

Validation Document for Beverage Grade Liquid Filters



domnick hunter

PROCESS FILTRATION

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1 Introduction

Filters that come into contact with beverage product, must conform to strictly defined quality standards.

When filters are used in the manufacture of beverage products, the process must be validated by taking into account all relevant details of the product and manufacturing process.

Guidelines for validation can be sourced from publications from FDA. This validation document has been produced with these guidelines in mind to enable the end user to incorporate this information within their own validation documentation or standard operating procedures (SOP) for the process.

This validation guide shows that beverage grade filter cartridges from **domnick hunter** surpass the product specification requirements that have to be imposed on their use within the industry.

NOTE

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2 Quality Policy

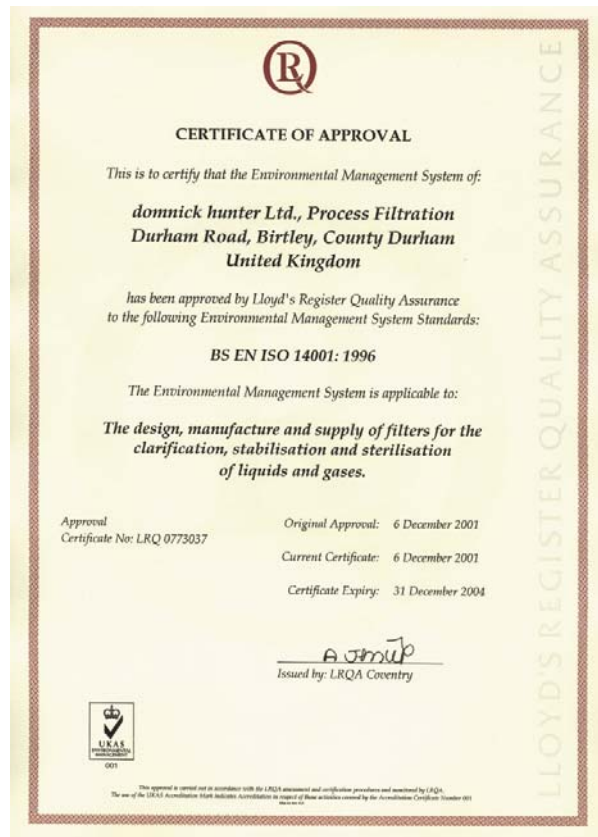
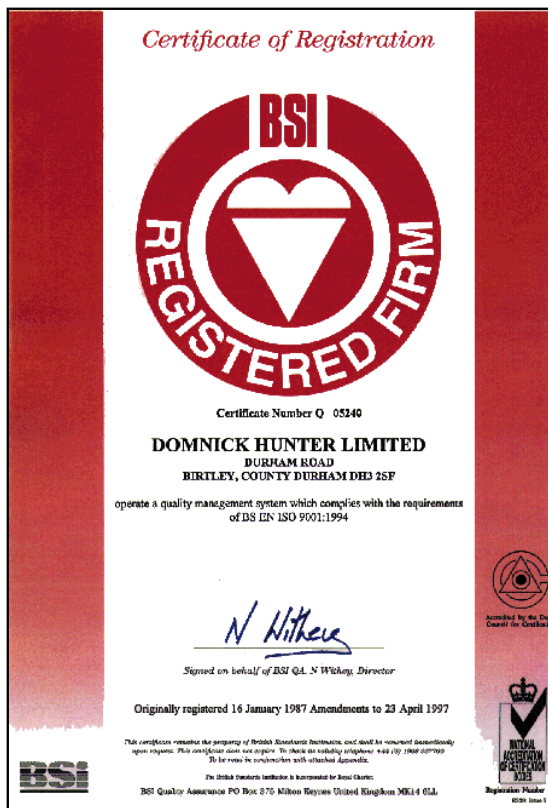
2.1 Quality Assurance

Quality is of paramount importance to **domnick hunter ltd**. The filtration products are manufactured under controlled environmental conditions to the highest quality regimes and are subjected to a demanding program of Quality Assurance. Inspection and test protocols are implemented from vendor assessment, specification and receipt of raw materials, through every stage of the manufacturing process culminating in a non-destructive integrity test of the filter prior to packing and release.

