



Subject: Notification of Pall Corporation's Allegro™ single-use systems with component article containing an SVHC (Substance of Very High Concern) in excess of 0.1%

Reference: 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 Corporation.

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

Name	CAS Number
Octamethylcyclotetrasiloxane (D4)	556-67-2
Decamethylcyclopentasiloxane (D5)	541-02-6
Dodecamethylcyclohexasiloxane (D6)	540-97-6

Allegro single-use systems are considered 'complex objects', as provided to our customers in the European Economic Area (EEA) and United Kingdom (UK). Please be aware that some Allegro single-use systems incorporate 'component articles' where our suppliers have advised the component contains a silicone material with one of more of D4, D5, D6 siloxanes above the 0.1% level. The identified component articles are certain brands of silicone tubing, silicone O-rings, silicone gaskets, connectors, and aseptic connectors (all non-Pall manufactured) with silicone gaskets and silicone O-rings.

As of January 5, 2021 Pall Corporation has provided entries for those Allegro single-use systems employing component articles with a REACH SVHC above 0.1% in the ECHA SCIP database – see <https://echa.europa.eu/scip>. This is in line with the requirements of Waste Framework Directive 2008/98/EC Article 9(1)(i) as amended by 2018/851/EU.

Pall Corporation has also notified Allegro customers of this action in a customer notification letter, reference number CN-RPII-BURQKN dated November 16, 2020. The customer notification letter also advised that Allegro single-use system labels would be updated to include a link to a regulatory letter (this letter). The label update action has also been completed.

For your reference; Addendum 1 to this letter contains a listing of the ECHA SCIP database entry numbers made by Pall Corporation alongside a description of the applicable component articles in the "Primary Article Identifier" field of SCIP. To check if your specific Allegro single-use system part number is covered by an entry, please consult the field marked "Other article Identifier" within the ECHA SCIP database, where the impacted Allegro single-use system part numbers (subject to that entry) have been listed. Alternatively, you can consult your Allegro single-use system drawing(s) for the component part numbers used in that system(s).

Addendum 2 to this letter contains a listing of all component part numbers which have been entered into the ECHA SCIP database. Please note that Addendum 2 is complete as of the date of this letter but is subject to continuous review as new supplier information is received or new components require additional entries into the ECHA SCIP database. We will update this letter on a periodic basis, but you should consider the ECHA SCIP database as the primary and most up-to-date source of information.

Pall Corporation wishes to advise you that the current REACH regulation does not impose restrictions on the use of silicone-based articles, containing D4, D5, D6 siloxanes, in biopharmaceutical production use. However, the REACH regulation does obligate all manufactures or importers of such articles, operating within the EEA or UK, to communicate the presence of these substances if above the 0.1% level to their customer. Pall Corporation has taken steps to notify with respect to Allegro single-use systems, in order to comply with this aspect of the REACH regulation.



Prepared by: Pall 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.

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Addendum 1:
Pall Corporation SCIP entry tracker

ECHA SCIP Record Number:	Record Primary Article Identifier (Allegro product type):
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3271af42-bb90-49fe-9617-351644359e80	Pall Customised Disposable System with Tube Assembly (Combination 12)
99d8aa49-f325-44e9-9b68-71ab52077272	Pall Customised Disposable System with Silicone Tube Type 4 (Combination 1)
63fc1786-3896-4ae2-b2d6-d99bc1a1eed2	Pall Customised Disposable System with Silicone Tube Type 4 and O Ring (Combination 1, 13)
92c0f9b2-3dd1-4654-9ec6-c1c2ab17dc76	Pall Customised Disposable System with Silicone Tube Type 4, O Ring and Silicone Tube Type 3 (Combination 1, 13, 14)
9d19e924-e3ad-4a5d-8d70-15b5e417c27b	Pall Customised Disposable System with Silicone Tube Type 4 and Silicone Tube Type 3 (Combination 1, 14)
14e84e8d-1ce1-495b-822c-09f2ecdd71db	Pall Customised Disposable System with Silicone Tube Type 4 and Sanitary Connector (Combination 1, 4)
6523e643-2d82-4131-a52d-14821cd3caeb	Pall Customised Disposable System with Silicone Tube Type 4, Sanitary Connector and O-ring (Combination 1, 4, 13)
9329560c-675a-4d8a-9c24-9ca21470bbbff	Pall Customised Disposable System with Silicone Tube Type 4, Sanitary Connector, O ring and Silicone Tube Type 3 (combination 1, 4, 13, 14)
1b1c901c-e0b0-46ab-b94a-493394c1bae3	Pall Customised Disposable System with Silicone Tube Type 4, Sanitary Connector and Silicone Tube Type 3 (Combination 1, 4, 14)
73a144b7-03a1-46a6-9835-1ce2977eef14	Pall Customised Disposable System with Silicone Tube Type 4, Sanitary Connector and Silicone Tube Type 2 (Combination 1, 4, 8)
019e7507-b041-4339-a550-7baa94c1ed60	Pall Customised Disposable System with Silicone Tube Type 4, Sanitary Connector, Silicone Tube Type 2 and Braided Tubing (Combination 1, 4, 8, 9)
935a54ba-0b11-4ca1-a880-5a1986a7f342	Pall Customised Disposable System with Silicone Tube Type 4 and Silicone Tube Type 2 (Combination 1, 8)
9192145e-8e93-42e7-b8be-aa074715820f	Pall Customised Disposable System with Silicone Tube Type 4, Silicone Tube Type 2 and O Ring (Combination 1, 8, 13)
161739c6-2f4c-4029-802f-020dbeeb1d15	Pall Customised Disposable System with Silicone Tube Type 4, Silicone Tube Type 2 and Silicone Tube Type 3 (Combination 1, 8, 14)
5317dfcb-4211-47ec-ba67-ad0c54020a86	Pall Customised Disposable System with Silicone Tube Type 4 , Silicone Tube Type 2 and Braided Tubing (Combination 1, 8, 9)
94ddaf4b-e577-4c96-83b2-fd6076bf930a	Pall Customised Disposable System with Silicone Tube Type 4 and Braided Tubing (Combination 1, 9)
7c33cb03-2642-439b-ae14-76685ba53dc8	Pall Customised Disposable System with O Ring (Combination 13)
b93ef8c1-91c9-4f9d-8ee6-a843c19c9f1c	Pall Customised Disposable System with O ring and Silicone Tube Type 3 (Combination 13, 14)
0e9c01c1-2501-469e-b49a-5cc98518e67d	Pall Customised Disposable System with Silicone Tube Type 3 (Combination 14)

