European Chemicals Agency

Opinion on the administrative change of the Union authorisation of the biocidal product: **Bioquell HPV-AQ**

Opinion N° UAD-C-1650176-34-00/F

10 March 2023

Opinion of the European Chemicals Agency

on administrative changes of the Union authorisation of biocidal product Bioquell HPV-AQ

In accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013 of the European Commission 18 May 2013 on changes of biocidal products authorised in accordance with Biocidal Product Regulation (EU) No 528/2012 (BPR), the European Chemicals Agency (ECHA) has prepared this opinion on the administrative changes to the Union authorisation of:

Name of the biocidal product: Bioquell HPV-AQ

Authorisation holder: Ecolab Deutschland GmbH

Target asset number: EU-0027469-0000

Active substance common name: Hydrogen peroxide

Product types: PT 2, 3 and 4

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on **24 January 2023**, and recorded in R4BP 3 under case number **BC-EE084020-66**.

Following its acceptance by ECHA, the evaluation of the notification was initiated on **8 March 2023**.

The evaluation included a check that the proposed changes of an existing authorisation are of a purely administrative nature involving no change to the properties or efficacy of the biocidal product in accordance with Article 3(1)aa of the BPR.

The scope of the assessment itself was based on and limited to the information provided by the authorisation holder in the supporting document for the notification for an administrative change of a Union or simplified authorisation under Regulation (EU) No 354/2013 supplied via R4BP 3.

ECHA prepared this opinion containing the conclusions of its assessment.

2. Detailed opinion and background

2.1. ECHA opinion

During the evaluation, ECHA has assessed whether the changes made in the SPC document provided by the applicant are administrative changes in accordance with Implementing Regulation (EU) No 354/2013.

It is ECHA's opinion that the following changes to the biocidal product sought by the authorisation holder are changes falling under Article 3(1)(aa) of the BPR, and, after the implementation of the changes, the conditions of Article 19 of the BPR will still be met:

- Title 1, section **1** of the Annex to the Regulation (EU) No 354/2013 - *Manufacturer(s) of the active substance(s)* - change N°5: *Addition of a manufacturer of the active substance or change in the manufacturer's identity or in manufacturing location or process, where the technical equivalence between the substances from the two manufacturers, manufacturing locations and processes has been established by the Agency in accordance with Article 54 of Regulation (EU) No 528/2012, and the manufacturer or importer is listed in accordance with Article 95(2) of Regulation (EU) No 528/2012*

- Title 1, section **2** of the Annex to the Regulation (EU) No 354/2013 - *Formulator(s) of the biocidal product* - change N°2: *Change in the name, the administrative details or the formulating location of the biocidal product formulator, where the biocidal product composition and the formulating process remain unchanged.*

- Title 1, section **2** of the Annex to the Regulation (EU) No 354/2013 - *Formulator(s) of the biocidal product* - change N°4: *Addition of a formulator of the biocidal product, where the biocidal product composition and the formulating process remain unchanged.*

Accordingly, it is proposed that the Commission amends the existing authorisation with the below listed administrative changes to the biocidal product sought by the authorisation holder.

2.2. ECHA assessment

2.2.1. Description of the changes as proposed by the authorisation holder

Changes as described by the authorisation holder in their supporting document supplied via R4BP 3.

Identification	**Description**
1.	Addition of Evonik Operations GmbH (Acting for Evonik Active Oxygens LLC) as a supplier of the active substance. Evonik Operations GmbH, Evonik Active Oxygens LLC and Evonik Peroxide Spain are all operational divisions of Evonik Industries. This administrative change is to add the Evonik manufacturing location in Bayport, Texas as a back-up supply source, as a risk mitigation measure, in case of the unlikely event the Spanish plant is unable to supply (i.e. catastrophic accident). Both Evonik manufacturing locations would supply the Durox LRA grade of hydrogen peroxide used in Bioquell HPV-AQ. Evonik Active Oxygens LLC (United States) was previously called PeroxyChem LLC (United States) and was a reference source for the hydrogen peroxide active substance. The address of the Evonik Active Oxygens LLC (United States) manufacturing location is 12000 Bay Area Blvd, Pasadena, Texas, 77507, USA.
2.	Change of manufacturer name from "Ecolab SNC" to "Ecolab Europe GmbH". This change is an administrative change to align the name of the manufacturer with other Ecolab BPR authorisations.

