Helsinki, 1 June 2018

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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-1296386-37-00/F
Case number: BC-QM037256-26
Asset number: EU-0018516-0000

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 334/2014[1], has assessed your submission for the purposes of inclusion on the list of active substances and suppliers (the Article 95 list) for:

Active substance:	**D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine(2:1) (CHDG), EC No: 242-354-0, CAS No: 18472-51-0**
Product types (PT):	**PT 1 (Human hygiene), PT 2 (Disinfectants and algaecides not intended for direct application to humans or animals), PT 3 (Veterinary hygiene)**
Applicant:	**RN EUROPE** (Acting for RN LABORATORIES PVT LTD (India))
Role:	**Substance supplier and Product supplier**

[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.

To support inclusion on the Article 95 list, on 25/01/2018 RN EUROPE 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 31/01/2018 once the fee was paid.

The draft decision was sent on 23/03/2018 by ECHA for commenting within 1 month. An amended LoA was submitted by the applicant on 29/03/2018. This second LoA was unclear as regards the scope of the studies concerned and the contact details of the grantee. Thereafter, a further version of the LoA was submitted on 23/05/2018. This LoA was found to be compliant with Article 61 of the BPR.

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 RN EUROPE (Acting for RN LABORATORIES PVT LTD (India)) in the active substances and suppliers list (Article 95 list) published on ECHA's website. The Article 95 list is updated regularly.

As specified in Article 95(2), 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**.**

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 Biocides Assessment[2]

[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.