Every stage of the manufacturing process has well defined assembly protocols laid down thus ensuring operational repeatability.

domnick hunter's responsibility as a manufacturer of quality extends beyond the site at Birtley in the UK, through to the world-wide network of filter and separation specialists.

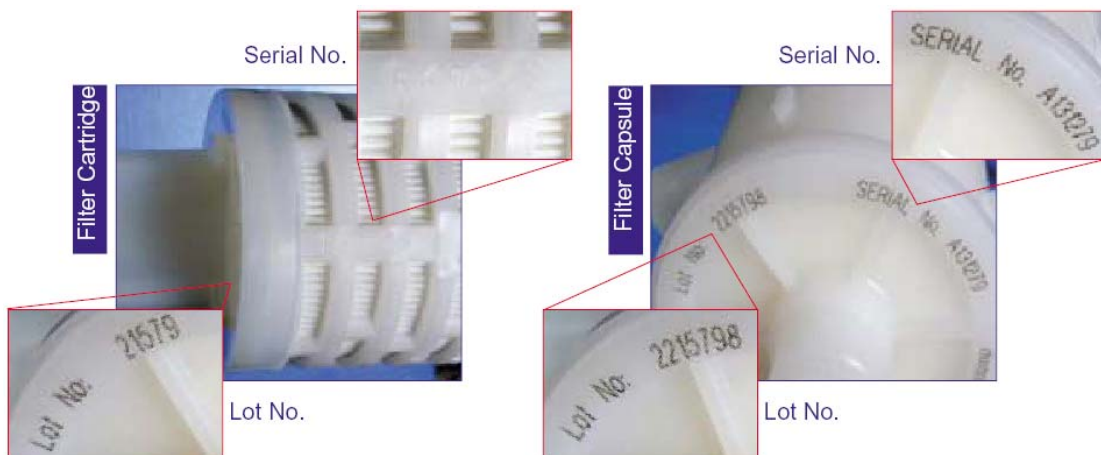
The Quality Assurance Department operates with a well-equipped Laboratory Services Department, in which specialised personnel are employed to perform the essential quality inspections. **domnick hunter** has been assessed by the British Standards Institution and is registered to BS EN ISO 9001:1994, which defines the standards for quality systems, model for quality assurance in design, development, production, installation and servicing. As a concerned environmentally aware manufacturer, **domnick hunter** is also audited and certified to BS EN ISO 14001:1996 for its Environmental Management System.



3 Product Traceability

All beverage grade membrane filters are non-destructively integrity tested and flushed with Purified Water. They are then dried using HEPA filtered air and sealed in a protective polyethylene bag within the controlled manufacturing environment prior to despatch.

To enable full traceability of all beverage grade filter products, each filter module is marked with an individual serial number. In addition, each filter product is marked with a lot number, product code and general description which is also shown on both the protective polyethylene bag in which the filter is sealed and on the outer surface of the final product packaging.



4 Summary of Test Methods

A number of the critical procedures used within this validation document are based on external methods sourced from publications issued by the USP, EP, FDA, ISO¹ and ASTM². The remaining procedures are in-house methods prepared using **domnick hunter's** relevant experience and industry accepted standards in the fine filtration field. The comprehensive nature of these procedures ensures high batch to batch compliance to the specification.

| Media Validation | | Filter Validation and Testing | | | | |
|---------------------|------------------------|-------------------------------|----------------------------|------------------|-------------------------------------|------------------------|
| Physical | Chemical / Biological | Integrity Testing | Retention | Flow Parameters | Durability | Chemical / Biological |
| Bubble Point | Chemical Compatibility | Pressure Hold | Liquid Bacterial Challenge | Clean Water Flow | Max Allowable Steam life | Chemical Compatibility |
| Water Flow | Extractables | Diffusional Flow | Particle / Fibre Shedding | | Max continuous running Temperature | Extractables |
| Thickness | Pyrogen Extractables | | Particle Retention Testing | | Max Allowable Differential Pressure | Bio-Compatibility |
| Bacterial Challenge | Oxidisables | | | | | Pyrogen Extractables |
| Burst Strength | Bio-Compatibility | | | | | Oxidisables |
| Autoclavability | | | | | | |
| Pore Size Analysis | | | | | | |

