



Subject: Notification of Pall Biotech Allegro™ Single-use Systems with component article containing an SVHC in excess of 0.1%

European REACH Regulations (EC 1907/2006), plus UK implementation statues, and amendments in respect of ECHA SVHC levels in articles and component articles supplied by Pall Biotech.

Silicone based materials are heavily used throughout the biotech industry as elastomeric seals, gaskets, and tubing. On 27th June 2018, decision ED/61/2018 was published by the European Chemicals Agency (ECHA) which added 3 cyclosiloxane compounds to the European REACH Annex XIV 'Candidate list of substances of very high concern' (SVHCs). These cyclosiloxane compounds, D4, D5 and D6 being commonly used in the production of silicone based materials.

<u>Name</u>	<u>CAS No.</u>
Octamethylcyclotetrasiloxane (D4)	556-67-2
Decamethylcyclopentasiloxane (D5)	541-02-6
Dodecamethylcyclohexasiloxane (D6)	540-97-6

Pall Allegro Single-use Systems are considered 'complex article', as provided to our customers in the European Economic Area (EEA) and United Kingdom (UK). Please be aware that Allegro Single-use Systems may employ component articles which our supplier has advised contain a silicone material with D4, D5, D6 siloxanes above the 0.1% level. Additionally, from January 5th 2021 Pall will register these articles in the ECHA SCIP database in line with the requirements of Waste Framework Directive 2008/98/EC Article 9(1)(i) as amended by 2018/851/EU.

Should you have any questions related to this statement please do not hesitate to contact RA_SUT@pall.com,

Prepared by Pall Biotech, Quality Assurance and Regulatory Affairs

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To the best of our knowledge this information is accurate as of the date of issuance. However, these statements are subject to change as new information becomes available. We recommend that you periodically confirm this information.