330fcbff-617a-499a-afdd-c0b42383e2eb	Pall Customised Disposable System with Liner (Combination 15)
a3fb7630-1287-4955-8f48-f8c4b5729d3c	Pall Customised Disposable System with Aseptic, Quick Connector (Combination 2)
b01ed706-39ef-4258-9a64-1b2bb0ec9420	Pall Customised Disposable System with Aseptic, Quick Connector and Silicone Tube Type 2 (Combination 2, 8)
27165a7a-91e9-4183-8c60-0c4738fac76a	Pall Customised Disposable System with Aseptic, Quick Connector, Silicone Tube Type 2 and O ring (Combination 2, 8, 13)
b1ebdc6c-58e0-465c-b690-7bc20ca58681	Pall Customised Disposable System with Aseptic, Quick Connector, Silicone Tube Type 2, Braided Tubing and O ring (Combination 2, 8, 9, 13)
8869724b-706e-4f0a-b347-bcbf2e781869	Pall Customised Disposable System with Aseptic, Quick Connector and Braided Tubing (Combination 2, 9)
1e6e94b0-234c-4d7a-8cae-0ac7f3a0e5c6	Pall Customised Disposable System with Aseptic, Quick Connector, Braided Tubing and O ring (Combination 2, 9, 13)
d950d210-cd6b-453b-b5f0-f3623c996483	Pall Customised Disposable System with Sanitary Connector (Combination 4)
0e07c248-80be-4e7e-a765-bee9949051b5	Pall Customised Disposable System with Sanitary Connector and O ring (Combination 4, 13)
a1beec48-ff6b-4bdd-90ae-16f4db68eb04	Pall Customised Disposable System with Sanitary Connector and Silicone Tube Type 3 (Combination 4, 14)
501f3f64-52ca-4245-9abd-408206c7d99b	Pall Customised Disposable System with Sanitary Connector and Liner (Combination 4, 15)
fdfa1edf-b378-4f44-a7b6-1f276b6a8c5b	Pall Customised Disposable System with Sanitary Connector and Silicone Tube Type 2 (Combination 4, 8)
bf01ce9b-14de-4ed9-83aa-9cae0a407a70	Pall Customised Disposable System with Sanitary Connector, Silicone Tube Type 2 and O ring (Combination 4, 8, 13)
9a19fe22-54bb-4f06-bfae-07a689d23d0b	Pall Customised Disposable System with Sanitary Connector, Silicone Tube Type 2, O ring and Silicone Tube Type 3 (Combination 4, 8, 13, 14)
bdeb075d-9454-4561-b042-2ad8406686e8	Pall Customised Disposable System with Sanitary Connector, Silicone Tube Type 2 and Silicone Tube Type 3 (Combination 4, 8, 14)
f23b0f41-c06f-486d-8ae1-120cdd8c155d	Pall Customised Disposable System with Sanitary Connector, Silicone Tube Type 2 and Liner (Combination 4, 8, 15)
e053eac0-102c-46a8-9dcb-6860d1f604f8	Pall Customised Disposable System with Sanitary Connector, Silicone Tube Type 2 and Braided Tubing (Combination 4, 8, 9)
823b1373-eba9-46a8-8967-2741156367e3	Pall Customised Disposable System with Sanitary Connector, Silicone Tube Type 2, Braided Tubing and O ring (Combination 4, 8, 9, 13)
ac9c76e5-da3c-427d-9bb6-ddc82f2a688f	Pall Customised Disposable System with Sanitary Connector, Silicone Tube Type 2, Braided Tubing and Silicone Tube Type 3 (combination 4, 8, 9, 14)

