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REACH regulatory compliance approach

Compliance with regulatory requirements is of highest importance for Cytiva and its businesses. Cytiva business units consisting of Bioprocessing, Genomic Medicine, Discovery and Medical and Biotechnology Integrated Solutions continuously monitor regulatory requirements and guidelines affecting raw materials used in the manufacture of its products or the products themselves.

In the European Economic Area (EEA) a regulation called Registration, Evaluation, Authorization and Restriction of Chemicals (REACH - EC No 1907/2006) addresses the manufacture, import, and/or use of hazardous chemical substances, and their potential impacts on human health and the environment. This regulation has wide-spread effects on industries and companies manufacturing, using or importing chemicals within the EEA. Similar regulations are in place globally.

Cytiva complies and will continue to comply with the REACH regulation through a dedicated organization that supervises the various requirements and activities within sourcing and manufacturing operations. There are programs in place to minimize the exposure of hazardous chemicals to humans and the environment on our production sites and surrounding environments. As a leading supplier, we play an active role in several industry groups and associations working on the REACH regulation. We contribute by influencing publications and advocacy activities to ensure that the socio-economic impacts of the REACH regulation on our industry are well understood and communicated to the competent authorities.

We actively monitor the Candidate list (Annex XV) of Substances of Very High Concern (SVHC) to identify SVHC used in our products or during manufacturing operations. In the rare cases when one of these SVHC is used in our manufacturing operations, we evaluate alternatives with the objective to replace the SVHC within manufacturing and to minimize the potential impact on product performance and customer operations. If the SVHC is placed on the REACH authorization list (Annex XIV) and no technically or otherwise viable alternative exists, we will pursue other available risk management options. This includes the preparation of an application for authorization for continued use of the SVHC to increase the time frame for identifying and implementing a suitable alternative.

Article 33 of the REACH regulation applies to articles (i.e., instruments) and regulates the obligation to communicate information on the presence of SVHC in articles. Cytiva articles do not intentionally release SVHC under normal conditions of use. We continuously collect information from our suppliers regarding components they supply to us and the presence of SVHC in these components in quantities greater than 0.1% (w/w).

With the merger between Cytiva and Pall, we are going through a transition to have all our SVHC data in one place.

For products previously sold by Cytiva. To the best of our knowledge and based on information received from suppliers, articles containing SVHC are listed in the ***Cytiva SVHC affected articles page.***

For products previously sold by Pall Lifesciences, please reach out via Cytivas "Contact us" portal or through sales channels to receive statements on products containing SVHC.

Our aim is to be transparent and inform our customers if SVHC used in the manufacturing of our products are subject to REACH-authorization, and if we apply to receive authorization for continued use of these SVHC. As a trusted supplier, we are committed to supporting customers with a sustainable product supply, while minimizing interruptions to the greatest extent possible.

Cytiva is committed to meet the requirements of Waste Framework Directive 2008/98/EC Article 9(1)(i) as amended by 2018/851/EU by registering articles and complex objects it places on the EEA market in the SCIP data base where necessary.

Emmanuel Ligner
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Cytiva
October 30, 2023

Ludovic Brellier
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October 30, 2023