



2025/534

25.3.2025

**COMMISSION IMPLEMENTING REGULATION (EU) 2025/534
of 21 March 2025**

**amending Implementing Regulation (EU) 2022/1226 as regards administrative changes to the Union
authorisation for the single biocidal product 'Bioquell HPV-AQ'**

(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 50(2) thereof,

Whereas:

- (1) On 14 July 2022, Commission Implementing Regulation (EU) 2022/1226 ⁽²⁾ granted a Union authorisation, under number EU-0027469-0000, to Ecolab Deutschland GmbH for the making available on the market and use of the single biocidal product 'Bioquell HPV-AQ'. The Annex to that Implementing Regulation provides the summary of product characteristics ('SPC') for that single biocidal product.
- (2) On 24 January 2023 and 24 April 2024, Ecolab Deutschland GmbH submitted to the European Chemicals Agency ('the Agency'), in accordance with Article 11(1) of Commission Implementing Regulation (EU) No 354/2013 ⁽³⁾, notifications of administrative changes to the Union authorisation for the single biocidal product 'Bioquell HPV-AQ', recorded in the register for biocidal products under case numbers BC-EE084020-66 and BC-VW094451-98. The notified proposed changes concern the addition of active substance manufacturers and formulators of biocidal products, a change of the manufacturer name from 'Ecolab SNC' to 'Ecolab Europe GmbH' to align with other Ecolab biocidal product authorisations and the addition of one packaging size within the packaging range assessed during the evaluation.
- (3) On 10 March 2023 and 20 May 2024 ⁽⁴⁾, the Agency submitted to the Commission in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013, opinions on the notified administrative changes to the Union authorisation for the single biocidal product 'Bioquell HPV-AQ'. In the opinions, the Agency concludes that the proposed changes are administrative changes as referred to in Article 50(3), point (a), of Regulation (EU) No 528/2012 and as specified in Title 1, Section 1, of the Annex to Implementing Regulation (EU) No 354/2013, and that after the implementation of the changes, the conditions of Article 19 of Regulation (EU) No 528/2012 will still be met.
- (4) On 29 April 2024, the Agency transmitted to the Commission the revised summary of the biocidal product characteristics of the Union authorisation for the single biocidal product 'Bioquell HPV-AQ' in all official languages of the Union, covering all administrative changes applied for, in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.
- (5) The Commission concurs with the opinions of the Agency and therefore considers it appropriate to amend the Union authorisation for the single biocidal product 'Bioquell HPV-AQ' to introduce the administrative changes requested by Ecolab Deutschland GmbH.
- (6) Except for the amendments regarding the administrative changes, all other information included in the summary of the biocidal product characteristics of 'Bioquell HPV-AQ' as set out in the Annex to Implementing Regulation (EU) 2022/1226 remains unchanged.

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

⁽²⁾ Commission Implementing Regulation (EU) 2022/1226 of 14 July 2022 granting a Union authorisation for the single biocidal product 'Bioquell HPV-AQ' (OJ L 189, 18.7.2022, p. 3, ELI: http://data.europa.eu/eli/reg_impl/2022/1226/oj).

⁽³⁾ 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).

⁽⁴⁾ ECHA Opinion No UAD-C-1650176-34-00/F and UAD-C-1732722-38-00/F of 10/03/2023 and 20/05/2024 on the administrative change of the Union authorisation of the single biocidal product 'Bioquell HPV-AQ', <https://echa.europa.eu/opinions-on-applications-for-union-authorisation>.

- (7) In order to enhance clarity and to ease the access of users and interested parties to the consolidated version of the summary of the biocidal product characteristics which is to be published by the Agency, the Annex to Implementing Regulation (EU) 2022/1226 should be replaced in its entirety. Due to a change in the format used for the generation of the summary of biocidal product characteristics in the register for biocidal products in 2024, the summary of biocidal product characteristics in that Annex, should also include some minor editorial and layout changes.
- (8) Implementing Regulation (EU) 2022/1226 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2022/1226 is replaced by the text set out in the Annex to this Regulation.

