



20 January 2022

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[www.msd.com](http://www.msd.com)

Subject: Information Regarding the Registration, Evaluation, Authorization and Restriction of  
Chemicals (REACH)

Dear Customer:

MSD is committed to protecting the environment and complying with applicable hazardous substance regulations. To that end, MSD tracks the material content of its products and makes relevant information available to recipients and consumers.

This letter provides information regarding compliance with the European Union's ("EU") REACH Regulations (Regulation No 1907/2006), which addresses the production and use of chemical substances and their potential impacts on human health.

Regulation (EC) No 1907/2006 – REACH

Article 59 (10) of the REACH regulation require the identification of Substances of Very High Concern (SVHC) contained in articles above the 0.1% (by weight per article) threshold manufactured and marketed in the EU.

Medicinal products for human use and veterinary medicinal products are exempted from registration, notification, and communication obligations under REACH. However, packaging materials and medical device components are considered separate articles under REACH and are



not exempted. The registration and communication obligations apply for any article known to contain an SVHC Candidate List substance.

#### EU REACH Article 33 (1) Information Obligation

Article 33 (1) of the REACH regulations requires suppliers to inform the recipients if an article contains more than 0.1% (by weight per article) of any substance(s) on the Substances of Very High Concern (SVHC) Candidate List (CL).

As summarised in **Attachment 1** below, MSD has identified SVHCs present in certain articles contained within select packaging materials and medical devices components. To meet our obligations, we have registered our known articles that contain SVHCs above 0.1% threshold.

Registration involved the submission to the European Chemicals Agency (ECHA) of a technical dossier for each article. The information in this communication references the 07/2021 SVHC Candidate List released by ECHA on July 9th, 2021, containing a total of 219 chemical substances.

<https://echa.europa.eu/candidate-list-table>

The information provided is based upon data obtained from our suppliers of packaging materials and medical device components. We will continue to monitor the content of our products as part of our ongoing compliance activities and shall update this communication as needed.

Sincerely,

A handwritten signature in black ink, appearing to read "Cameron Downie".

Cameron Downie

MSD - Ethics & Compliance Organization



## Attachment 1

### List of SVHC present above 0.1% by weight in certain of MSD's products considered as articles.

SVHC = Substances of Very High Concern

Product Type	Article	Substance Name	EC No.	CAS No.	ECHA Candidate List Date of Inclusion	> 0.1 wt% in Article (Yes/No)
Packaging Component (Blister Pack)	PVC Film	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	239-622-4	15571-58-1	17-Dec-2014	Yes
Medical Device (Inhaler)	Actuator	Lead	231-100-4	439-92-1	27-Jun-2018	Yes
Medical Device (Inhaler)	Actuator	Lead monoxide (lead oxide)	215-267-0	1317-36-8	19-Dec-2012	Yes