Reckitt Benckiser (Belgium) SA/NV
Allée de la Recherche 20 Researchdreef
1070 Bruxelles/Brussel
Phone : +32 (0)2 526 18 11

Friday, May 12, 2023

To the attention of: Reckitt Benckiser (Belgium) SA/NV Distributors

Subject: REACH Regulation and the Product Safety Data Sheet requirement

Sir, Madam,

We want to provide you with the best possible support to ensure your full awareness on our products, in particular their safe use. Therefore, we would like to share with you the different regulations related to the safety of our products for each of their classifications.

The REACH regulation no 1907/2006 article 31 defines the requirements for Safety Data Sheet to be provided by the supplier and article 2 defines the application.

- For a **medicine**, the REACH regulation no 1907/2006 article 2 paragraph 6 applies. It stipulates that the provisions of Title IV (Article 31 included) shall not apply to the following preparations in the finished state, intended for the final user (a) *medicinal products for human* as defined in Regulation (EC) No 726/2004, Directive 2001/83/EC on the Community code relating to medicinal products for human use, as of article 2 paragraph 6 of the regulation no 1907/2006.
  In other words, medicines are outside of the scope for safety data sheet.
  Medicines have an authorization prior to launch on a market, all the precautions are available to the end-user in the leaflet of the medicines and also on the authorities websites.

- For a **medical device**, the REACH regulation no 1907/2006 article 2 paragraph 6 applies. It stipulates that the provisions of Title IV (Article 31 included) shall not apply to the following preparations in the finished state, intended for the final user *(c) medical devices* which are invasive or used in direct physical contact with the human body as defined in Directive 1999/45/EEC. All the precautions are indicated on the label according to the Medical Device Directive 93/42/EEC and/or the Medical Device Regulation 2017/745/EEC.
  In other words, medical devices which are invasive or used in direct physical contact with the human body are outside of the scope for safety data sheet.
  Medical devices may require a notified body certification prior to launch on a market and all the precautions are available on the label of the medical device to the end-user.

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- For a **cosmetic product,** the REACH regulation no 1907/2006 article 2 paragraph 6 applies. It indicates that the provisions of Title IV (Article 31 included) shall not apply to the following preparations in the finished state, intended for the final user *(b) cosmetic products as* defined in Directive 76/768/EEC, and the Cosmetic Regulation 1223/2009. All the precautions of use are indicated on the label according to article 19 of the Cosmetic Regulation 1223/2009.
  In other words, cosmetic products are outside of the scope for safety data sheet.
  The cosmetic products have a European notification (CPNP notification) prior to launch on a market and all the precautions of use are available on the label of the cosmetic product to the end-user.

Yours sincerely,

Chantal Tankou
Head of Regulatory Affairs France Benelux

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T +32 (0)2 526 18 11 **W** reckitt.com

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