

Summary of product characteristics for a biocidal product

Product name: PHASE VTA

Product type(s): PT04 - Food and feed area (Disinfectants)

Authorisation number: ES/APP(NA)-2023-04-00864

R4BP 3 asset reference number: ES-0024361-0000

Table Of Contents

Administrative information	1
1.1. Trade names of the product	1
1.2. Authorisation holder	1
1.3. Manufacturer(s) of the biocidal products	1
1.4. Manufacturer(s) of the active substance(s)	2
2. Product composition and formulation	2
2.1. Qualitative and quantitative information on the composition of the biocidal product	3
2.2. Type of formulation	3
3. Hazard and precautionary statements	3
4. Authorised use(s)	4
5. General directions for use	6
5.1. Instructions for use	6
5.2. Risk mitigation measures	6
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	7
5.4. Instructions for safe disposal of the product and its packaging	7
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	7
6. Other information	8

Administrative information

1.1. Trade names of the product

PHASE VTA

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Evonik Peroxide Spain s.l.u.
	Address	Afuera s/n 50784 La Zaida Spain
Authorisation number		ES/APP(NA)-2023-04-00864
R4BP 3 asset reference number		ES-0024361-0000
Date of the authorisation		19/04/2023
Expiry date of the authorisation		19/04/2033

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Evonik Peroxide Spain s.l.u.
Address of the manufacturer	Afuera s/n 50784 La Zaida (Zaragoza) Spain
Location of manufacturing sites	Afuera s/n 50784 La Zaida (Zaragoza) Spain

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

Name of the manufacturer	Evonik Peroxid GmbH
Address of the manufacturer	Industriestraße 1 AT-9721 Weißenstein Austria
Location of manufacturing sites	Industriestraße 1 AT-9721 Weißenstein Austria

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

Active substance	1340 - Peracetic acid
Name of the manufacturer	Evonik Peroxide Spain s.l.u.
Address of the manufacturer	Afueras s/n 50784 La Zaida (Zaragoza) Spain
Location of manufacturing sites	Afueras s/n 50784 La Zaida (Zaragoza) Spain

Active substance	1340 - Peracetic acid
Name of the manufacturer	Evonik Operations GmbH (Acting for Evonik Active Oxygens, LLC (US))
Address of the manufacturer	One Commerce Square 2005 Market Street Suite 3200 PA 19103 Philadelphia United States
Location of manufacturing sites	35 Sawyer Avenue NY 14150 Tonawanda United States

Active substance	1340 - Peracetic acid
Name of the manufacturer	Evonik Peroxid GmbH
Address of the manufacturer	Industriestraße 1 AT-9721 Weißenstein Austria
Location of manufacturing sites	Industriestraße 1 AT-9721 Weißenstein Austria

2. Product composition and formulation

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	15
Hydrogen peroxide		Non-active substance	7722-84-1	231-765-0	10
Acetic acid		Non-active substance	64-19-7	200-580-7	35

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.
Toxic in contact with skin.
Harmful if swallowed.Harmful if inhaled.
Causes severe skin burns and eye damage.
Very toxic to aquatic life with long lasting effects.
Corrosive to the respiratory tract.

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 dust.
Do not breathe fume.
Do not breathe gas.
Do not breathe mist.
Do not breathe vapours.
Do not breathe spray.
Wash - thoroughly after handling.
Do no eat, drink or smoke when using this product.
Use only outdoors or in a well-ventilated area.

Wear gloves/protective clothing/eye protection/face protection/hearing protection.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Take off immediately all contaminated clothing. And wash it before reuse.

Store in a well-ventilated place.

Store locked up.

Avoid release to the environment.

Collect spillage.

Dispose of contents to and/or its container as hazardous waste according to regulation in force.

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 1 – Industrial. Aseptic packaging: Disinfection by peracetic acid vaporization with hot air.

Product type

PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised use

The biocidal product is for use in aseptic food processing on food packaging materials to achieve commercial sterility.

Target organism(s) (including development stage)

Scientific name: Bacterial spores
 Common name: .
 Development stage: .

Field(s) of use

Indoor
 .

Application method(s)

Method: Closed system: Vaporization by hot air
 Detailed description:
 The product is diluted in an automated process and applied in a closed system (i.e. in aseptic filling machines). The biocidal product is diluted with deionized water to a targeted peracetic acid concentration and fed into the vaporizing unit at a certain flow rate becoming a vapour. The vapour is carried by heated air (vaporization temperature) into a package that needs to be sterilized. The vapour condensates inside the package during a certain time (seconds) to form a thin uniform layer. The sterilization is achieved by peracetic acid inside the condensate. Finally, ambient air is fed (drying temperature) into the treated package to remove the condensate and to dry out the package.