6ed9b01b-3223-44c4-9beb-1a83153fe9e6	Pall Customised Disposable System with Sanitary Connector, Silicone Tube Type 2, Braided Tubing and Liner (Combination 4, 8, 9, 15)
0b4f97ce-82f9-4628-8431-1fc9b0ba898a	Pall Customised Disposable System with Sanitary Connector and Braided Tubing (Combination 4, 9)
0905cb38-0a4f-439c-b917-f59bca0b9b54	Pall Customised Disposable System with Sanitary Connector, Braided Tubing and O ring (Combination 4, 9, 13)
6beac1bf-ff39-4f55-84df-653f1664e616	Pall Customised Disposable System with Sanitary Connector, Braided Tubing and Liner (Combination 4, 9, 15)
2799b86b-dd18-42e0-8ce0-a01fe9d909aa	Pall Customised Disposable System with Silicone Tube Type 2 (Combination 8)
b44425a8-8131-462b-915f-ba3bf4c35c47	Pall Customised Disposable System with Silicone Tube Type 2 and Tube Assembly (Combination 8, 12)
98b9ec0b-9a55-4679-a940-065656dc2460	Pall Customised Disposable System with Silicone Tube Type 2 and O ring (Combination 8, 13)
473d8626-b107-41ce-a884-d29bd0a51019	Pall Customised Disposable System with Silicone Tube Type 2 and Silicone Tube Type 3 (Combination 8, 14)
2abb10fa-a6dd-45a1-961c-d9e02b0b29ea	Pall Customised Disposable System with Silicone Tube Type 2 and Liner (Combination 8, 15)
f6d4bcb2-d88c-4d5b-9c46-b04a20b2f86d	Pall Customised Disposable System with Silicone Tube Type 2 and Braided Tubing (Combination 8, 9)
c4851329-0f47-4548-8543-7ac3b8bda9c3	Pall Customised Disposable System with Silicone Tube Type 2, Braided Tubing and Tube Assembly (Combination 8, 9, 12)
3f37de98-134c-4896-8a4d-b8ab9161387d	Pall Customised Disposable System with Silicone Tube Type 2, Braided Tubing and O ring (combination 8, 9, 13)
49efa185-7b3a-409c-a6b4-329f914ba9a7	Pall Customised Disposable System with Silicone Tube Type 2, Braided Tubing and Silicone Tube Type 3 (Combination 8, 9, 14)
ad7d724c-9387-40d8-a4de-3ae0943eb239	Pall Customised Disposable System with Silicone Tube Type 2, Braided Tubing and Liner (Combination 8, 9, 15)
65fc3aeb-3781-40a0-aa65-4d4d08c58eb0	Pall Customised Disposable System with Braided Tubing (Combination 9)
3c7b95e3-c331-4e5e-b484-d4cec58359c3	Pall Customised Disposable System with Braided Tubing and O ring (Combination 9, 13)
a446fb9d-f9b2-43bf-840a-eaba14f418c6	Pall Customised Disposable System with Braided Tubing and Silicone Tube Type 3 (Combination 9, 14)
a13ab25f-baeb-4acd-9c35-970791695a38	Pall Customised Disposable System with Braided Tubing and Liner (Combination 9, 15)

Addendum 2:
Component part numbers listed in ECHA SCIP "Other article Identifier" (identified as containing Cyclosiloxane compounds above 0.1%)

NL03415	2100554M	FY02622	NL03496	SC00038	NL05178	SC01390	SC01102	SC01754
NL04770	SC01726	FY02193	NL04221	SC00988	NL04536	SC01375	SC00820	SC01751
NL03204	SC01712	FY02697	NL04222	SC01597	NL00259	SC01374	SC00819	SC01127
NL03203	SC01716	FY02058	NL04228	NL05187	NL03878	SC01373	SC00821	SC00822
NL03205	SC01725	FY02049	NL08214	NL04218	NL03879	SC01389	SC01877	SC01388
NL03206	FY02036	FY02065	NL04224	NL04223	NL03959	SC01391	SC00823	SC00818
NL03207	FY02038	SC01003	NL04220	NL04229	NL04699	SC01753	SC00825	701563
NL04064	FY02035	FY02089	SC00036	SC01096	NL04746	SC01752	SC00827	701562
NL03498	FY02037	FY02425	SC00037	SC01153	NL05125	SC01684	SC01017	701560
NL04817	FY02204	FY02202	SC00957	SC00811	NL04553	SC01431	SC00824	701561
NL03508	FY02205	FY02203	SC00974	SC01745	8.51E+08	SC01426	SC01126	
NL05191	FY02192	FY02910	SC00836	FY03041	SC01624	SC01371	SC01815	
SC00351	FY02034	SC00113	SC00035	FY03042	SC01663	SC01130	SC01814	
NL03833	FY02594	SC00114	SC00982	NL04701	SC01664	SC01112	SC01813	
SC00219	FY02048	SC00802	SC01011	8.51E+08	SC00826	SC01111	SC01113	