogen peroxide and 0,5 mg/m³ for peracetic acid, or a lower relevant national reference value).

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

Where in-air hydrogen peroxide, peracetic acid and/or acetic acid concentrations exceed the respective in-air AEC values or where monitoring of in-air concentrations is not possible exposed individuals/users shall wear appropriate respiratory protective equipment

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

For the undiluted product:

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for 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 CENTRE 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 or an 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, formic acid or propionic acid

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.

Initiate life support measures if needed, thereafter call a POISON CENTRE.

For diluted product (0,5 % and 6,7 %):

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor. For Spill or exposure, call the Emergency Response Service from Europe in English and 23 European language telephone CARECHEM24 at +44 1235 239 670, for Arabic language + 44 1235 239 671.

Emergency measures to protect the environment:

Avoid (direct) release (of undiluted product) to the environment/sewage system..

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

Ensure container is completely empty.

Do not reuse the empty container.

Handle empty containers with the same care and safety precautions as filled containers. Triple rinse or flush empty container with tap water, then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or incinerate or burn empty container, if allowed by national and local authorities.

Disposal of this packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Keep in a cool place.

Keep product in its original vented container.

Do not store on side or inverted

Avoid damaging or denting the packaging.

Do not contaminate water, food or feed during storage and disposal of the product.

Keep container tightly closed

Store above 0 °C and below 30 °C

Shelf life: 2 years.

6. OTHER INFORMATION

Full titles of EN standards and legislation mentioned

EN 14387 – Respiratory protective devices – Gas filter(s) and combined filter(s) – Requirements, testing, marking

EN 16321 – Eye and face protection for occupational use

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

EN 13034 – Protective clothing against liquid chemicals. Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment).

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).
