LE GOUVERNEMENT DU GRAND-DUCHÉ DE LUXEMBOURG Ministère du Développement durable et des Infrastructures

Administration de l'environnement

Roam Technology NV c/o Mr. Dennis Lecis Geleenlaan 24 B-3600 Genk

votre réf.: notre réf.: 279-281/16/L dossier suivi par: Jeff Zigrand / Guy Schmit

Notification of placing on the market of the biocidal products

1	Huwa-San TR-3	279/16/L
2	Huwa-San TR-5	280/16/L
3	Huwa-San TR-50	281/16/L

Dear Mr. Lecis,

I herewith acknowledge receipt of your notifications of 29th September 2016 concerning the placing on the market of the above-mentioned biocidal products during the transitional period.

Since the biocidal active substance contained in the products N° 1 - 3 (Hydrogen peroxide, CAS: 7722-84-1, date of approval : 01/02/2017¹) was notified under the review program for evaluation under product-types 2, 3 and 4, I can agree to the placing on the market of the products N° 1 - 3 for use in product-type 2 (Disinfectants and algaecides not intended for direct application to humans or animals), for use in product-type 3 (Veterinary hygiene) and for use in product-type 4 (Food and feed area) in accordance with the conditions laid down by article 89(2) of the Regulation (EU) no 528/2012² and article 4 of the law of 4 September 2015 on biocidal products³.

Please note that Article 69 of Regulation (EU) 1272/2008 on classification, labelling and packaging is applicable to all biocidal products notified during the transitional period. In Luxembourg the "official languages" referred to by the Regulation (EU) no 528/2012 are the French and German language. Consequently, the labelling of biocidal products must be in German or French.

Furthermore, the information submitted during the notification of a biocidal product must, if applicable, be kept up to date by the person responsible for the placing on the market by additional submissions of updated information. The present agreement may be withdrawn in accordance with article 5 of the law of 4 September 2015 on biocidal products.

RE:

¹ COMMISSION IMPLEMENTING REGULATION (EU) 2015/1730 of 28 September 2015 approving hydrogen peroxide as an existing active substance for use in biocidal products for product-types 1, 2, 3, 4, 5 and 6.

² Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

³ Loi du 4 septembre 2015 a) concernant certaines modalités d'application et les sanctions du règlement (UE) n° 528/2012 du Parlement européen et du Conseil du 22 mai 2012 concernant la mise à disposition sur le marché et l'utilisation des produits biocides; b) relative à l'enregistrement de fabricants et de vendeurs; c) abrogeant la loi modifiée du 24 décembre 2002 relative aux produits biocides.

Consequently, the commercialization of the products N° 1 - 3 is admitted up to the 01/02/2017, the date of approval of the active substance for product-types 2, 3 and 4 as per COMMISSION IMPLEMENTING REGULATION (EU) 2015/1730.

Please note that in accordance with article 89(3) of the Regulation (EU) no 528/2012, an application for authorization for each of the above-mentioned products shall be submitted at the aforementioned date of approval, preferably through the procedure of mutual recognition in parallel.

In absence of an application for product authorization by the aforementioned date of approval, the placing on the market and selling-out of the products shall be discontinued within the time periods specified in the 3rd paragraph of article 89(3), or in the 2nd paragraph of article 89(2) of the Regulation (EU) no 528/2012 respectively.

As of 1 September 2015, a biocidal product shall not be made available on the European market if the manufacturer or importer of the active substance(s) contained in the product, or, where relevant, the importer of the biocidal product, is not included in the list established in accordance with article 95 of the Regulation (EU) no 528/2012.

Finally, in accordance with article 73 of the Regulation (EU) no 528/2012, article 45 of Regulation (EC) 1272/2008⁴ is applicable to all products covered by the Regulation (EU) no 528/2012. The implementation of the aforementioned article 45 in Luxembourg falls within the remit of the Ministry of Health. The latter has commissioned the execution of the tasks arising from article 45 to the Belgian *Centre Antipoisons de Bruxelles* by a convention. Consequently, we call upon the persons responsible for the placing on the market to declare the pertinent information to the poison center before the making available on the market accordingly to the instructions attached in the annex. Callers from Luxembourg can reach the Belgian poison center 24 hours a day, 7 days a week, by telephone at the following number (+352) 8002 5500. This number should also normally appear under Section 1.4 of "Emergency telephone number" of the product's safety data sheet.

Yours respectfully,

On behalf of the Minister of Environment,

Joëlle Welfring Deputy Director

This decision may be subject to appeal at the administrative court. The appeal period is 40 days from the notification of the decision. The appeal must be made by application signed by a lawyer (registered in List I of the Bar Council)

Annex: Information on how to declare information to the national poison center.

⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006