

Chemical Compatibility Guide for Polymeric Materials in Pall Components

Revision Number: 1.0
Date: March 04, 2022
Author: Paul Jourdainnaud, Alireza Shokri
Signature

A handwritten signature in black ink, appearing to read "Paul", is positioned below the "Signature" label.

Contents

1	Scope.....	3
2	Explanation of Chemical Compatibility Ranking	3
3	Disclaimer	3
4	Chemical Compatibility Tables.....	4
5	Supporting References.....	6

1 Scope

A wide range of polymer materials are used in bioprocess single-use systems. Materials used in single-use components such as filters, connectors, biocontainers (bags) and tubing must have good resistance to process fluids to avoid the risk of component degradation, swelling, and functionality loss. End users must also ensure that interaction of components with process solutions or any other liquids (and gases) in contact with the material do not affect safety, strength, and quality of the drug product. Therefore, chemical compatibility of single-use components should be assessed prior to the process development.

This document summarizes available information on the general chemical compatibility of polymers, commonly used in bioprocess single-use systems, with various chemical fluids representative of those typically used in pharmaceutical and biopharmaceutical processes.

2 Explanation of Chemical Compatibility Ranking

Compatibility data in the following tables are based on the rankings below:

- Generally resistant. Where material shows no signs of damage such as discoloration or swelling when used with the specific chemical fluid for 24 hours of constant exposure at room temperature.
- Limited resistance. Where material might show signs of slight damage such as discoloration or swelling when used with the specific chemical fluids for 24 hours of constant exposure at room temperature. Practical testing necessary.
- Not resistant. Where material is damaged when used with specific chemical fluids for 24 hours of constant exposure at room temperature.
- Insufficient information. Where no generic information exists for materials used with specific chemical fluids for 24 hours of constant exposure at room temperature.

3 Disclaimer

Please read this disclaimer carefully before using the chemical compatibility tables in this document:

- 1) Chemical compatibility ratings in the tables were compiled from generic data found in chemical compatibility literature for the respective polymer categories. The tables can be useful in assessing likely process compatibility, but should not be considered a substitute for full risk assessment and testing in the proposed process application (e.g. evaluation of leachables).
- 2) The chemical compatibility of a polymeric material is impacted by the nature of the fluid, concentration, temperature, exposure time and whether the polymeric material is under stress. The following data in the tables are applicable for indicated concentrations at room temperature for 24 hours exposure without applied stresses.
- 3) Each polymer category covers a wider range of polymer brands and types of resin, some of which may be more or less resistant than others. It has been assumed that all polymers in a category have similar chemical compatibility.
- 4) The chemical compatibility table for Pall components is generally based on the primary materials of construction and the compatibility rating of those materials, Not on specific testing performed on the Pall component itself.

4 Chemical Compatibility Tables

Table 1.
Chemical compatibility guide for polymers commonly used in bioprocess components.

Fluids	PP	LDPE	HDPE	PS	PEEK	PET	PSU	Nylon	PTFE	Cellulose	PVC	PVDF	PES	PEI	PC	FEP	Silicone	TPE/Nitrile	PUE	EPDM	PBT
Phosphoric acid, 0.1 M	●	●	●	●	●	●	●	●	●	●	●	●	●	○	●	●	●	○	●	●	○
NaOH, 0.5 N	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Citric acid, 0.2%	●	●	●	●	●	●	●	●	●	○	●	●	●	●	●	●	●	●	●	●	○
Acetic acid, 0.1%	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Ammonium acetate, 0.5%	●	●	●	●	●	●	●	●	●	○	●	○	○	○	●	●	●	●	○	●	○
Ammonium sulfate, 0.1%	●	●	●	●	●	●	●	●	●	○	●	●	●	○	●	●	●	●	●	●	○
Benzoic acid, 0.1%	●	●	●	●	●	●	●	●	●	○	●	●	●	○	●	●	●	●	●	●	●
Benzyl alcohol, 2%	●	●	●	●	●	○	●	●	●	○	●	●	●	○	●	●	●	●	●	●	○
Carbonic acid, 0.1%	●	●	●	○	●	○	●	●	●	○	●	●	●	○	○	●	●	●	○	●	○
Casein hydrolysate, 3%	●	●	●	○	●	○	●	●	●	●	○	●	●	○	●	○	●	○	●	●	●
Citrate buffer, 0.01 M	●	●	●	○	○	○	●	●	●	○	○	●	●	○	●	○	●	●	●	●	○
Dichloromethane, 0.5%	●	●	○	○	●	○	●	●	●	○	●	○	●	●	○	●	○	○	○	●	●
Diethanolamine, 5%	●	●	●	○	○	○	○	●	●	○	○	○	○	○	○	●	○	●	○	●	○
Dimethylacetamide, 10%	●	●	●	●	●	○	○	●	●	●	●	○	●	○	○	●	●	○	●	○	○
Dimethylformamide, 5%	●	●	●	●	●	●	●	●	●	●	●	●	●	○	●	●	●	●	●	●	●
Ethanol, 50%	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Formic acid, 10%	●	●	●	●	●	●	●	●	●	○	●	●	●	●	●	●	●	●	●	●	●
Guanidine HCl, 0.6 M	●	●	●	○	○	○	○	●	○	○	○	○	○	○	○	○	○	○	○	○	○
HCl / KCl buffer, pH 3, 0.2%	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Isobutyl alcohol, 2%	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	○
Peracetic acid, 1%	○	○	○	○	○	●	●	●	●	○	○	●	○	○	○	○	○	○	○	○	○
Phenoxyethanol, 0.10%	○	●	●	○	○	○	●	●	○	○	○	○	●	○	○	○	○	○	○	●	○
Phosphate buffer, pH 10, 0.3 M	●	●	●	●	●	○	●	●	○	●	●	●	●	○	○	○	○	○	○	○	○
Polyethylene glycol, 0.5%	●	●	●	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Potassium phosphate, 1%	●	●	●	●	●	○	○	●	●	○	●	○	●	●	○	○	○	○	○	○	○
Propylene glycol, 1%	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	○	●	○
Sulfuric acid, 0.1%	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	○	●	○
Hydrogen peroxide, 0.1%	●	●	●	●	●	●	●	●	●	●	●	●	●	○	○	○	○	○	○	○	○
Tris buffer, pH 11, 0.1 M	●	●	●	●	○	●	●	●	○	○	●	●	○	○	○	○	○	○	○	○	○
Tween 80, 0.1%	●	●	●	●	○	●	○	○	●	●	●	●	●	○	○	○	○	○	○	○	○
Triton X-100, 0.1%	●	●	●	●	○	●	○	○	○	○	●	●	○	○	○	○	○	○	○	○	○

