

Summary of product characteristics for a biocidal product

Product name: 4-b

Product type(s): PT03 - Veterinary hygiene (Disinfectants)

Authorisation number:

R4BP 3 asset reference number: EU-0024303-0004

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Administrative information

1.1. Trade names of the product

OxyFoamPlus
MEPA Foampro D
Predip PLUS

1.2. Authorisation holder

Name and address of the authorisation holder

Name	Ecolab Deutschland GmbH
Address	Ecolab Allee 1 40789 Monheim am Rhein Germany
Authorisation number	1-4

R4BP 3 asset reference number

EU-0024303-0004
15/09/2022
31/08/2032

Date of the authorisation

Expiry date of the authorisation

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Ecolab Europe GmbH
Address of the manufacturer	Richtistrasse 7 8304 Wallisellen Switzerland
Location of manufacturing sites	A.F.P. GmbH Otto-Brenner-Straße 16 21337 Lüneburg Germany
	ACIDEKA S.A. Edificio Feria. Capuchinos de Basurto 6, 4a planta 48013 Bilbao. Bizkaia Spain
	ADIEGO HNOS CTRA DE VALENCIA, KM 5,900 50410 CUARTE DE HUERVA (ZARAGOZA) 50410 Zaragoza Spain
	ALLIED PRODUCTS Allied Hygiene Unit 11, Belvedere Industrial Estate Fishers Way DA17 6BS Belvedere, Kent United Kingdom
	Arkema GmbH Morschheimer Strasse 19 D-67292 Krichheimbolanden Germany
	AZELIS DENMARK Lundtoftegårdsvej 95 2800 Kgs. 2800 Kgs Lyngby Denmark
	Belinka Zasavska Cesta 95 1001 Ljubljana Slovenia
	BENTUS LABORATORIES LTD. RUSSIA, 105005, MOSCOW, RADIO STREET, 24 BLD.1 105005 Moscow Russian Federation
	BIO PRODUCTIONS 72 VICTORIA ROAD, VICTORIA INDUSTRIAL ESTATE, BURGESS HILL, WEST SUSSEX RH159LH Burgess Hill United Kingdom
	BIOXAL SA Route des Varennes - Secteur A – BP 30072 71103 Chalon sur Saône Cedex France
	Bores Srl Via Pioppa, 179 44020 Pontegradella Italy
	BRENNTAG ARDENNES Route de Tournes CD n 2 FR-08090 FR-08090 Cliron France
	BRENNTAG CEE - GUNTRAMSDORF Brenntag CEE GmbH Mixing / Blending Bahnstr. 13 A-2353 Guntramsdorf Austria
	BRENNTAG Duisburg/Glauchau/Hamburg/Heilbronn Brenntag GmbH Humboldttring 15 45472 Muehlheim Germany
	BRENNTAG Kaiserslautern Brenntag Merkurstr. 47 67663 Kaiserslautern Germany
	BRENNTAG Kleinkarlbach/Lohfelden Brenntag GmbH Humboldttring 15 45472 Muehlheim Germany
	BRENNTAG Nordic - HASLEV Høsten Teglværksvej 47 4690 Haslev Denmark
	Brenntag Nordic, Strandgade 35 7100 Vejle Denmark
	BRENNTAG Normandy Brenntag Normandie 12 Sente des Jumelles - BP 11 76710 76710 Montville France
	BRENNTAG PL -Zgierz ul. Kwasowa 5 95-100 Zgierz Poland