¹ ISO – International Organisation for Standardisation

² ASTM – American Society for Testing and Materials

5 Preparation of Beverage Grade Filters

5.1 Beverage Grade Standard

Beverage grade filters must meet stringent standards to be certified as fit for purpose by **domnick hunter**. The standards that must be met are:

1 Materials of construction

All components of the cartridge are manufactured from materials suitable for contact with food and conform to the following requirements:

- Biological safety per current USP Class VI - 121°C Plastics.
- Relevant requirements of the United States FDA Code of Federal Regulations Title 21 Part 177 'Indirect food additives: Polymers'.

2 Product Integrity

All membrane filters successfully pass a water-wet non-destructive integrity test prior to despatch.

3 Cleanliness

Where required, filters are flushed with purified water prior to despatch. Filters have been validated to meet the following effluent quality criteria.

- USP Total Organic carbon <643>
- USP Water Conductivity <645>
- USP Particulate Matter in Injections <788>

4 Thermal Stability

The cartridges are validated to ensure that they maintain integrity after in situ steaming under defined conditions and limits.

5.2 Quality of Purified Water used in the preparation of Beverage Grade Filters

The current USP and Ph Eur standards for Purified Water and Highly Purified Water specify a maximum conductivity of 1.1 $\mu\text{S}/\text{cm}$ @ 20°C (68°F) and a maximum TOC (Total Organic Carbon) content of 0.5 mg (500ppb) of carbon per litre.

The water used in the flushing stages of beverage grade filters exceeds these Pharmacopoeial requirements.



In addition, two other tests are carried out on samples taken from point of use and from a number of points in the supply pipework: -

- A Membrane Filtration Method Standard Plate Count Technique, to establish the microbial content.
- A gel clot LAL (Limulus Amoebocyte Lysate) test, for detection of bacterial endotoxins at 0.125 EU/ml sensitivity.

6 Certificate of Conformance

To certify that **domnick hunter's** beverage grade filter products meet the highest beverage quality and performance requirements, a Certificate of Conformance is issued.

Examples of non-membrane and membrane based product certificates are given below.

| | |
|--|---|
| Certificate of Conformance | |
| For Beverage Grade xxxxxxxxxxxx Pre Filters | |
| <i>This certifies that the domnick hunter filter xxxxxxxxxxxx</i> | |
| Recorded Lot Number xxxxxxxx | |
| has been manufactured in a purpose built facility within a controlled environment and where applicable subjected to a purified water flush. | |
| Materials of Construction | |
| All components of this cartridge are manufactured from materials suitable for contact with food and conform to the biological safety requirements as laid down in the current USP Class VI - 121°C Plastics. | |
| The filters also meet the domnick hunter quality control and assurance standards. | |
| During validation, filter samples underwent the following tests and satisfactorily met the respective criteria specified:- | |
| Effluent Quality | |
| TOC Met the requirements of USP Total Organic Carbon <643> | |
| Water Conductivity Met the requirements of USP Water Conductivity <645> | |
| Particle Release Met the requirements of USP Particulate Matter in Injections <788> | |
| Thermal Stability (Sterilisable Grades) Integrity was maintained after xxx steam cycles of xxx minutes at xxx°C | |
|  FM 39187 |  |
| Quality Manager [date of issue] | |
| <small>domnick hunter limited - Process Filtration, Durham Road, Birtley, Co. Durham, England DH3 2SF Tel: +44(0) 191 4105121 Fax: +44 (0) 191 4105312</small> | |

Certificate of Conformance

| | | |
|--|------------|----------------|
| For Beverage Grade | XXXXXXXXXX | Filters |
| Rated To | xxxx | Micron(s) |
| <i>This certifies that the domnick hunter filter</i> | XXXXXXXXXX | |
| Recorded Lot Number | XXXXXXXXXX | |

has been manufactured in a purpose built facility within a controlled environment and subjected to a purified water flush.

