

Helsinki, 12/03/2021

Applicant
REACH COMPLIANCE SERVICES LIMITED
[Acting for Bath Concept Cosmetics (DongGuan) Co., Ltd. (China)]
Paramount Court, Corrig Road, Sandyford
Dublin 18
Ireland

Copy to: Case Owner Bath Concept Cosmetics (DongGuan) Co., Ltd. No.20 Dushang North Road, WanJiang District 523052 Dongguan City, GuangDong China

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-1499555-32-00/F

Case number: BC-TQ064968-93

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<sup>1</sup>, has assessed your submission for the purposes of inclusion on the list of active substances and suppliers (the Article 95 list) for:

Active substance: Ethanol, EC No: 200-578-6, CAS No: 64-17-5

Product types (PT): PT 1 (Human hygiene), PT 2 (Disinfectants and algaecides not

intended for direct application to humans or animals), PT 4

(Food and feed area)

Annex I, Category 6: No

Role: Substance supplier, Product supplier

To support inclusion on the Article 95 list, on 01/03/2021 you 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 07/03/2021 once the fee was paid.

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

<sup>&</sup>lt;sup>1</sup> 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.



## 1. Result of the assessment

The outcome of this assessment is that your 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 your inclusion 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.

Under the Biocidal Products Regulation, additional regulatory obligations also apply before a biocidal product can be made available on the market and used.

## 3. Additional information

Additional information/data on the active substance may be required in other processes, e.g. at the product authorisation stage.

Furthermore, note that when an active substance/PT combination is approved and eventually renewed, all Article 95 suppliers who are not the renewal applicants will need to submit a LoA to the relevant renewal data within 12 months of the AS/PT renewal in order to comply with Article 95(7) of the BPR. A failure to do so means removal from the Article 95 list. For further details, please refer to the relevant CA document<sup>2</sup>.

## 4. 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 <a href="http://curia.europa.eu">http://curia.europa.eu</a>.

Yours faithfully,

(e-signed)<sup>3</sup>

DAMSTEN Micaela Article 95 Process Coordinator Biocidal Active Substances

<sup>&</sup>lt;sup>2</sup> CA-Sept20-Doc.7.1.b - Relevant Renewal Data under Article 95\_FINAL

<sup>&</sup>lt;sup>3</sup> As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.