● = Generally Resistant; ● = Limited Resistance; ● = Not Recommended; ○ = Insufficient Information.

Notes: Compatibility data shown here applies to indicated specific concentration at 20 °C for 24 hours. Polymer stress level is not considered due to lack of information.

List of abbreviations; PP = Polypropylene; LDPE = Low Density Polyethylene; HDPE = High Density Polyethylene; PS = Polystyrene; PEEK = Polyether Ether Ketone; PET = Polyethylene Terephthalate; PSU = Polysulfone; PTFE = Polytetrafluoroethylene; PVC = Polyvinyl Chloride; PVDF = Polyvinylidene Fluoride; PES = Polyethersulfone; PEI = Polyetherimide; PC = Polycarbonate; FEP = Fluorinated Ethylene Propylene; TPE = Thermoplastic Elastomer; PUE = Polyurethane; EPDM = Ethylene Propylene Diene Monomer; PBT = Polybutylene Terephthalate.

¹ High concentrations are not compatible with LDPE, HDPE, and PES.

² Higher than 0.1% is generally ranked as "NR" with PES.

Table 2.
Compatibility of Pall bioprocess components with common pharmaceutical and biopharmaceutical process fluids.

Pall Components	Kleenpak™ Capsule with Supor® EKV Media	Kleenpak Nova Capsule with Supor EKV Media	Kleenpak® Presto Sterile Connector	Kleenpak Sterile Disconnecter	Kleenpak HT Sterile Connector	Kleenpak Nova Capsule with Fluorodyne® II DFL Media	Kleenpak™ Capsule with Emflon II Media	Ultipor® N66 Sterilizing-Grade Filter Cartridges	Silicone Tubing	TPE Tubing	Magnetic Mixer Impeller	LevMixer® System
Primary Materials of Construction	PP, PES, EPDM	PP, PES, Silicone	PES, Silicone	PSU, Silicone	PC	PVDF, PP, Silicone	PVDF, PP, EPDM	Nylon, PE, EPDM	Silicone	TPE	HDPE, PVDF	HDPE, LDPE
Phosphoric acid, 0.1 M	●	●	●	●	●	●	●	●	●	○	●	●
NaOH, 0.5 N	●	●	●	●	●	●	●	●	●	●	●	●
Citric acid, 0.2%	●	●	●	●	●	●	●	●	●	●	●	●
Acetic acid, 0.1%	●	●	●	●	●	●	●	●	●	●	●	●
Ammonium acetate, 0.5%	○	○	○	●	●	○	○	●	●	●	○	●
Ammonium sulfate, 0.1%	●	●	●	●	●	●	●	●	●	●	●	●
Benzoic acid, 0.1%	● ⁴	● ⁴	● ⁴	●	●	●	●	●	●	●	●	●
Benzyl alcohol, 2%	● ¹	● ¹	● ¹	●	●	●	●	● ¹	●	●	● ¹	● ¹
Carbonic acid, 0.1%	●	●	●	●	○	●	●	●	●	●	●	●
Casein hydrolysate, 3%	●	●	●	●	●	●	●	●	●	○	●	●
Citrate buffer, 0.01 M	●	●	●	●	●	●	●	●	●	●	●	●
Dichloromethane, 0.5%	●	●	●	●	○	●	●	●	○	○	○	●
Diethanolamine, 5%	○	○	○	○	○	○	○	●	○	●	○	●
Dimethylacetamide, 10%	○	●	●	○	○	○	○	●	●	○	○	●
Dimethylformamide, 5%	● ¹	●	●	●	●	●	●	●	●	●	●	●
Ethanol, 50%	●	●	●	●	●	●	●	●	●	●	●	●
Formic acid, 10%	●	●	●	●	●	●	●	●	●	●	●	●
Guanidine HCl, 0. 6 M	○	○	○	○	●	○	○	○	○	●	○	●
HCl / KCl buffer, pH 3, 0.2%	●	●	●	●	●	●	●	●	●	●	●	●
Isobutyl alcohol, 2%	●	●	●	●	●	●	●	●	●	●	●	●
Peracetic acid, 1%	○	○	○	○	○	○	○	●	○	○	○	○
Phenoxyethanol, 0.10%	●	●	●	●	○	○	○	●	○	○	○	●
Phosphate buffer, pH 10, 0.3 M	●	●	●	●	●	●	●	●	●	●	●	●