Materials of Construction

All components of this cartridge are manufactured from materials suitable for contact with food and conform to the biological safety requirements as laid down in the current USP Class VI - 121°C Plastics. They also conform with the requirements for non fibre releasing filters as laid down in the United States FDA Title 21 CFR 211.72 and 210.3(b),(6).

The filters also meet the **domnick hunter** quality control and assurance standards.

Product Integrity

This product has successfully passed a non destructive integrity test.

Diffusional flow value did not exceed xxxx mL/min at a test pressure of xxxx mbar

During validation, filter samples underwent the following tests and satisfactorily met the respective criteria specified:-

Effluent Quality

TOC

Met the requirements of USP Total Organic Carbon <643>

Water Conductivity

Met the requirements of USP Water Conductivity <645>

Particle Release

Met the requirements of USP Particulate Matter in Injections <788>

Thermal Stability (Sterilisable Grades)

Integrity was maintained after xxx steam cycles of xxx minutes at xxx °C



FM 39187



Quality Manager
[date of issue]

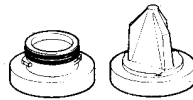
domnick hunter limited - Process Filtration, Durham Road, Birtley, Co. Durham, England DH3 2SF
Tel: +44(0) 191 4105121 Fax: +44 (0) 191 4105312

7 Endcap Configuration Diagrams

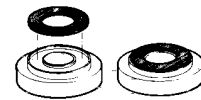


domnick hunter
PROCESS FILTRATION

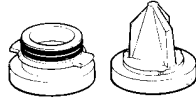
A Style
223 'O' Rings



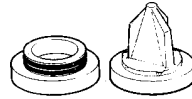
B,L Style
Flat Gaskets



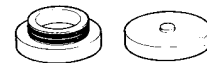
C Style
226 'O' Rings



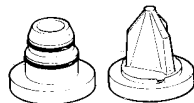
D Style
222 'O' Rings



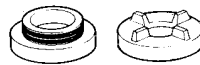
E Style
222 'O' Rings



F Style
216/218 'O' Rings



G Style
222 'O' Rings



J Style
S.O.E.



K Style
214 'O' Rings

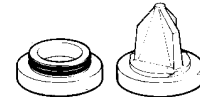


M Style
214 'O' Rings

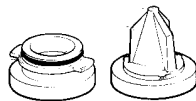


N Style
213 'O' Rings

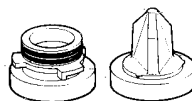
P Style
227 'O' Rings



Q Style
226 'O' Rings



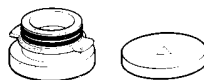
R Style
222 'O' Rings



SK Style



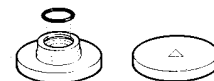
T Style
126 'O' Rings



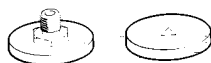
V Style
Flat Gaskets



W Style
111 'O' Rings



X Style
Flat Gaskets



Y Style
116 'O' Rings (Internal)



Z Style
116 'O' Rings (Internal)



8 Product Specification

Individual data sheets are available for all beverage grade liquid filters and related products.

For the purpose of this guide, please request datasheets for any of the following products using the given reference numbers:

Beverage Grade Liquid Pre-filter Products

| | |
|------------------------|-------------|
| PEPLYN [®] HD | 17 950 1456 |
| PEPLYN [®] HA | 17 950 1457 |
| PREPOR [®] GF | 17 950 1458 |
| PREPOR [®] GP | 17 950 1459 |
| PREPOR [®] PP | 17 950 1460 |

Beverage Grade Liquid Membrane products

| | |
|------------------------|-------------|
| BEVPOR [®] PS | 17 950 1461 |
| BEVPOR [®] PH | 17 950 1462 |
| BEVPOR [®] PT | 17 950 1463 |

9 Chemical Compatibility

Testing has been carried out that shows beverage grade filters have a broad range of chemical compatibility with chemicals commonly used in the beverage industry.

