



FPS Health, Food Chain Safety and Environment  
General Direction Environment  
EUROSTATION ? BLOC II, Victor Hortaplein 40 bus 15, B - 1060 Brussels

Department of Product Policy and Chemical Substances  
Biocides Service

Your letter from:

Your reference:

Our reference Date: MRB/ /2019 /22469/

Annexe(s): 1

STERIS IRELAND LIMITED  
IDA Business and Technology Park  
0  
IE - R35X865 Tullamore

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E-Mail : Info.biocides@health.fgov.be

**Concerns: Prolongation of the existing national registration during the evaluation of the Union authorization application**

Dear Sir, Madam,

You have been granted a Belgian national registration to place on the Belgian market the following biocidal product:

**Spor-Klenz Ready to Use ETO Process Packaged Cold Sterilant  
Registration number BE-REG-00007**

In view of the pending Union Authorization application submitted to the European Chemical Agency and according to the transitional measures as laid out in article 89, §2 of the Biocidal Product Regulation (EU) No 528/2012 we can provide you with a prolongation of making your product available on the Belgian market until 3 years after the date of approval of the last active substances to be approved in this given biocidal product.

**Your product may remain on the Belgian market**, under the same conditions as those mentioned in the Belgian registration BE-REG-00007, and **at the latest until 01/10/2020**.

This letter is the **official notification of the new date of validity** of the mentioned Belgian registration.

The biocidal product concerned will continue to be included in the list of the registered biocidal products, which can be found at [www.biocide.be](http://www.biocide.be).

In addition, in accordance with the Royal decree of 13 November 2011 laying down the charges and contributions to be paid to the Budgetary fund of raw materials and products, as modified, the already granted registration is amended as per annex I to this letter. This letter is the sole official proof of the previously mentioned amendment and extended validity of the existing registration.

This letter remains **valid until the Union Authorization** is granted and will terminate on 01/10/2020 at the latest. The granted Union Authorization will provide a period of grace to continue to market the biocidal product concerned with the current registration (180 days for the making available on the Belgian market and an additional maximum period of 180 days). If the Commission shall adopt an implementing decision stating that the Union Authorization



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has not been granted, the biocidal product concerned will no longer be made available on the market 180 days after the implementing regulation has been adopted. The use of existing stocks remains authorized until a maximum of 365 days after the date of adoption of the Commission decision.

Best regards,

FOR THE MINISTER OF ENVIRONMENT

Head of the biocides service  
L. Louis



**Annex I to the letter referenced: MRB//2019/22469 for the product  
Spor-Klenz Ready to Use ETO Process Packaged Cold Sterilant**

If the existing registration is composed in Dutch, the paragraph "Score van het product" shall be amended and read as follows:

"Overeenkomstig de bepalingen in artikel 7, § 1 en 2 van het KB van 13/11/2011 tot vaststelling van de retributies en bijdragen verschuldigd aan het Begrotingsfonds voor de grondstoffen en de producten, werd de volgende score toegekend aan het biocide voor de berekeningen van de jaarlijkse bijdrage: 3,0"

If the existing registration is composed in French, the paragraph "Score du produit" shall be amended and read as follows:

"Conformément aux dispositions de l'article 7, §1 et 2 de l'AR du 13/11/2011 fixant les rétributions et cotisations dues au Fonds budgétaire des matières premières et des produits, le score suivant a été attribué au produit biocide en vue des calculs de la cotisation annuelle : 3,0"

FOR THE MINISTER OF ENVIRONMENT,

Celhoofd cel biociden - Chef de cellule de la cellule biocides  
Lucrèce Louis

02/08/2019 16:08:44