Polyethylene glycol, 0.5%	● ²	● ²	● ²	○	●	○	○	○	●	○	○	●
Potassium phosphate, 1%	●	●	●	○	○	○	○	●	●	○	○	●
Propylene glycol, 1%	●	●	●	●	●	●	●	●	●	●	●	●
Sulfuric acid, 0.1%	●	●	●	●	●	●	●	●	● ⁵	●	●	●
Hydrogen peroxide, 0.1%	●	●	●	●	●	●	●	●	●	●	●	●
Tris buffer, pH 11, 0.1 M	○	○	○	●	○	●	○	○	●	●	●	●
Tween 80, 0.1%	● ³	●	●	○	○	●	●	○	●	●	●	●
Triton X-100, 0.1%	● ¹	● ¹	● ¹	○	●	●	●	○	●	●	●	●

● = Generally Resistant; ● = Limited Resistance; ● = Not Recommended; ○ = Insufficient Information.

Notes: Compatibility data shown here applies to indicated specific concentration at 20 °C for 24 hours. Polymer stress level is not considered due to lack of information.
List of abbreviations; PP = Polypropylene; LDPE = Low Density Polyethylene; HDPE = High Density Polyethylene; PS = Polystyrene; PEEK = Polyether Ether Ketone; PET = Polyethylene Terephthalate; PSU = Polysulfone; PTFE = Polyterafluoroethylene; PVC = Polyvinyl Chloride; PVDF = Polyvinylidene Fluoride; PES = Polyethersulfone; PEI = Polyetherimide; PC = Polycarbonate; FEP = Fluorinated Ethylene Propylene; TPE = Thermoplastic Elastomer; PUE = Polyurethane; EPDM = Ethylene Propylene Diene Monomer; PBT = Polybutylene Terephthalate.

¹High concentrations are not compatible with LDPE, HDPE and PES.
²Bacteria retention study recommended.
³Solution of 0.1% tween is compatible for use in batch filtration.
⁴Higher than 0.1% benzoic acid is not recommended with PES.
⁵According to supplier information, silicone tubing has excellent compatibility against sulfuric acid

5 Supporting References

For chemical compatibility test results performed on Pall single use components please check the following documents:

- 1) Pall Allegro™ 2D Biocontainers, Integrated into Enhanced Single-use Systems for Bioprocessing Applications, USD 2471⁽¹⁾.
- 2) Guide to Extractables in Effluents from Pall Ultipor® N66 and Posidyne® Filter Cartridges, Validation Guide USTR 2521
- 3) Kleenpak® Presto Sterile Connector, Validation Guide USTR 3130b

**Corporate Headquarters**

Port Washington, NY, USA
+1-800-717-7255 toll free (USA)
+1-516-484-5400 phone

European Headquarters

Fribourg, Switzerland
+41 (0)26 350 53 00 phone

Asia-Pacific Headquarters


Singapore
+65 6389 6500 phone

Visit us on the Web at www.pall.com/biotech

Contact us at www.pall.com/contact

Pall Corporation has offices and plants throughout the world. To locate the Pall office or distributor nearest you, visit www.pall.com/contact.

The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

© Copyright 2022, Pall Corporation. Pall, , Allegro, Emflon, Kleenpak, LevMixer, Posidyne, and Ultipor are trademarks of Pall Corporation. ® Indicates a trademark registered in the USA.

USTR 3614 Rev 1.0
March 2022