9.1 Chemical Compatibility Summary Chart for Beverage and Related Products

| | ASYPOR | BIO-X II | HIGH FLOW BIO-X | HIGH FLOW BIO-X VENT AUTOCLAVE | HIGH FLOW PREPOR GFA | HIGH FLOW TETPOR | HIGH FLOW TETPOR H.T. | HIGH FLOW TETPOR VENT AUTOCLAVE | ALL PEPLYN products and PREPOR PP | PREPOR GF and PREPOR GP | ALL BEVPPOR P products | TETPOR AIR | EPDM O'Ring | VITON O'Ring | SILICONE O'Ring |
|---|--------|----------|-----------------|--------------------------------|----------------------|------------------|-----------------------|---------------------------------|-----------------------------------|-------------------------|------------------------|------------|-------------|--------------|-----------------|
| Acetic acid 3.5N | LC | C | C | C | C | C | C | C | C | C | C | C | C | C | C |
| Acetic acid 8.75N | LC | C | C | - | C | C | C | C | C | C | - | C | LC | LC | NC |
| Acetic acid conc.17.5N | NC | C | C | - | C | C | C | C | C | C | - | C | LC | NC | NC |
| Acetone | NC | C | C | - | C | C | C | C | C | C | NC | C | NC | NC | NC |
| Acetonitrile | NC | C | C | - | LC | C | C | C | C | LC | - | C | NC | NC | NC |
| Acidbrite 4 (Diversey) 3.0% _{vv} | NC | - | - | - | C | - | - | - | C | C | - | - | C | C | C |
| Ammonium Hydroxide 8N | NC | C | C | C | C | C | C | C | C | C | LC | C | C | C | C |
| Ammonium Oxalate 0.07N | - | C | C | C | C | C | C | C | C | C | - | C | C | C | C |
| Amyl Acetate | NC | C | C | C | LC | C | C | C | C | LC | LC | C | NC | NC | LC |
| Aqueous Ammonia 15.5N | NC | C | C | C | LC | C | LC | C | C | LC | LC | C | C | C | C |
| Benzyl Alcohol | NC | C | C | C | NC | C | C | C | NC | NC | - | C | C | C | C |
| Benzalkonium Chloride 0.1% | LC | C | C | C | C | C | C | C | C | C | - | C | C | C | C |
| Boric acid,saturated | C | C | C | C | C | C | C | C | C | C | - | C | C | C | C |
| Butan-1-ol | NC | C | C | C | C | LC | LC | LC | C | C | C | NC | C | C | C |
| Butan-2-ol | NC | C | C | C | C | C | C | C | C | C | C | C | LC | C | C |
| Carbon Tetrachloride | NC | C | C | C | NC | C | C | C | NC | NC | - | NC | NC | C | NC |
| Chloroform | NC | C | C | C | NC | C | C | C | NC | NC | NC | NC | NC | LC | NC |
| Cyclohexane | NC | C | C | C | NC | - | - | - | NC | NC | - | LC | NC | NC | NC |
| 1,4 – Dioxane | NC | C | C | C | LC | C | C | C | C | LC | - | C | NC | NC | NC |
| Diverflow (Diversey) 3%v/v | NC | - | - | - | NC | - | - | - | C | NC | C | - | C | C | LC |
| Diversey 212G 0.6%v/v | NC | - | - | - | C | - | - | - | C | C | - | - | C | C | C |
| Divosan Forte 0.5%v/v | LC | - | - | - | C | - | - | - | C | C | C | - | C | C | C |
| Divosan XT 1%v/v | C | - | - | - | C | - | - | - | C | C | - | - | C | C | C |
| Ethanol | NC | C | C | C | C | C | - | C | C | C | C | C | C | C | LC |
| Ethanol 45% | LC | - | - | - | C | - | - | - | C | C | C | C | C | C | C |
| Ethyl Acetate | NC | LC | LC | LC | LC | LC | LC | LC | LC | LC | NC | LC | C | NC | LC |
| Formaldehyde 0.3% | LC | C | C | C | C | C | C | C | C | C | C | C | C | C | C |
| Formaldehyde 37% | NC | C | C | C | C | C | C | C | C | C | - | C | C | C | C |
| Formic acid conc. | NC | C | C | C | NC | C | C | C | C | NC | - | C | C | NC | NC |