Name of the manufacturer	Ecolab Europe GmbH
Address of the manufacturer	Richtistrasse 7 8304 Wallisellen Switzerland
Location of manufacturing sites	Brenntag Quimica S.A. - Madrid. Calle Gutemberg nº 22, Poligono Industrial El Lomo 28906 Madrid Spain
	BRENNTAG Schweizerhall Brenntag Schweizerhall AG Elsaesserstr. 231 CH-4056 Basel Switzerland
	Budich International GmbH Dieselstrasse 10 32120 Hiddenhause Germany
	Caldic Deutschland Chemie B.V Caldic Deutschland GmbH & Co.Kg Am Karlshof 10 D 40231 Duesseldorf Germany
	Carbon Chemicals Group Ltd, Ringaskiddy P43 R772 County Cork Ireland
	COLEP BAD SCHMIEDEBERG ColepCCL Bad Schmiedeberg GmbH Kemberger Str. 3 06905 Bad Schmiedeberg Germany
	COMERCIAL FARMACEUTICA CASTEL: LANA, S.A. "COFARCAS" Condado de Treviño, 46 P.I. Villalonquejar 09080 – BURGOS 09080 Burgos Spain
	COMERCIAL GODO França, 13 08700 – IGUALADA (BARCELONA) 08700 BARCELONA Spain
	COURTOIS SARL ZA SOUS LE BEER Route de Pacy 27730 BUEIL France
	DAN MOR (DR WIPE) DAN-MOR Natural Products and Chemicals Ltd. Or Akiva Industrial Zone 30600 Akiva Industrial Zone Israel
	Denteck BV Heliumstraat 8 2718 SL ZOETERMEER Netherlands
	DETERGENTS BURGUERA DETERGENTS BURGUERA, S.L. Joan Ballester 50 07630 CAMPOS (ILLES BALEARES) Spain
	ECL Biebesheim NLC Biebesheim Justus-von-Liebig-Straße 11 64584 Biebesheim am Rhein Germany
ECL Celra NALCO - Celra C/ Tramuntana s/n Poligona Industrial Celra 17460 Girona Spain	
ECL Châlons AVENUE DU GENERAL PATTON 51000 CHALONS EN CHAMPAGNE France	
ECL Cisterna Nalco Italiana Manufacturing Srl.Via Ninfina II 04012 Cisterna di Latina Italy	
ECL Fawley NLC Fawley Cadland Road, Hythe, SO45 3NP Southampton, Hampshire United Kingdom	
ECL Leeds ECOLAB Lotherton Way Garforth Leeds LS25 2JY LS25 2JY Leeds United Kingdom	
ECL Mandra 25TH KM OLD NATIONAL ROAD OF ATHENS TO THIVA, GR 19600 GR 19600 ATHENS Greece	
ECL Maribor Vajngerlova 4, SI-2001 Maribor SI-2001 Maribor Slovenia	

Name of the manufacturer	Ecolab Europe GmbH
Address of the manufacturer	Richtstrasse 7 8304 Wallisellen Switzerland
Location of manufacturing sites	ECL MICROTEK BV MICROTEK MEDICAL B.V. GESINKKAMPSTRAAT 19, 7051 HR, VARSSEVELD 7051 HR VARSSEVELD Netherlands
	ECL MICROTEK MOSTA SORBONNE CENTRE, F20 MOSTA TECHNOPARK, MOSTA MST 3000 MOSTA Malta
	ECL Mullingar Ecolab Ltd. Forrest Park Zone C Mullingar Industrial Estate Mullingar Co. Westmeath Westmeath Ireland
	ECL Nieuwegein BRUGWAL 11 A, 3432 NZ NIEUWEGEIN 3432 NZ NIEUWEGEIN Netherlands
	ECL Rovigo EsoformEsoform S.p.A. Laboratorio Chimico Farmaceutico Viale del Lavoro 10 45100 Rovigo Italy
	ECL Rozzano Via A. Grandi, 20089 Rozzano MI 20089 Rozzano Italy
	ECL Tesjoki NLC Tesjoki Kivikumuntie 1, Tesjoki 07955 Tesjoki Finland
	ECL Tessenderlo INDUSTRIEZONE RAVENSHOUT 4 3980 Tessenderlo Belgium
	ECL Weavergate NLC Weavergate Northwich, Cheshire West and Chester CW8 4EE Northwich United Kingdom
	Ecolab Ltd Baglan/Swindon, Plot 7a Baglan Energy Park, Baglan, Port Talbot SA11 2HZ Port Talbot United Kingdom
	EXTRUPLAST ZI Fief du Passage 56 rue Robert Geffré 17000 La Rochelle France
	Ferdinand Eimermacher GmbH & Co. KG Westring 24 48356 Nordwalde Germany
	F.E.L.T. BP 64 10 rue du Vertuquet 59531 NEUVILLE EN FERRAIN France
Gallows Green Services Ltd. Cod Beck Mill Industrial Estate Dalton Lane YO7 3HR Thirsk North Yorkshire United Kingdom	
GERDISA GERMAN RGUEZ DROGAS IND Gerdisa Polígono Industrial Miralcampo parc.37 19200 Azuqueca de Henares Guadalajara Spain	
GIRASOL NATURAL PRODUCTS BV De Veldoven 12-14 3342 GR Hendrik-Ido-Ambacht 3342 GR Hendrik-Ido-Ambacht Netherlands	
HENKEL ENGELS Henkel Engels 413116 Engels Prospekt StroiTel ei Russia 413116 Engels Russian Federation	
Imeco GmbH & Co. KG Boschstraße 5 D-63768 Hösbach Germany	
INTERFILL LLC-TOSNO INTERFILL LLC 187000, Moskovskoye shosse 1 187000 Tosno - Leningradskaya Russian Federation	
JODEL - PRODUCTOS QUIMICOS Jodel Zona Industrial 2050 Aveiras de Cima 2050 Aveiras de Cima Portugal	