3.	Addition of Ecolab manufacturing locations to align the list of possible manufacturing sites with other Ecolab BPR authorisations (for example EU-0024303-0001). The primary manufacturing sites for Bioquell HPV-AQ will remain 153 Quai de Rancy, Bonneuil-sur-Marne, France and 53 Royce Close, Andover, UK. The sites to be added are: A.F.P. GmbH Otto-Brenner-Straße 1621337 Lüneburg Germany ACIDEKA S.A. Edificio Feria. Capuchinos de Basurto 6, 4a planta 4801 3Bilbao. 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 Srtrasse 19D-67292 Krichheimbolanden Germany AZELIS DENMARK Lundtoftegårdsvej 95 2800 Kgs.2800 KgsLyngby Denmark Belinka Zasavska Cesta 951001 Ljubljana Slovenia BENTUS LABORATORIES LTD. RUSSIA, 105005, MOSCOW, RADIO STREET, 24 BLD.1105005 Moscow Russian Federation BIO PRODUCTIONS 72 VICTORIA ROAD, VICTORIA INDUSTRIAL ESTATE, BURGESS HILL, WEST SUSSEX RH15 9LH Burgess Hill United Kingdom BIOXAL SA Route des Varennes - Secteur A – BP 3007271103 Chalon sur Saône Cedex France Bores Srl Via Pioppa, 17944020 Pontegradella Italy BRENNTAG ARDENNES Route de Tournes CD n 2 FR-08090FR-08090 Cliron France BRENNTAG CEE - GUNTRAMSDORF Brenntag CEE GmbH Mixing / Blending Bahnstr. 13A-2353 Guntramsdorf Austria BRENNTAG Duisburg/Glauchau/Hamburg/Heilbronn Brenntag GmbH Humboldtring 1545472 Muehlheim Germany BRENNTAG Kaiserslautern Brenntag Merkurstr. 4767663 Kaiserslautern Germany BRENNTAG Kleinkarlbach/Lohfelden Brenntag GmbH Humboldtring 1545472 Muehlheim Germany BRENNTAG Nordic - HASLEV Høsten Teglværksvej 474690 Haslev Denmark Brenntag Nordic, Strandgade 357100 Vejle Denmark BRENNTAG Normandy Brenntag Normandie 12 Sente des Jumelles - BP 11 7671076710 Montville France BRENNTAG PL -Zgierz ul. Kwasowa 595-100 Zgierz Poland Brenntag Quimica S.A. - Madrid. Calle Gutemberg nº 22,.Poligono Industrial El Lomo 28906 Madrid Spain BRENNTAG Schweizerhall Brenntag Schweizerhall AG Elsaesserstr. 231CH-4056 Basel Switzerland Budich International GmbH Dieselstrasse 1032120 Hiddenhause Germany Caldic Deutschland Chemie B.V Caldic Deutschland GmbH & Co.Kg Am Karlshof 10 D40231 Duesseldorf Germany Carbon Chemicals Group Ltd, Ringaskiddy P43 R772 County Cork Ireland COLEP BAD SCHMIEDEBERG ColepCCL Bad Schmiedeberg