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, 21 March 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Bioquell HPV-AQ

Product type(s)

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

PT03: Veterinary hygiene

PT04: Food and feed area

Authorisation number: EU-0027469-0000**R4BP asset number:** EU-0027469-0000**1. ADMINISTRATIVE INFORMATION****1.1. Trade name(s) of the product**

Trade name(s)	Bioquell HPV-AQ
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Ecolab Deutschland GmbH
	Address	Ecolab Allee 1 40789 Monheim am Rhein DE
Authorisation number	EU-0027469-0000	
R4BP asset number	EU-0027469-0000	
Date of the authorisation	7 August 2022	
Expiry date of the authorisation	31 July 2032	

1.3. Manufacturer(s) of the product

Name of manufacturer	Ecolab Europe GmbH
Address of manufacturer	Richtistrasse 7 8304 Wallisellen Switzerland
Location of manufacturing sites	Ecolab Europe GmbH site 1 153 Quai de Rancy, Bonneuil-sur-Marne 94380 Paris France Ecolab Europe GmbH site 2 53 Royce Close SP10 3TS Andover United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 3 Unit E4, Eastway Business Park, Ballysimon Road V94 K267 Limerick Ireland Ecolab Europe GmbH site 4 A.F.P. GmbH Otto-Brenner-Straße 16 21337 Lüneburg Germany