	For packaging form 5 to 30kg manual loading is authorised.
Application rate(s) and frequencies	<p>Application Rate: 20000- 150000 ppm peracetic acid Dilution (%): . Number and timing of application:</p> <p>For each aseptic packaging system, the biocidal product contact time, vapour temperature, the air flow and drying air temperature need to be determined. Application dose range: 20000- 150000 ppm peracetic acid Final concentration on packaging: 60mg PAA/m² Contact time: 2.8-20 seconds Vaporization Temperature: 85°C</p>
Category(ies) of users	Industrial
Pack sizes and packaging material	Jerry can. 5, 20, 25 and 30 kg. HDPE

4.1.1 Use-specific instructions for use

See generic directions for use.

4.1.2 Use-specific risk mitigation measures

See generic directions for use.

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 generic directions for use.

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

See generic 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 generic directions for use.

5. General directions for use

5.1. Instructions for use

Intended only for Industrial users.

For industrial users: the user of the product must have received adequate training within the framework of that industry, in a way that allows him to have the knowledge and skills in handling chemical products and in the correct use of the necessary personal protective equipment for the safe performance of his work.

Use in accordance with the requirements for aseptic packaging machines.

Read the label carefully before using.

The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed. Aerosolised or vaporised application should be use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber. Load manually or automatically the product into the machine depending on packaging:

- For packaging form 5 to 30kg manual loading is authorised.

Efficacy was demonstrated against bacterial spores at the achieve target concentration of 60 mg PAA/m² were 3% VTA (as PAA), 3.8 sec and 85°C vapour temperature and 7g/min of flow rate. The optimization of conditions in the machines is case by case.

The machine dilute automatically the product with deionized water to a targeted peracetic acid concentration of 60 mg PAA/m², fed the biocidal product into the vaporizing unit at a certain flow and temperature (vaporization temperature) and let the product condensates inside the package during the stablished contact time (seconds) to form a thin uniform layer. Finally, fed ambient air (drying temperature) into the treated package to remove the condensate and to dry out the package.

For each aseptic packaging system, the biocidal product contact time, vapour temperature, the air flow and drying air temperature need to be determined.

Application dose range: 20000 - 150000 ppm peracetic acid

Final concentration on packaging: 60mgPAA/m²

The user of the biocidal product shall always carry out a microbiological validation with a suitable test organism (e.g. spores of *Geobacillus stearothermophilus*) at least once to ensure efficacy of the disinfection process in the respective aseptic packaging systems, after which a protocol for disinfection of these packagings can be made and use thereafter.

In case there are methods available for chemically monitoring the active substance on surfaces, chemical validation should be performed besides biological validation.

When it concerns a "standard packaging" for which a protocol is available, the validation may be limited to only a chemical validation.

The product is intended to be used for didinfecting PET and HDPE bottles and cartons.

Inform the registration holder if the treatment is ineffective.

Pre-clean and dry surfaces prior to disinfection.

5.2. Risk mitigation measures

Wear protective chemical-resistant gloves, protective coverall, footwear and full-face mask APF10 (materials and types of personal protective equipment will be specified in the product information by the authorization holder). During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation). During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area.

1. The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.
2. Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed.
3. In case of maintenance of the aseptic packaging plant (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment, chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information.

Aerosolised or vaporised application should be used only in closed aseptic packaging machines with no emission to water and negligible emission to air. Emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

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.

Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

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.

Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

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 After washing the skin: Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor: Initiate life support measures, thereafter call a POISON CENTRE.

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 MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER

Emergency measures to protect environment in case of accident:

Prevent spillage from reaching soil, ground, surface water or any kind of sewer.

Dike to collect large liquid spills.

Contain spills with earth or sand or inert absorbent.

Stop leak and contain spill if this can be done safely.

If safe to do so, move product to secure area.

Control runoff and isolate discharged material for proper disposal.

Do not seal waste material, do not use textiles, tissues, saw dust or combustible materials to clean the spill.

Do not return product to the original storage container/tank due to risk of decomposition.

Residual hydrogen peroxide, if allowed to dry on combustible materials such as paper, fabrics, leather, or wood, can cause the material to ignite and result in a fire.

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

Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations.

Do not release to soil, ground, surface water or any kind of sewer.

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

Keep in a dry, cool, and well-ventilated place. Containers must be vented.
Keep at temperatures below 30°C. Temperatures above 35°C will accelerate decomposition resulting in loss of assay.
Store protected from light.
Do not store near combustible materials.
Packaging material: High density polyethylene. Avoid any other material.
Materials to avoid: Oxidizing agents; Strong reducing agents; Combustible materials; Heavy metals.
Shelf-life: 6 months.

6. Other information

Explanatory note (only for Spain authorisation):

The conclusions reached in this SPC which affect the category of "Industrial", will be applicable to Industrial (Trained professional and Professional) users at the Spanish level.

Definitions:

· Industrial users :
Industrial factory workers.