

29 May 2018

GALEN-N LTD.

23 Tvardishki prohod Str., Sofia, Bulgaria 1404, Sofia Bulgaria

Submission date: **23 May 2018** Submission number: **PL473406-22** Decision number: **SUB-D-2114423132-67-01/F** EC number: **289-995-2**

DECISION ON YOUR REGISTRATION

Based on Article 20(2) of Regulation (EC) No 1907/2006 ('REACH'),

Your registration for the substance with EC number **289-995-2** is complete. This registration entitles you to manufacture/import the substance, or produce or import an article containing it.¹

Your registration covers:

• the tonnage band between 10 and 100 tonnes/year

The registration number is: **01-2120746582-51-0068**

The registration date is: 11 May 2018

Further observations

In accordance with Article 20(2) of REACH, the completeness check ascertains that all the elements required have been provided. However, this check does not include an assessment of the quality or adequacy of data provided. Such an assessment may occur later in a compliance check.

Also the verification of the eligibility for any claimed fee reductions (for example such resulting from the declared company size) is not part of the completeness check, but it may follow at any time in accordance with Article 13(3) of Fee Regulation (EC) No 340/2008.

In accordance with Article 22(1) of REACH, registrants are on their own initiative required to update their registrations without undue delay with relevant new information (for instance, change in status, substance composition or quantities).

Certain information from this registration dossier will be published without further notice at <u>https://echa.europa.eu/information-on-chemicals</u>.

Note to registrants in the United Kingdom: The UK has notified its intention to leave the EU. As this decision on your registration only applies within the framework of the EU REACH legislation, your registration risks becoming non-existent once the UK withdrawal from the EU takes effect. ECHA advises you to regularly consult its webpages on the UK's withdrawal at <u>https://echa.europa.eu/uk-withdrawal-from-the-eu</u>. There you will find updated information on the validity of registrations by UK registrants, and on any action that you may need to take to maintain access to the EU market.



Should you have any questions please contact ECHA via the contact form at <u>https://echa.europa.eu/contact</u>.

Mercedes Viñas Head of Unit C1 – Dossier Submission and PIC Directorate of Registration +358 9 68618116 mercedes.vinas@echa.europa.eu