	Ecolab Europe GmbH site 5 ACIDEKA S.A. Edificio FERIA. Capuchinos de Basurto 6, 4a planta 48013 Bilbao. Bizkaia Spain Ecolab Europe GmbH site 6 ADIEGO HNOS CTRA DE VALENCIA, KM 5,900 50410 CUARTE DE HUERVA (ZARAGOZA) 50410 Zaragoza Spain Ecolab Europe GmbH site 7 ALLIED PRODUCTS Allied Hygiene Unit 11, Belvedere Industrial Estate Fishers Way DA17 6BS Belvedere, Kent United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 8 Arkema GmbH Morschheimer Strasse 19 D-67292 Krichheimbolanden Germany Ecolab Europe GmbH site 9 AZELIS DENMARK Lundtoftegårdsvej 95 2800 Kgs. 2800 Kgs Lyngby Denmark Ecolab Europe GmbH site 10 Belinka Zasavska Cesta 95 1001 Ljubljana Slovenia Ecolab Europe GmbH site 11 BENTUS LABORATORIES LTD. RUSSIA, 105005, MOSCOW, RADIO STREET, 24 BLD.1 105005 Moscow Russian Federation (the) Ecolab Europe GmbH site 12 BIO PRODUCTIONS 72 VICTORIA ROAD, VICTORIA INDUSTRIAL ESTATE, BURGESS HILL, WEST SUSSEX RH15 9LH Burgess Hill United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 13 BIOXAL SA Route des Varennes - Secteur A – BP 30072 71103 Chalon sur Saône Cedex France Ecolab Europe GmbH site 14 Bores Srl Via Pioppa, 179 44020 Pontegradella Italy Ecolab Europe GmbH site 15 BRENNTAG ARDENNES Route de Tournes CD n 2 FR-08090 FR-08090 Cliron France Ecolab Europe GmbH site 16 BRENNTAG CEE - GUNTRAMSDORF Brenntag CEE GmbH Mixing / Blending Bahnstr. 13 A-2353 Guntramsdorf Austria Ecolab Europe GmbH site 17 BRENNTAG Duisburg/Glauchau/Hamburg/Heilbronn Brenntag GmbH Humboldttring 15 45472 Muehlheim Germany Ecolab Europe GmbH site 18 BRENNTAG Kaiserslautern Brenntag Merkurstr. 47 67663 Kaiserslautern Germany Ecolab Europe GmbH site 19 BRENNTAG Kleinkarlbach/Lohfelden Brenntag GmbH Humboldttring 15 45472 Muehlheim Germany
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	Ecolab Europe GmbH site 20 BRENNTAG Nordic - HASLEV Høsten Teglværksvej 47 4690 Haslev Denmark Ecolab Europe GmbH site 21 Brenntag Nordic, Strandgade 35 7100 Vejle Denmark Ecolab Europe GmbH site 22 BRENNTAG Normandy Brenntag Normandie 12 Sente des Jumelles - BP 11 76710 76710 Montville France Ecolab Europe GmbH site 23 BRENNTAG PL -Zgierz ul. Kwasowa 5 95-100 Zgierz Poland Ecolab Europe GmbH site 24 Brenntag Quimica S.A. - Madrid. Calle Gutemberg n° 22, Poligono Industrial El Lomo 28906 Madrid Spain Ecolab Europe GmbH site 25 BRENNTAG Schweizerhall Brenntag Schweizerhall AG Elsaesserstr. 231 CH-4056 Basel Switzerland Ecolab Europe GmbH site 26 Budich International GmbH Dieselstrasse 10 32120 Hiddenhouse Germany Ecolab Europe GmbH site 27 Caldic Deutschland Chemie B.V Caldic Deutschland GmbH & Co.Kg Am Karlshof 10 D 40231 Duesseldorf Germany Ecolab Europe GmbH site 28 Carbon Chemicals Group Ltd, Ringaskiddy P43 R772 County Cork Ireland Ecolab Europe GmbH site 29 COLEP BAD SCHMIEDEBERG ColepCCL Bad Schmiedeberg GmbH Kemberger Str. 3 06905 Bad Schmiedeberg Germany Ecolab Europe GmbH site 30 COMERCIAL FARMACEUTICA CASTEL: LANA, S.A. "COFARCAS" Condado de Treviño, 46 P.I. Villalonquejar 09080 – BURGOS 09080 Burgos Spain Ecolab Europe GmbH site 31 COMERCIAL GODO França, 13 08700 – IGUALADA (BARCELONA) 08700 BARCELONA Spain Ecolab Europe GmbH site 32 COURTOIS SARL ZA SOUS LE BEER Route de Pacy 27730 BUEIL France Ecolab Europe GmbH site 33 DAN MOR (DR WIPE) DAN-MOR Natural Products and Chemicals Ltd. Or Akiva Industrial Zone 30600 Akiva Industrial Zone Israel Ecolab Europe GmbH site 34 Denteck BV Heliumstraat 8 2718 SL ZOETERMEER Netherlands (the)
