

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

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 document provides information regarding compliance with the European Union's ("EU") REACH Regulation (Regulation No 1907/2006 in its current consolidated form), which addresses the production and use of chemical substances and their potential impacts on human health. This document uses terminology defined in REACH §3 (Definitions).

Regulation (EC) No 1907/2006 – REACH

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 January 17th, 2023, containing a total of 233 chemical substances.

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

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

Attachment 1

List of SVHC present above 0.1% by weight in certain of MSD's Human Health and Animal Health 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)
Secondary Packaging component	Label	2-Benzyl-2-(dimethylamino)-4'-mopholinobutyrophenone	404-360-3	119313-12-1	16-Jan-2020	Yes
Primary Packaging Component	Seal Stopper	6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol	204-327-1	119-47-1	17-Jan-2022	Yes
Packaging Component	PVC Film	Tris(nonylphenyl) phosphite	N/A	26523-78-4	16-Jul-2019	Yes
Packaging Component	PVC Film	Nonylphenol	N/A	25154-52-3	19-Dec-2012	Yes
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