	GmbH Kemberger Str. 306905 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 82718 SLZOETERMEER Netherlands DETERGENTS BURGUERA DETERGENTS BURGUERA, S.L. Joan Ballester 50 07630 CAMPOS (ILLES BALEARES) Spain ECL Biebesheim NLC Biebesheim Justus-von-Liebig-Straße 1164584 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 II04012 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 Leeds United Kingdom ECL Mandra 25TH KM OLD NATIONAL ROAD OF ATHENS TO THIVA, GR 19600GR 19600 ATHENS Greece ECL Maribor Vajngerlova 4, SI-2001 Maribor SI-2001 Maribor Slovenia ECL MICROTEK BV MICROTEK MEDICAL B.V. GESINKKAMPSTRAAT 19, 7051 HR, VARSSEVELD 7051 HRVARSSEVELD Netherlands ECL MICROTEK MOSTA SORBONNE CENTRE, F20 MOSTA TECHNOPARK, MOSTA MST 3000 MOSTA Malta ECL Nieuwegein BRUGWAL 11 A, 3432 NZ NIEUWEGEIN 3432 NZ NIEUWEGEIN Netherlands ECL Rovigo Esoform Esoform S.p.A. Laboratorio Chimico Farmaceutico Viale del Lavoro 1045100 Rovigo Italy ECL Rozzano Via A. Grandi, 20089 Rozzano MI20089 Rozzano Italy ECL Tesjoki NLC Tesjoki Kivikummuntie 1, Tesjoki 07955 Tesjoki Finland ECL Tessenderlo INDUSTRIEZONE RAVENSHOUT 43980 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 2448356 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.3719200 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 Stroi Tel ei Russia 413116 Engels Russian Federation Imeco GmbH & Co. KG Boschstraße 5D-63768 Hösbach Germany INTERFILL LLC-TOSNO INTERFILL LLC 187000, Moskovskoye shosse 1187000 Tosno – Leningradskaya Russian Federation JODEL - PRODUCTOS QUIMICOS Jodel Zona Industrial 2050 Aveiras de Cima 2050 Aveiras de Cima Portugal Kleinmann GmbH Am Trieb 1372820 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, 5841500 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 7-923812 Wahlstedt Germany Lonza GmbH Morianstr. 3242103 Wuppertal Germany McBride SA Polígon Industrial L'Illa C / Ramon Esteve, 20-2208650 Sallent Spain Multifill BV Constructieweg 25-A 3641 SB Mijdrecht 3641 Mijdrecht Netherlands NOPA NORDISK PARFUMERIVARE Nordisk Parfumerivarefabrik A/S Hvedevej 2-22DK-8900 Randers Denmark PAL INTERNATIONAL LTD Pal International Ltd. Sandhurst Street, Oadby Leicester Leicester United Kingdom Planol GmbH Maybachstr. 1763456 Hanau Germany Plum A/S Frederik Plums Vej 2DK 5610 Assens Denmark PRODUCTOS LC LA CORBERANA, S.L. Crta. 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 Sebadal05005LAS PALMAS DE GRAN CANARIA Spain RNM PRODUCTOS QUIMICOS RNM - Produtos Quimicos, Lda Rua da Fabrica, 1234765-080 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 Staub & Co. – Silbermann GmbH , Industriestraße 3D-86456 Gablingen Germany Stockmeier Chemie Eilenburg GmbH & Co. KG Gustav-

	Adolf-Ring 504838 Eilenburg Germany SYNERLOGIC BV (- IN2FOOD) Synerlogic BV afd. L.J. Costerstraat 56827 ARNHEM Netherlands Univar Ltd, Argyle House, Epsom Avenue SK9 3RN Wilmslow United Kingdom Univar SPA Via Caldera 2120-153 Milano Milano Italy van Dam Bodegraven B.V Postbus 48NL 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 1106618 Naumburg Germany Sima Pharma, 54 Avenue de la Plaine, ZI13106 Rousset Cedex France Techtex (Technical Textile Services Ltd) Units 7 & 8, Rhodes Business Park, Silburn Way, Middleton, M24 4NE Manchester United Kingdom Helico B.V. Hoogschaijksestraat 315374 EC Schaijk Netherlands INCARE BV Keizersveld 995803 AP Venray Netherlands ECL Mullingar Ecolab Ltd (IE). Forrest Park Zone C Mullingar Industrial Estate Mullingar Co.Westmeath Westmeath Ireland ECL Mullingar. Ecolab Manufacturing IE Ltd (IE) Forest Park, Zone C Mullingar Ind. Estate N91 Mullingar, Co.Westmeath Westmeath Ireland 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 ECL Weavergate, Ecolab Ltd (UK) Winnington Avenue CW8 3AA Northwich, Cheshire United Kingdom ECL Weavergate, Ecolab Manufacturing UK Ltd (UK) Winnington Avenue CW8 3AA Northwich, Cheshire United Kingdom

2.2.2. Assessment of the changes as proposed by the authorisation holder

The assessment of the changes sought by the authorisation holder is presented in the following table:

Identification	Corresponding reference in the Annex to Regulation (EU) No 354/2013	Evaluation	Result of the evaluation	Comments
1.	Title 1, section 1, change n° 5	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification

2.	Title 1, section 2, change n° 2	The new manufacturer of the active substance is a reference source	Acceptable	
3.	Title 1, section 2, change n° 4	The requested change matches the description in the Regulation	Acceptable	

o0o

Annex

Draft Summary of Product Characteristics