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	Ecolab Europe GmbH site 35 DETERGENTS BURGUERA DETERGENTS BURGUERA, S.L. Joan Ballester 50 07630 CAMPOS (ILLES BALEARES) Spain Ecolab Europe GmbH site 36 ECL Biebesheim NLC Biebesheim Justus-von-Liebig- Straße 11 64584 Biebesheim am Rhein Germany Ecolab Europe GmbH site 37 ECL Celra NALCO - Celra C/ Tramuntana s/n Poligona Industrial Celra 17460 Girona Spain Ecolab Europe GmbH site 38 ECL Châlons AVENUE DU GENERAL PATTON 51000 CHALONS EN CHAMPAGNE France Ecolab Europe GmbH site 39 ECL Cisterna Nalco Italiana Manufacturing Srl.Via Ninfina II 04012 Cisterna di Latina Italy Ecolab Europe GmbH site 40 ECL Fawley NLC Fawley Cadland Road, Hythe, SO45 3NP Southampton, Hampshire United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 41 ECL Leeds ECOLAB Lotherton Way Garforth Leeds LS25 2JY LS25 2JY Leeds United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 42 ECL Mandra 25TH KM OLD NATIONAL ROAD OF ATHENS TO THIVA, GR 19600 GR 19600 ATHENS Greece Ecolab Europe GmbH site 43 ECL Maribor Vajngerlova 4, SI-2001 Maribor SI-2001 Maribor Slovenia Ecolab Europe GmbH site 44 ECL MICROTEK BV MICROTEK MEDICAL B.V. GESINKKAMPSTRAAT 19, 7051 HR, VARSSEVELD 7051 HR VARSSEVELD Netherlands (the) Ecolab Europe GmbH site 45 ECL MICROTEK MOSTA SORBONNE CENTRE, F20 MOSTA TECHNOPARK, MOSTA MST 3000 MOSTA Malta Ecolab Europe GmbH site 46 ECL Nieuwegein BRUGWAL 11 A, 3432 NZ NIEUWEGEIN 3432 NZ NIEUWEGEIN Netherlands (the) Ecolab Europe GmbH site 47 ECL Rovigo Esoform Esoform S.p.A. Laboratorio Chimico Farmaceutico Viale del Lavoro 10 45100 Rovigo Italy Ecolab Europe GmbH site 48 ECL Rozzano Via A. Grandi, 20089 Rozzano MI 20089 Rozzano Italy
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	Ecolab Europe GmbH site 49 ECL Tesjoki NLC Tesjoki Kivikummuntie 1, Tesjoki 07955 Tesjoki Finland Ecolab Europe GmbH site 50 ECL Tessenderlo INDUSTRIEZONE RAVENSHOUT 4 3980 Tessenderlo Belgium Ecolab Europe GmbH site 51 ECL Weavergate NLC Weavergate Northwich, Cheshire West and Chester CW8 4EE Northwich United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 52 Ecolab Ltd Baglan/Swindon, Plot 7a Baglan Energy Park, Baglan, Port Talbot SA11 2HZ Port Talbot United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 53 EXTRUPLAST ZI Fief du Passage 56 rue Robert Geffré 17000 La Rochelle France Ecolab Europe GmbH site 54 Ferdinand Eimermacher GmbH & Co. KG Westring 24 48356 Nordwalde Germany Ecolab Europe GmbH site 55 F.E.L.T. BP 64 10 rue du Vertuquet 59531 NEUVILLE EN FERRAIN France Ecolab Europe GmbH site 56 Gallows Green Services Ltd. Cod Beck Mill Industrial Estate Dalton Lane YO7 3HR Thirsk North Yorkshire United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 57 GERDISA GERMAN RGUEZ DROGAS IND Gerdisa Polígono Industrial Miralcampo parc.37 19200 Azuqueca de Henares Guadalajara Spain Ecolab Europe GmbH site 58 GIRASOL NATURAL PRODUCTS BV De Veldoven 12-14 3342 GR Hendrik-Ido-Ambacht 3342 GR Hendrik-Ido- Ambacht Netherlands (the) Ecolab Europe GmbH site 59 HENKEL ENGELS Henkel Engels 41 3116 Engels Prospekt StroiTel ei Russia 41 3116 Engels Russian Federation (the) Ecolab Europe GmbH site 60 Imeco GmbH & Co. KG Boschstraße 5 D-63768 Hösbach Germany Ecolab Europe GmbH site 61 INTERFILL LLC-TOSNO INTERFILL LLC 187000, Moskovskoye shosse 1 187000 Tosno - Leningradskaya Russian Federation (the) Ecolab Europe GmbH site 62 JODEL - PRODUCTOS QUIMICOS Jodel Zona Industrial 2050 Aveiras de Cima 2050 Aveiras de Cima Portugal
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	Ecolab Europe GmbH site 63 Kleinmann GmbH Am Trieb 13 72820 Sonnenbühl Germany Ecolab Europe GmbH site 64 Kompak Nederland B.V. Ambachtsweg 4, 4854 MK, Bavel Netherlands (the) Ecolab Europe GmbH site 65 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 Ecolab Europe GmbH site 66 LABORATOIRES ANIOS Pavé du moulin 59260 Lille- Hellemmes France Ecolab Europe GmbH site 67 LABORATOIRES ANIOS 3330 Rue de Lille 59262 Sainghin-en-Mélantois France Ecolab Europe GmbH site 68 LICHTENHELDT GmbH Lichtenheldt Industriestrasse 7-9 23812 Wahlstedt Germany Ecolab Europe GmbH site 69 Lonza GmbH Morianstr.32 42103 Wuppertal Germany Ecolab Europe GmbH site 70 McBride SA Polígono Industrial L'illa C / Ramon Esteve, 20- 22 08650 Sallent Spain Ecolab Europe GmbH site 71 Multifill BV Constructieweg 25-A 3641 SB Mijdrecht 3641 Mijdrecht Netherlands (the) Ecolab Europe GmbH site 72 NOPA NORDISK PARFUMERIVARE Nordisk Parfumerivarefabrik A/S Hvedevej 2-22 DK-8900 Randers Denmark Ecolab Europe GmbH site 73 PAL INTERNATIONAL LTD Pal International Ltd. Sandhurst Street, Oadby Leicester Leicester United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 74 Planol GmbH Maybachstr. 