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11 March 2022

**Kleenpak™ Presto sterile connector containing Cyclosiloxane compounds in excess of 0.1%**

Dear Sir/ Madam,

Pall Biotech complies with provisions of Article 33 (1) of the European Union REACH Regulation No. 1907 / 2006 regarding communication of Substances of Very High Concern (SVHC) candidate listed substances in excess of 0.1% w/w, with respect to the following Cyclosiloxane compounds.

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

The following component part numbers have been identified as containing Cyclosiloxane compounds above 0.1%. Please be aware that this information is based upon statements provided by raw materials suppliers in the supply chain.

Impacted component:	Description within ECHA SCIP Database:	SCIP UUID number:
PSC1G05 PSC1G06 PSC1G07 PSC1G08 PSC1G10 PSC1G11	Kleenpak™ Presto sterile connector	2c33087c-4665-4d2a-82af-85af8a777679

For your information, Pall Biotech has performed highly sensitive extraction testing to BPOG standards on the Kleenpak Presto sterile connector and can report that the level of siloxane detected in these studies is well below the REACH limit. However, these methods are not designed to extract all of the compounds from the material, which would require complete dissolution or more aggressive solvents that do not model biotech manufacturing processes. Therefore, we have updated the ECHA SCIP database to include the above components in line with the requirements of Waste Framework Directive 2008/98/EC Article 9(1)(i) as amended by 2018/851/EU. This information will be accessible for review by users, waste operators, and the general public.

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.  
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Pall Biotech also wishes to advise you that the current REACH regulation does not impose restrictions on the industrial use of silicone-based articles which contain D4, D5, D6 siloxanes above a concentration of 0.1% w/w. The regulation merely obligates a manufacture or importer of such articles, operating within the EEA or UK, to communicate the presence of these substances above the 0.1% level to their customer(s).

I hope you will find this information satisfactory.

Yours faithfully,



Donna Drury  
Regulatory Affairs Specialist.  
Pall Biotech