



EUROPEAN COMMISSION
DG INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMEs

Director-General

Brussels,
GROW/D/4/RM/bl(2019)
grow.ddg1.d.4(2019)1259781

***By registered letter with
acknowledgment of receipt***

Mme Marie Toulemonde
2 Calle de los Estudios
28012 Madrid
Spain

Dear Ms Toulemonde,

Subject: Your application for access to documents – Ref GestDem 2019/0823.

We refer to your e-mail dated 12/02/2019 in which you make a request for access to documents, registered on the same date under the above-mentioned reference number.

We regret to inform you that the Commission does not hold any documents that would correspond to the description given in your application.

According to Article 23 (Communication of serious undesirable effects) to Regulation (EC) No 1223/2009 serious undesirable effects must be reported to the competent authority of the Member State where the effect occurred. That competent authority must immediately transmit the information on the serious undesirable effect to the competent authorities of the other Member States. However, there is no provision under Regulation (EC) No 1223/2009 that would require this information to be transmitted to the European Commission.

Competent authorities may use the information referred to in Article 23 for the purposes of in-market surveillance, market analysis, evaluation and consumer information.

Under provisions of Annex I to Regulation (EC) No 1223/2009 the cosmetic product safety report must contain all available data on both undesirable and serious undesirable effects to the cosmetic product or, where relevant, other cosmetic products. This includes statistical data. The cosmetics product safety report can be made accessible by the responsible person to the competent authority of the Member State only in which the report is kept. Therefore, the European Commission does not have access to this data.

As specified in Article 2(3) of Regulation 1049/2001, the right of access as defined in that regulation applies only to existing documents in the possession of the institution.

Given that no such documents, corresponding to the description given in your application, are held by the Commission, the Commission is not in a position to fulfil your request.

In accordance with Article 7(2) of Regulation 1049/2001, you are entitled to make a confirmatory application requesting the Commission to review this position.

Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretariat-General of the Commission at the following address:

European Commission
Secretariat-General
Transparency, Document Management & Access to Documents (SG.C.1)
BERL 7/076
B-1049 Bruxelles

or by email to: sg-acc-doc@ec.europa.eu

Yours faithfully,



Lowri Evans