17 63456 Hanau Germany Ecolab Europe GmbH site 75 Plum A/S Frederik Plums Vej 2 DK 5610 Assens Denmark Ecolab Europe GmbH site 76 PRODUCTOS LC LA CORBERANA, S.L. Crta. Corbera – Polinyá 46612 Valencia Spain Ecolab Europe GmbH site 77 THE PROTON GROUP LTD Ripley Drive, Normanton Industrial Estate WF6 1QT Wakefield United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 78 QUIMICAS MORALES, S.L. Misiones, 11 - Urb. El Sebadal 05005 LAS PALMAS DE GRAN CANARIA Spain
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	Ecolab Europe GmbH site 79 RNM PRODUCTOS QUIMICOS RNM - Produtos Quimicos, Lda Rua da Fabrica, 123, 4765-080 Segade Portugal Ecolab Europe GmbH site 80 ROQUETTE & BARENTZ Roquette Freres Route De La Gorgue F-62136 Lestrem France Ecolab Europe GmbH site 81 RUTPEN LTD MEMBURY AIRFIELD RG16 7TJ LAMBOURN United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 82 SOLIMIX Solimix Montseny 17-19 Pol. Ind. Sant Pere Molanta 08799 Barcelona Spain Ecolab Europe GmbH site 83 Staub & Co. – Silbermann GmbH , Industriestraße 3 D-86456 Gablingen Germany Ecolab Europe GmbH site 84 Stockmeier Chemie Eilenburg GmbH & Co. KG Gustav-Adolf-Ring 5 04838 Eilenburg Germany Ecolab Europe GmbH site 85 SYNERLOGIC BV (- IN2FOOD) Synerlogic BV afd. L.J. Costerstraat 5 6827 ARNHEM Netherlands (the) Ecolab Europe GmbH site 86 Univar Ltd, Argyle House, Epsom Avenue SK9 3RN Wilmslow United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 87 Univar SPA Via Caldera 21 20-153 Milano Milano Italy Ecolab Europe GmbH site 88 van Dam Bodegraven B.V Postbus 48 NL 2410 AA Bodegraven Netherlands (the) Ecolab Europe GmbH site 89 Laboratoires Prodene Klint Rue Denis Papin, 2 Z.I. Mitry Compans F-77290 Mitry Mory F-77290 Mitry Mory France Ecolab Europe GmbH site 90 Simagec Z.I. de Rousset / Peynier, 54 Avenue de la Plaine 13790 Rousset France Ecolab Europe GmbH site 91 INNOVATE GmbH, Innovate GmbH Am Hohen Stein 11 06618 Naumburg Germany Ecolab Europe GmbH site 92 Sima Pharma, 54 Avenue de la Plaine, ZI 13106 Rousset Cedex France Ecolab Europe GmbH site 93 Techtex (Technical Textile Services Ltd) Units 7 & 8, Rhodes Business Park, Silburn Way, Middleton, M24 4NE Manchester United Kingdom of Great Britain and Northern Ireland (the)
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	Ecolab Europe GmbH site 94 Helico B.V. Hoogschaijksestraat 31 5374 EC Schaijk Netherlands (the) Ecolab Europe GmbH site 95 INCARE BV Keizersveld 99 5803 AP Venray Netherlands (the) Ecolab Europe GmbH site 96 ECL Mullingar Ecolab Ltd (IE). Forrest Park Zone C Mullingar Industrial Estate Mullingar Co. Westmeath Westmeath Ireland Ecolab Europe GmbH site 97 ECL Mullingar. Ecolab Manufacturing IE Ltd (IE) Forest Park, Zone C Mullingar Ind. Estate N91 Mullingar, Co. Westmeath Westmeath Ireland Ecolab Europe GmbH site 98 ECL Weavergate Site: Nalco Manufacturing Limited, Winnington Avenue, CW8 3AA Northwich, Cheshire (Postal Address: PO Box 11, Winnington Avenue, Northwich, Cheshire CW8 4DX) United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 99 ECL Weavergate, Ecolab Ltd (UK) Winnington Avenue CW8 3AA Northwich, Cheshire United Kingdom of Great Britain and Northern Ireland (the) Ecolab Europe GmbH site 100 ECL Weavergate, Ecolab Manufacturing UK Ltd (UK) Winnington Avenue CW8 3AA Northwich, Cheshire United Kingdom of Great Britain and Northern Ireland (the)
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1.4. Manufacturer(s) of the active substance(s)