Name of the manufacturer	Ecolab Europe GmbH
Address of the manufacturer	Richtstrasse 7 8304 Wallisellen Switzerland
Location of manufacturing sites	Kleinmann GmbH Am Trieb 13 72820 Sonnenbühl Germany
	Kompak Nederland B.V. Ambachtsweg 4, 4854 MK, Bavel Netherlands
	La Antigua Lavandera SL LA ANTIGUA LAVANDERA, S.L. Ctra. Antigua Sevilla-Alcalá Km.1,5 (SE-410) Apartado de Correos, 58 41500 Sevilla Spain
	LABORATOIRES ANIOS Pavé du moulin 59260 Lille-Hellemmes France
	LABORATOIRES ANIOS 3330 Rue de Lille 59262 Sainghin-en-Mélantois France
	LICHTENHELDT GmbH Lichtenheldt Industriestrasse 7-9 23812 Wahlstedt Germany
	Lonza GmbH Morianstr.32 42103 Wuppertal Germany
	McBride SA Polígono Industrial L'Illa C / Ramon Esteve, 20- 22 08650 Sallent Spain
	Multifill BV Constructieweg 25-A 3641 SB Mijdrecht 3641 Mijdrecht Netherlands
	NOPA NORDISK PARFUMERIVARE Nordisk Parfumerivarefabrik A/S Hvedevej 2-22 DK-8900 Randers Denmark
	PAL INTERNATIONAL LTD Pal International Ltd. Sandhurst Street, Oadby Leicester Leicester United Kingdom
	Planol GmbH Maybachstr. 17 63456 Hanau Germany
	Plum A/S Frederik Plums Vej 2 DK 5610 Assens Denmark
	PRODUCTOS LC LA CORBERANA, S.L. Ctra. Corbera – Polinyá 46612 Valencia Spain
THE PROTON GROUP LTD Ripley Drive, Normanton Industrial Estate WF6 1QT Wakefield United Kingdom	
QUIMICAS MORALES, S.L. Misiones, 11 - Urb. El Sebadal 05005 LAS PALMAS DE GRAN CANARIA Spain	
RNM PRODUCTOS QUIMICOSRNM - Produtos Quimicos, Lda Rua da Fabrica, 123 4765-080 Segade Portugal	
ROQUETTE & BARENTZ Roquette Freres Route De La Gorgue F-62136 Lestrem France	
RUTPEN LTD MEMBURY AIRFIELD RG16 7TJ LAMBOURN United Kingdom	
SOLIMIX Solimix Montseny 17-19 Pol. Ind. Sant Pere Molanta 08799 Barcelona Spain	

Name of the manufacturer	Ecolab Europe GmbH
Address of the manufacturer	Richtistrasse 7 8304 Wallisellen Switzerland
Location of manufacturing sites	Staub & Co. – Silbermann GmbH , Industriestraße 3 D-86456 Gablingen Germany
	Stockmeier Chemie Eilenburg GmbH & Co. KG Gustav-Adolf-Ring 5 04838 Eilenburg Germany
	SYNERLOGIC BV (- IN2FOOD) Synerlogic BV afd. L.J. Costerstraat 5 6827 ARNHEM Netherlands
	Univar Ltd, Argyle House, Epsom Avenue SK9 3RN Wilmslow United Kingdom
	Univar SPA Via Caldera 21 20-153 Milano Milano Italy
	van Dam Bodegraven B.V Postbus 48 NL 2410 AA Bodegraven Netherlands
	Laboratoires Prodene Klint Rue Denis Papin, 2 Z.I. Mitry Compans F-77290 Mitry Mory F-77290 Mitry Mory France
	Simagec Z.I. de Rousset / Peynier, 54 Avenue de la Plaine 13790 Rousset France
	INNOVATE GmbH, Innovate GmbH Am Hohen Stein 11 06618 Naumburg Germany

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

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Evonik Degussa Antwerpen NV
Address of the manufacturer	Tijsmanstunnel West 2040 Antwerpen Belgium
Location of manufacturing sites	Tijsmanstunnel West 2040 Antwerpen Belgium

