

# EDWARDS' ANALYTICAL

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## TEST REPORT

**Title:** TESTING OF MATERIALS TO THE USA'S  
CODE OF FEDERAL REGULATIONS  
TITLE 21

**Client:** domnick hunter ltd

**Report Number:** 050327B.rep

**Version:** Second, Further components

**Date samples received:** 21/3/05

**Date of tests:** 25/3/05 to 30/6/05

**Report issue date** 7/7/05

**Tests performed by:**



J H & D.J.H. Edwards

**Tests & report witnessed and checked by:**



C Anderson BSc

**Report prepared and written by:**



D.J.H. Edwards CChem MRSC, CSci MIM<sup>3</sup>, MInstPkg  
Principal, Edwards' Analytical



1431

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**Page** 2 of 4

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**Client:** domnick hunter Ltd  
**Address:** Dukesway  
Team Valley Industrial Estate  
Gateshead  
Tyne & Wear  
NE11 0PZ

## **Introduction:**

Components of carbon dioxide gas filter units were received for compliance testing to the USA's Code of Federal Regulations, Title 21 "Food and Drugs", Part 177 Indirect Food Additives.

Components were from the following filters and purifiers:

- MPlus PCO2
- Maxi PCO2
- CDPlus & CDP PCO2
- Evolution Filter (Standard Product)
- Oil-X & IP filters (Modified PCO2 versions)
- Mini PCO2

The following items are generally regarded as safe as food contact materials, and are therefore exempt from testing.

- Metals
- Treated metals (Including Alocrom 1200)
- Silicone grease
- Activated alumina
- Maxi/Maxi Plus Strap
- Activated Carbon
- Auto-drain 3000-02 (695044220)
- Manual drains, pressure relief valves and pressure gauges
- Peplyn discs

In selecting specimens for tested:

- Test only Items that come into contact with CO2 and other gases whilst purifiers are in normal use.

- Common materials combined to above list.

- Component size does not matter.

- All materials will be identification by infra red spectroscopy and where indicated:

- DSC - Differential scanning calorimetry,

- TGA - Thermo gravimetric analysis.

- Materials are in repeated use at a temperature less than 100 Deg C.

- That the above conditions of extraction are greater than the extractive power of use.

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**Page 3 of 4**

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The solvating power of carbon dioxide is less than the specified extractants.

As requested by the client, each component is reported separately as annexes to this report.

## Samples:

ITEM	PART No	MATERIAL	MONOGRAPH
O rings	051001140	High nitrile rubber	177.2600
O rings	051190262	Viton (Fluoro rubber)	177.2400
White sock	041001000	Polyester	177.1630
Sock foam	072021700	Polyurethane	177.1680
Poreweb	041000800	Polyester	177.1630
Evolution End Caps	011182010	Nylon 6:6	177.1500
PC52 Support net	044131080	Polypropylene	177.1520
Filter media / End pads	044030500	Acrylic coated borosilicate glass	177.2260
Washer in DP fastener	274012100	Nylon 6:6	177.1500
Adhesives / coatings	401000759	Epoxides	175.105 & 177.1440
Coatings	eg221183022	PTFE	175.105 & 177.1380
Molecular sieve	048200180	MS SZ-5	173.40
T12T Media	04117 0125	Polyester	177.1630
<i>Endcaps</i>			
<i>(Mpus/Maxi PC02)</i>	<i>276031188</i>	<i>Glass filled Nylon 6:6</i>	<i>177.1500 &amp; 177.2355</i>
End Caps PCO2	27 100 3830	Polypropylene	177.1520
Midi plug	27100 3180	Nylon 6:6	177.1500
Dowty seals	05119 0150	Metal rings with nitrile rubber	177.2600
Molecular sieve	04820018	MSC534	173.40
Caps	35 118 1560	Polypropylene	177.1520

## Client reference:

Purchase order I40/170093, dated 23/3/05 and I40/176116 dated 16/6/05 and also documents with samples.

## Our sample reference:

05/EA/3/27a to l respectively.

05/EA/5/17

05/EA/6/13

05/EA/6/23

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**Report No:** 050327B.rep

**Version:** Second

**Page** 4 of 4

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## Test methods:

21CFR 173 - Secondary direct food additives permitted in food for human consumption

21CFR 175 - Indirect food additives: Adhesives and components of coatings

21CFR 177 - Indirect food additives: Polymers

The Infra red spectra of thermoplastics were recorded of cast thin films in transmission, those of thermosets were recorded by reflectance, both using a Perkin Elmer Spectrum 2000 FT-IR spectrophotometer.

The DSC thermograms were recorded on thermally conditioned specimens of each sample using a Stanton Redcroft DSC700. The melting points reported were the endotherm maxima of the thermograms.

The TGA thermograms were recorded on sample using as Stanton Redcroft TG770.

Where required for "solid" materials, density / specific gravity was performed on the samples as received. For the net and fibrous samples, the materials were melted, cooled and tested.

Samples of metal plates coated with the epoxide & PTFE coating were tested rather than actual parts.

All other tests were as per the monographs.

## Results:

Results for each component are reported as annexes to this report.

## Conclusions:

All the materials tested all meet the requirements of the pertinent monographs of the USA's Code of Federal Regulations, Title 21 "Food and Drugs" ;-.

21CFR 173 - Secondary direct food additives permitted in food for human consumption

21CFR 175 - Indirect food additives: Adhesives and components of coatings

21CFR 177 - Indirect food additives: Polymers

This report covers purifiers for carbon dioxide, nitrogen and compressed air gases.

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