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Peroxide Spain
Address of manufacturer	Beethoven 15, Sobreatico 08021 Barcelona Spain
Location of manufacturing sites	Evonik Peroxide Spain site 1 C/ Afueras s/n La Zaida 50784 Zaragoza Spain

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Operations GmbH (Acting for Evonik Active Oxygens, LLC (US))
Address of manufacturer	Creavis, Rellinghauser Straße 1-11 45128 Essen Germany
Location of manufacturing sites	Evonik Operations GmbH (Acting for Evonik Active Oxygens, LLC (US)) site 1 12000 Bay Area Blvd 77507 Pasadena, TX United States (the)

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Peroxid GmbH
Address of manufacturer	Industriestrasse 1 A-9721 Weissenstein Austria
Location of manufacturing sites	Evonik Peroxid GmbH Industriestrasse 1 A-9721 Weissenstein Austria

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Operations GmbH
Address of manufacturer	Creavis, Rellinghauser Straße 1-11 45128 Essen Germany
Location of manufacturing sites	Evonik Operations GmbH site 1 Untere Kanatstrabe 3 79618 Rheinfelden Germany

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 (%)
Hydrogen peroxide		active substance	7722-84-1	231-765-0	35 % (w/w)

2.2. Type(s) of formulation

HN Hot fogging concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H272: May intensify fire; oxidiser. H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P220: Keep away from clothing or other combustible materials. P261: Avoid breathing vapours. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection. P301+P312: IF SWALLOWED: Call a Poison Center or doctor/physician if you feel unwell. P330: Rinse mouth. P302+P352: IF ON SKIN: Wash with plenty of water. P332+P313: If skin irritation occurs: Get medical attention.

	P362+P364: Take off contaminated clothing and wash it before reuse. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. 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 CENTER or doctor/physician.. P312: Call a POISON CENTER/doctor if you feel unwell. P370+P378: In case of fire: Use water to extinguish. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents to waste in accordance with applicable local, national and international regulations.
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4. AUTHORISED USE(S)

4.1. Use description

Table 1

Surface disinfection in small (0,25 m³ - 4 m³) enclosures

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT03: Veterinary hygiene PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: bacteria spores Development stage: no data Scientific name: no data Common name: Mycobacteria Development stage: no data Scientific name: no data Common name: fungi Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: Viruses Development stage: no data Scientific name: no data Common name: bacteriophage Development stage: no data

Field(s) of use	indoor use Hard, non-porous surfaces in small (0,25 m ³ to 4 m ³) sealed enclosures by vapourisation, with prior cleaning. PT2 – clean conditions in, for example, isolators, pass-through chambers, cabinets, material airlocks, cupboards, filling lines, emergency vehicles. PT3 – pre-cleaned animal cages/racks within biomedical and animal laboratory facilities PT4 – clean conditions in, for example, aseptic filling lines, storage containers.
Application method(s)	Method: vapourisation Detailed description: Vapourisation with Bioquell Hydrogen Peroxide Vapour system followed by microcondensation – to deliver the disinfectant to surfaces in closed systems. Temperature range: room temperature Humidity range: 10 % - 80 %
Application rate(s) and frequency	Application rate: 100 g/m ³ of undiluted product, contact time of 35 minutes (after diffusion). 0 Number and timing of application: Users should carry out decontaminations in line with their requirements and operating procedures
Category(ies) of users	professional
Pack sizes and packaging material	75 ml, 150 ml, 500 ml, 950 ml, 1 000 ml, 2 000 ml, 5 000 ml, 20 L, and 25 L. Bottles are constructed of HDPE

4.1.1. Use-specific instructions

See general directions for use.

4.1.2. Use-specific risk mitigation measures

See general 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 general directions for use.

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

Only recycle completely emptied packaging. Dispose of any residual product in accordance with EWC 160903

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

Protect from frost. Do not store at temperatures above 35 °C

Shelf life 18 months.

