

Helsinki, 21 January 2019

Enviolyte Industries International LtdRävala pst 8-C603
EE-10143 Tallinn*Sent via R4BP 3***DECISION ON INCLUSION IN THE LIST OF ACTIVE SUBSTANCES AND SUPPLIERS
(Article 95 list) UNDER ARTICLE 95(1) REGULATION (EU) No 528/2012****Decision number: ACC-D-1363339-51-00/F**
Case number: BC-WN048302-26
Asset number: EU-0020088-0000

Dear Sir or Madam,

The European Chemicals Agency (ECHA), in accordance with Article 95 of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (Biocidal Products Regulation), as amended by Regulation (EU) No 334/2014¹, has assessed your submission for the purposes of inclusion on the list of active substances and suppliers (the Article 95 list) for:

Active substance: Active chlorine released from hypochlorous acid (Redefined from Active Chlorine: manufactured by the reaction of hypochlorous acid and sodium hypochlorite produced in situ), EC No: Not allocated, CAS No: Not allocated**Product types (PT): PT 1 (Human hygiene), PT 2 (Disinfectants and algacides not intended for direct application to humans or animals), PT 3 (Veterinary hygiene), PT 4 (Food and feed area), PT 5 (Drinking water)****Applicant: Enviolyte Industries International Ltd****Role: Substance supplier and Product supplier**

To support inclusion on the Article 95 list, on 02/01/2019 Enviolyte Industries International Ltd submitted a Letter of Access ("LoA") to a complete substance dossier in relation to a relevant substance, as per the second subparagraph of Article 95(1) of the Biocidal Products Regulation. The assessment of compliance with Article 95(1) of the Biocidal Products Regulation was initiated on 10/01/2019 once the fee was paid.

The draft decision was sent on 11/01/2019 by ECHA for commenting within 1 month.

On 14/01/2019, the Applicant responded that they did not have any comments to the draft decision.

¹ Article 95 of the Biocidal Products Regulation has been amended by Article 1, point 24, of Regulation (EU) No 334/2014. According to Article 2 of Regulation (EU) No 334/2014, the amendments to Article 95 apply retroactively from 1 September 2013.

In accordance with Article 95(1) of that Regulation, ECHA has taken the decision set out herein.

1. Result of the assessment

The outcome of this assessment is that the application for inclusion in the Article 95 list is **approved**.

2. Consequences of this decision

In accordance with Article 95(1) of the Biocidal Products Regulation, this decision **supports** the inclusion of Envirolyte Industries International Ltd in the active substances and suppliers list (Article 95 list) published on ECHA's website. The Article 95 list is updated regularly.

The active substance Active chlorine released from hypochlorous acid in product-type PT 1 is a new active substance which has not yet been approved. Products containing it may not be made available on the market or used until the active substance is approved and the relevant biocidal products are authorised, in accordance with Article 17(1) of the Biocidal Products Regulation. This contrasts to existing active substances in the review programme, where the active substance and biocidal product may be made available on the market and used during the transitional period, in accordance with Article 89 of the Biocidal Products Regulation.

In addition, Article 95(2) provides that as of 1 September 2015, a biocidal product consisting of, containing or generating a relevant substance, included in the Article 95 list, shall not be made available on the market unless either the substance supplier or the product supplier is included in this list for the product-type(s) to which the product belongs.

Accordingly, the obligation for a supplier to be included on the Article 95 list for a relevant substance which is a new active substance only applies as from the time the active substance is approved for the relevant product-type and product authorisations are granted.

For further information please see *Guidance on active substance suppliers* available at https://echa.europa.eu/documents/10162/23036412/biocides_guidance_active_substance_suppliers_en.pdf and *Guidance on information requirements* available at <https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>, Part A, Volume I-IV.

3. Information on legal remedies

In accordance with Article 263 of the Treaty on the Functioning of the European Union, you **may lodge an application for the annulment** of this decision with the General Court of the European Union. The procedure for lodging an application for annulment is described at <http://curia.europa.eu>.

Yours faithfully,

(e-signed)

Hugues Kenigswald
Head of Unit Biocidal Products²

² As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.