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Evonik Degussa GmbH
Address of the manufacturer	Untere Kanalstr. 3 79618 Rheinfelden Germany
Location of manufacturing sites	Untere Kanalstr. 3 79618 Rheinfelden Germany

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Evonik Peroxid GmbH
Address of the manufacturer	Industriestraße 1 9721 Weißenstein Austria
Location of manufacturing sites	Industriestraße 1 9721 Weißenstein Austria

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Evonik Peroxide Netherlands BV
Address of the manufacturer	Oosterhorn 14 9936 HD Farmsum Netherlands
Location of manufacturing sites	Oosterhorn 14 9936 HD Farmsum Netherlands

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Belinka Perkemija D.O.O
Address of the manufacturer	Zasavska cesta 95 1231 Ljubljana-Črnuče Slovenia
Location of manufacturing sites	Zasavska cesta 95 1231 Ljubljana-Črnuče Slovenia

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Solvay Chemie SA
Address of the manufacturer	Rue Solvay 39 B-5190 Jemeppe-sur-Sambre Belgium
Location of manufacturing sites	Rue Solvay 39 B-5190 Jemeppe-sur-Sambre Belgium

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Solvay Chimica Italia S.p.A
Address of the manufacturer	Via Piave 6 I-57013 Rosignano Solvay LI Italy
Location of manufacturing sites	Via Piave 6 I-57013 Rosignano Solvay LI Italy

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Solvay Chemicals GmbH
Address of the manufacturer	Köthensche Strasse 1-3 D-06406 Bernburg Germany
Location of manufacturing sites	Köthensche Strasse 1-3 D-06406 Bernburg Germany

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Solvay Interlox Limited
Address of the manufacturer	Baronet Road WA4 6HB Warrington Cheshire United Kingdom
Location of manufacturing sites	Baronet Road WA4 6HB Warrington Cheshire United Kingdom

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Solvay Chemicals Finland OY
Address of the manufacturer	Yrjonojantie 2 45910 Voikkaa Finland
Location of manufacturing sites	Yrjonojantie 2 45910 Voikkaa Finland

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Solvay Interlox Produtos Peroxidados SA
Address of the manufacturer	Rua Eng. Clement Dumoulin P-2625-106 Povoá de Santa Iria Portugal
Location of manufacturing sites	Rua Eng. Clement Dumoulin P-2625-106 Povoá de Santa Iria Portugal

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Kemira Rotterdam BV
Address of the manufacturer	Moezelweg 151 3198 LS Europoort Rotterdam Netherlands
Location of manufacturing sites	Moezelweg 151 3198 LS Europoort Rotterdam Netherlands

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Kemira Chemical Oy
Address of the manufacturer	Typpitie PL 171 90101 Oulu Finland
Location of manufacturing sites	Typpitie PL 171 90101 Oulu Finland

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Kemira Kemi AB
Address of the manufacturer	Industrigatan 83 25109 Helsingborg Sweden
Location of manufacturing sites	Industrigatan 83 25109 Helsingborg Sweden

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	ARKEMA France – USINE DE JARRIE
Address of the manufacturer	Route National 85, BP 1 38560 JARRIE France
Location of manufacturing sites	Route National 85, BP 1 38560 JARRIE France

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	ARKEMA GMBH – NIEDERLASSUNG LEUNA
Address of the manufacturer	Am Haupttor, Bau 2410 06237 LEUNA Germany
Location of manufacturing sites	Am Haupttor, Bau 2410 06237 LEUNA Germany

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Ecolab Europe GmbH
Address of the manufacturer	Ecolab-Allee 1 40789 Monheim am Rhein Germany
Location of manufacturing sites	Ecolab-Allee 1 40789 Monheim am Rhein Germany