4.2. Use description

Table 2

Surface disinfection within large (> 4 m³) enclosures

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals PT03: Veterinary hygiene PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Mycobacteria Development stage: no data Scientific name: no data Common name: Bacteria spores Development stage: no data Scientific name: no data Common name: fungi Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: Viruses Development stage: no data Scientific name: no data Common name: bacteriophages Development stage: no data
Field(s) of use	indoor use Hard, non-porous surfaces in large (> 4 m³) sealed enclosures by vapourisation, with prior cleaning. PT2 – clean conditions in, for example hospitals, clean rooms, aseptic processing facilities, laboratories, nursing homes, research facilities, schools, cruise ships, emergency vehicles, veterinary hospitals (excluding animal housing), laboratories in veterinary institutions PT3 – pre-cleaned animal cages/racks within biomedical and animal laboratory facilities. PT4 – clean conditions in, for example, aseptic filling lines, food production facilities, storage containers
Application method(s)	Method: vapourisation Detailed description: Vapourisation with Bioquell Hydrogen Peroxide Vapour system followed by micro condensation – to deliver the disinfectant to surfaces in closed systems. Temperature range: Room temperature Humidity range: 10 % - 80 %

Application rate(s) and frequency	Application rate: 10g/m ³ of undiluted product, contact time of 35 minutes (after diffusion) 0 Number and timing of application: Users should carry out decontaminations in line with their requirements and operating procedures.
Category(ies) of users	professional
Pack sizes and packaging material	75 ml, 150 ml, 500 ml, 950 ml, 1 000 ml, 2 000 ml, 5 000 ml, 20 L, and 25 L. Bottles are constructed of HDPE.

4.2.1. *Use-specific instructions*

See general directions for use

4.2.2. *Use-specific risk mitigation measures*

See general directions for use

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*

Only recycle completely emptied packaging. Dispose of any residual product in accordance with EWC 160903

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

Protect from frost. Do not store at temperatures above 35 °C. Shelf life 18 months.

5. **GENERAL DIRECTIONS FOR USE** ⁽¹⁾

5.1. **Instructions for use**

Surfaces must be pre-cleaned and dry before disinfection and cupboard doors and drawers should be opened for the process to be effective.

Users should carry out decontaminations in line with their requirements and operating procedures.

For disinfection of pre-cleaned animal cages/racks within biomedical and animal laboratory facilities, disinfection can only take place on thoroughly cleaned non-porous surfaces (PT3), when possible use automated washing machines.

Do not mix with detergents or other chemicals. Undiluted.

Bioquell HPV-AQ is to be used with a Bioquell vaporisation module as a disinfectant for surfaces and other inanimate objects in enclosures.

Seal the enclosure (e.g. with tape) to ensure no leakage of the vapourised active substance outside the enclosure prior to initiating a cycle.

Refer to the Bioquell HPV-AQ Labelling insert prior to running a cycle.

At the end of the dwell period, the aeration phase is activated which removes the hydrogen peroxide. The aeration phase is deactivated by the user when the enclosure has been confirmed to be less than or equal to 1,25 mg/m³ (0,9 ppm) using an independent calibrated low-level hydrogen peroxide sensor.

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

Biological validation should be performed for enclosures to be disinfected. Where environmental conditions within an enclosure are well controlled, a protocol for disinfection of the enclosure should be made and used thereafter. Validated quantitative chemical indicators can be used in place of biological indicators for routine disinfection.

Biological or chemical indicators shall be placed in the enclosure to validate the cycle.

Users should not carry out manual cleaning operations (for example sweeping) immediately post-decontamination.

5.2. Risk mitigation measures

No person or animals are allowed to be present in a room during treatment.

Treated areas may not be entered until the concentration of hydrogen peroxide is $\leq 0,9$ ppm ($1,25\text{mg}/\text{m}^3$).

The professional user may only enter the room in emergency situations when the hydrogen peroxide level has dropped below 36 ppm ($50\text{ mg}/\text{m}^3$) considering RPE with APF 40 (Type of RPE to be specified by the authorisation holder within the product information) and suitable protective equipment (gloves, eye protection, coverall) must be worn.

Use a calibrated sensor to confirm the enclosure is $\leq 0,9$ ppm ($1,25\text{ mg}/\text{m}^3$) prior to re-entry.

When opening the container and preparing contents wear suitable personal protective equipment (gloves, eye protection, coverall).

Wash hands after use.

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

Possible exposure effects:

Skin – chemical burn – transient, non-permanent whitening of the skin

Eyes – potential for permanent damage

Inhalation - irritation of the throat and nose

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.

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: 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.

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 (sink, toilets ...) nor 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**

Protect from Frost. Do not store at temperatures above 35 °C.

Shelf life 18 months.

6. **OTHER INFORMATION**

Bioquell HPV-AQ is not intended for use as a terminal sterilant / disinfectant for medical devices.