| | ASYPOR | BIO-X II | HIGH FLOW BIO-X | HIGH FLOW BIO-X VENT AUTOCLAVE | HIGH FLOW PREPOR GFA | HIGH FLOW TETPOR | HIGH FLOW TETPOR H.T. | HIGH FLOW TETPOR VENT AUTOCLAVE | All PEPLYN products and PREPOR PP | PREPOR GF and PREPOR GP | All BEVOP P products | TETPOR AIR | EPDM O'Ring | VITON O'Ring | SILICONE O'Ring |
|-------------------------------------|--------|----------|-----------------|--------------------------------|----------------------|------------------|-----------------------|---------------------------------|-----------------------------------|-------------------------|----------------------|------------|-------------|--------------|-----------------|
| Glycerol | C | C | C | C | C | C | C | C | C | C | C | C | C | C | C |
| Hexane | LC | C | C | C | - | C | C | C | NC | - | - | - | NC | NC | NC |
| Hydrochloric acid 1N | C | - | - | - | C | - | - | - | C | C | C | C | C | C | C |
| Hydrochloric acid conc. | NC | - | - | - | NC | - | - | - | C | NC | - | C | NC | NC | NC |
| Hydrochloric acid conc.13% | - | C | C | C | - | C | C | C | - | - | - | - | NC | NC | NC |
| Hydrogen Peroxide | - | C | C | C | - | - | - | - | C | - | - | - | C | C | C |
| Hydrogen Peroxide 10 Vol | C | - | - | - | C | - | - | - | C | C | C | C | C | C | C |
| Hydrogen Peroxide 100 Vol | LC | - | - | - | C | C | C | C | C | C | - | C | C | C | C |
| Methanol | NC | C | C | C | C | C | C | C | C | C | C | C | C | NC | C |
| Methyl-Iso-Butylketone | NC | C | C | C | C | C | C | C | C | C | NC | C | NC | NC | LC |
| Methylene Chloride @ 40°C | - | - | - | - | LC | - | - | - | LC | LC | - | - | - | - | - |
| Nitric acid 2N 14.4% | C | C | C | C | C | C | C | C | C | C | C | C | LC | C | C |
| Nitric acid 15.8N | NC | C | C | C | NC | C | NC | C | C | NC | - | C | NC | NC | NC |
| Ozone | - | - | - | - | - | - | - | - | - | - | NC | - | - | - | - |
| Paraffin yellow | LC | LC | LC | LC | LC | C | C | C | C | LC | - | C | NC | C | NC |
| Pentane | LC | C | C | C | LC | - | - | - | LC | LC | - | LC | NC | C | NC |
| Peracetic acid 0.5% (10 wk test) | C | - | - | - | - | C | C | C | - | - | - | - | C | C | C |
| Peracetic acid 4% | C | C | C | C | C | C | C | C | C | C | C | C | C | C | C |
| Perchloroethylene | - | - | - | - | - | - | - | - | - | - | NC | - | - | - | - |
| Petroleum spirits | NC | - | - | - | NC | C | C | C | NC | NC | - | LC | NC | C | NC |
| Phenol (aq) 0.5N | - | C | C | C | - | NC | - | NC | - | - | - | - | - | - | - |
| Phenol 5% | NC | - | - | - | C | - | - | - | C | C | - | C | C | C | C |
| Phenol 0.25% | C | - | - | - | C | - | - | - | C | C | - | C | C | C | C |
| Polyethylene Glycol 600 | NC | LC | LC | LC | NC | C | C | C | LC | NC | NC | - | - | - | - |
| Polyglycol 2000-E | - | - | - | - | - | - | - | - | - | - | - | - | C | C | C |
| Potassium Dichromate 0.1N | LC | C | C | C | C | C | C | C | C | C | - | C | C | C | C |
| Potassium Iodine 0.6N | C | C | C | C | C | C | C | C | C | C | - | C | C | C | C |
| Potassium Hydroxide 10N | NC | C | C | C | NC | C | C | C | C | NC | LC | C | C | C | C |
| Potassium Permanganate 0.1N | NC | C | C | C | NC | C | LC | C | C | NC | C | C | C | C | C |
| Propan-1-ol | NC | C | C | C | NC | C | C | C | C | NC | C | C | C | C | LC |
| Propan-2-ol | C | C | C | C | NC | C | C | C | C | NC | C | C | C | C | LC |
| Propan-2-ol, 60:40 H ₂ O | C | C | C | C | NC | C | C | C | C | NC | C | C | C | C | C |
| Pyridine | NC | C | C | C | NC | C | C | C | C | NC | NC | C | C | NC | C |
| Sodium Chloride 0.5N | LC | C | C | C | C | C | C | C | C | C | C | C | C | C | C |
| Saline Lactose Broth | C | C | C | C | C | C | C | C | C | C | C | C | C | C | C |