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 (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,4
N-propanol	Propan-1-ol	Non-active substance	71-23-8	200-746-9	0
Citric acid monohydrate	2-hydroxypropane -1,2,3-tricarboxylic acid	Non-active substance	5949-29-1	201-069-1	0,9
Phenoxyethanol	2-Phenoxyethanol	Non-active substance	122-99-6	204-589-7	0,9
Sodium lauryl Sulphate	Sodium dodecyl sulphate	Non-active substance	151-21-3	205-788-1	3,88
L-Glutamic acid, N-coco acyl derivs., monosodium salts	Sodium;(4S)-4-amino-5-hydroxy-5-oxopentanoate	Non-active substance	68187-32-6	269-087-2	2
Sulfuric acid, mono-C12-14-alkyl esters, ammonium salts (Texapon ALS)	Sulfuric acid, mono-C12-14-alkyl esters, ammonium salts	Non-active substance	90583-11-2	292-209-0	1,12
Phosphoric acid	Orthophosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Nitric acid	Nitric acid	Non-active substance	7697-37-2	231-714-2	0
Alcohol EO phosphate ester	Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, mono-C8-10-alkyl ethers, phosphates	Non-active substance	68130-47-2		0
Alkylpolyglycoside C8-C10	(3R,4S,5S,6R)-2-decoxy-6-(hydroxymethyl)oxane-3,4,5-triol	Non-active substance	68515-73-1	500-220-1	0
Alcohols, C10-C16 ethoxylated propoxylated (Dehydol 980)	Alcohols, C10-C16 ethoxylated propoxylated	Non-active substance	69227-22-1		0
Capryleth-9 Carboxylic acid (mixture of alkyl ether carboxylic acid)	Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)- (4-11 EO)	Non-active substance	53563-70-5		0

Hexeth-4 Carboxylic Acid (mixture of alkyl ether carboxylic acid)	Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(hexyloxy)- (3 EO)	Non-active substance	105391-15-9	0
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2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

May be corrosive to metals.
Causes serious eye irritation.

Precautionary statements

Keep only in original packaging.
Wash hands thoroughly after handling.
Wear eye protection.
Wear face protection.
Absorb spillage to prevent material damage.
Store in a corrosion-resistant container with a resistant inner liner.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical attention.
If eye irritation persists: Get medical advice.

4. Authorised use(s)

4.1 Use description

Use 1 - Teat dips for pre-milking disinfection

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

-

Scientific name: Bacteria

Target organism(s) (including development stage)

Common name: Bacteria
Development stage:

Scientific name: Yeasts
Common name: Yeasts
Development stage:

Field(s) of use

Indoor

Application method(s)

Method: Manual dipping using a dip/foam cup (pre-milking disinfection)
Detailed description:
Pre-milking teat disinfection by manual dipping using a dip/foam cup.

Contact time for dipping at 30°C in clean conditions:
- 60 seconds for bacteria and yeasts.

Application rate(s) and frequencies

Application Rate: Application rate: 4 mL of product per application (i.e. 1 mL per teat therefore 4 mL product for animals with four teats)
Dilution (%): RTU product
Number and timing of application:
Application frequency: up to twice per day

Category(ies) of users

Professional

Pack sizes and packaging material

Light precluding HDPE Jugs, 1-100L
Light precluding HDPE Jerry can, 1-100L
Light precluding HDPE IBC, 600-1000L
Light precluding HDPE Drum, 60-220L
Light precluding HDPE Bottle, 0,1-5L

Light precluding HDPE; PE Pouch, 0,5-100L

4.1.1 Use-specific instructions for use

See general directions for use of meta SPC 4.

4.1.2 Use-specific risk mitigation measures

See general directions for use of meta SPC 4.

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 of meta SPC 4.

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

See general directions for use of meta SPC 4.

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 of meta SPC 4.

5. General directions for use

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions. The product should be applied pre-milking by use of a dipping/foam cup. The product must be brought to room temperature before use.
Clean teat with a dry wipe, fill foam cup with product and press foam cup until foam is generated. Dip teat into the cup. Apply foam for 60 seconds on the teat. Wipe the product away with a clean towel. Do not rinse after use.

5.2. Risk mitigation measures

Avoid splashes and spills.
Avoid hand to eye transfer.

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

FIRST AID MEASURES

In case of eye contact: Rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

In case of skin contact: Rinse with plenty of water.

If swallowed: Rinse mouth. Seek medical attention if symptoms occur.

If inhaled: Seek medical attention if symptoms occur.

ENVIRONMENTAL EMERGENCY MEASURES

Do not allow contact with soil, surface or ground water.

Consider the provision of containment around storage vessels.

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

Product : Where possible, recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with national regulations. Dispose of waste in an approved waste disposal facility.

Contaminated packaging : Dispose of container in accordance with national regulations.

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

Keep out of reach of children. Keep container tightly closed. Store in suitable, labelled containers.

Storage temperature: 0-25°C

Shelf life: 18 months

6. Other information

The product contains hydrogen peroxide (CAS No.: 7722-84-1), for which a European reference value of 1.25 mg/m³ for the professional user was agreed and used for the risk assessment of the product.