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|---|--------|----------|-----------------|--------------------------------|----------------------|------------------|-----------------------|---------------------------------|-----------------------------------|-------------------------|-----------------------|------------|-------------|--------------|-----------------|
| Sodium Hydroxide 2N 8% | NC | NC | NC | NC | C | C | C | C | C | C | C | C | C | C | C |
| Sodium Hydroxide 7N 28% | NC | NC | NC | NC | NC | C | C | C | C | NC | NC | C | C | C | LC |
| Sodium Hypochlorite (14% Free Cl ₂) | NC | C | C | C | C | C | C | C | C | C | C | C | C | C | C |
| Sodium thiosulphate 0.1N | LC | C | C | C | C | C | C | C | C | C | - | C | C | C | C |
| Sulphuric acid 1N | NC | C | C | C | LC | C | C | C | C | LC | C | - | C | C | C |
| Sulphuric acid conc. | NC | NC | NC | NC | LC | LC | NC | LC | LC | LC | NC | LC | - | - | - |
| Sulphurous acid | - | - | - | - | - | - | - | - | - | - | NC | - | - | - | - |
| Toluene | - | NC | NC | NC | - | NC | NC | NC | NC | - | NC | - | NC | LC | NC |
| 1,1,1 Trichloroethane | LC | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 1,1,2 Trichloroethane | - | C | C | C | LC | C | LC | C | LC | LC | NC | LC | NC | LC | LC |
| Trichloroacetic Acid 80% | LC | - | - | - | LC | - | - | - | C | LC | - | C | NC | LC | NC |
| Trichloroacetic Acid 5N | - | C | C | C | - | C | C | C | - | - | - | - | --- | | |
| Toluene | NC | - | - | - | NC | - | - | - | - | NC | - | - | NC | LC | NC |
| Xylene | NC | LC | LC | LC | NC | LC | LC | LC | NC | NC | LC | NC | C | LC | NC |

9.2 Chemical Compatibility User Instructions and Notes

- The chemicals are arranged in alphabetical order using their most common or trade names. If the chemical in question does not appear to be listed, it may be found elsewhere in the table under a pseudonym, in particular its IUPAC³ name.
- With regard to compatibility:
 - ◇ Any product that has Limited Compatibility (LC) at ambient temperatures should not be used at a higher temperature.
 - ◇ The list of compatibilities does not take into account any synergistic effects of more than one chemical present in the solution to be filtered.
 - ◇ Test Conditions – 72 hrs at ambient temperature and pressure, unless otherwise stated.
 - ◇ Contact **domnick hunter** for confirmation of compatibility with specific operating conditions.

³ IUPAC – International Union of Pure and Applied Chemistry



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