

1. Identification of the substance/preparation and the company/undertaking

Product: Microporous clarification filter cartridges and disposable capsules
Trade name: PEPLYN PLUS Pharmaceutical Grade Cartridge and DEMICAP Capsule Filters
Substance or preparation: Microporous clarification filter cartridges and disposable capsules containing polypropylene filtration media and support in a polypropylene/polyethylene copolymer body with Silicone Rubber o-rings as standard
Unique reference number(s): ZCPPx-xxxx-xx, ZEPPx-xxxx-xxx
Company / undertaking name and address: Durham Road, Birtley, Co. Durham, England, UK. DH3 2SF
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Specific control measures over and above those listed below may be required based on the particular medium filtered.

2. Composition

The PEPLYN PLUS Pharmaceutical Grade Cartridges and DEMICAP Capsule Filters in the as supplied condition are formed products consisting of the following components:

Component	Material of Construction	CAS Number	Classification
Filtration Media	Polypropylene	9003-07-0	Non Regulated
Upstream Support	Polypropylene	9003-07-0	Non Regulated
Downstream Support	Polypropylene	9003-07-0	Non Regulated
Inner Support Core	Polypropylene / polyethylene	9003-07-0 / 9010-79-1	Non Regulated
Outer Protection Cage	Polypropylene / polyethylene	9003-07-0 / 9010-79-1	Non Regulated
Endcaps	Polypropylene / polyethylene	9003-07-0 / 9010-79-1	Non Regulated
Endcap Insert	316 Stainless Steel	N/A	Non Regulated
Standard O-Rings	Silicone Rubber	7440-21-3	Non Regulated
Capsule Body	Polypropylene / polyethylene	9003-07-0 / 9010-79-1	Non Regulated
Capsule Vent Seals	Silicone Rubber	7440-21-3	Non Regulated
Filling Bell	Polycarbonate	25971-63-5	Non Regulated

3. Hazards identification

This product is not classified as being a dangerous preparation according to EC Directive 99/45/EC.

Component	Material of Construction	Most important hazards	Specific hazards
Filtration Media	Polypropylene	May be harmful if ingested in quantity or inhaled as dust. May irritate eyes.	n/a
Upstream Support	Polypropylene	"	"
Downstream Support	Polypropylene	"	"
Inner Support Core	Polypropylene / polyethylene	"	"
Outer Protection Cage	Polypropylene / polyethylene	"	"
Endcaps	Polypropylene / polyethylene	"	"
Endcap Insert	316 Stainless Steel	n/a	"
Standard O-Rings	Silicone Rubber	May be harmful if ingested in quantity or inhaled as dust. High concentrations of dust may cause pulmonary irritation. May irritate eyes.	"
Capsule Body	Polypropylene / polyethylene	"	"
Capsule Vent Seals	Silicone Rubber	"	"
Filling Bell	Polycarbonate	"	"

4. First aid measures

No first aid measures regarding skin or eye contact and ingestion are applicable to any of the components in an unused condition.

5. Fire fighting measures

General: The plastic components of these devices will melt and/or decompose under fire conditions. Once ignited, the plastic materials will add to the intensity of the fire with any specific potential hazard conditions listed below. Normally, molded parts burn slowly with a low smoke density and flaming drips, carbon monoxide and irritating oxygen containing organic substances are released.

Component	Material of Construction	Suitable extinguishing media	Hazard
Filtration Media	Polypropylene	Dry Powder, Carbon Dioxide or vaporising liquids.	Combustible
Upstream Support	Polypropylene	"	"
Downstream Support	Polypropylene	"	"
Inner Support Core	Polypropylene / polyethylene	"	"
Outer Protection Cage	Polypropylene / polyethylene	"	"
Endcaps	Polypropylene / polyethylene	"	"
Endcap Insert	316 Stainless Steel	n/a	n/a
Standard O-Rings	Silicone Rubber	n/a	n/a
Capsule Body	Polypropylene / polyethylene	Dry Powder, Carbon Dioxide or vaporising liquids.	Combustible
Capsule Vent Seals	Silicone Rubber	n/a	n/a
Filling Bell	Polycarbonate	Water spray or foam. CO ₂ & dry chemical are not recommended because their lack of cooling capacity may permit re-ignition.	Under fire conditions, polymeric materials decompose. Smoke may contain polymer fragments of varying compositions in addition to unidentified toxic and/or irritating compounds.

6. Accidental release measures

Due to the integral nature of these devices, they do not release materials to the environment when used within recommended operating temperature and pressure conditions. Liquids being processed through these devices may be released to the surroundings should the device fail due to temperature and pressure conditions outside of the recommended operating ranges. These releases should be dealt with according to the nature of the process liquids.

7. Handling and storage

General: Store in a cool dry location out of open sunlight, high temperatures and/or high humidity. Keep any containers closed when not in use.

Component	Material of Construction	Handling	Storage
Filtration Media	Polypropylene	No technical measures or specific precautions	No technical measures or specific precautions
Upstream Support	Polypropylene	"	"
Downstream Support	Polypropylene	"	"
Inner Support Core	Polypropylene / polyethylene	"	"
Outer Protection Cage	Polypropylene / polyethylene	"	"
Endcaps	Polypropylene / polyethylene	"	"
Endcap Insert	316 Stainless Steel	"	"
Standard O-Rings	Silicone Rubber	"	"
Capsule Body	Polypropylene / polyethylene	"	"
Capsule Vent Seals	Silicone Rubber	"	"
Filling Bell	Polycarbonate	"	"

8. Exposure controls

No measures regarding exposure controls are applicable to any of the components in an unused condition. Any ventilation, personal protection and respirator requirements will be dictated by the nature of the fluids being processed.

9. Physical and chemical properties

General: The polymeric material compounds of these devices are essentially chemically inert, water insoluble, with low vapour pressures. Chemical inertness varies with different polymers and the user should confirm the compatibility of these materials with the process fluids to be used.

Component	Material of Construction	Description	Odour	Melting Point (°C)	Solubility in water	Flash Point (°C)	Lower Explosive Limit	Auto Ignition Temp (°C)
Filtration Media	Polypropylene	Solid	n/a	155 - 170	Immiscible or Insoluble	n/a	n/a	n/a
Upstream Support	Polypropylene	"	"	"	"	"	"	"
Downstream Support	Polypropylene	"	"	"	"	"	"	"
Inner Support Core	Polypropylene / polyethylene	"	possible weak paraffinic	"	"	"	"	"
Outer Protection Cage	Polypropylene / polyethylene	"	possible weak paraffinic	"	"	"	"	"
Endcaps	Polypropylene / polyethylene	"	possible weak paraffinic	"	"	"	"	"
Endcap Insert	316 Stainless Steel	"	"	approx. 1200	"	"	"	"
Standard O-Rings	Silicone Rubber	"	"	approx. 250	"	"	"	"
Capsule Body	Polypropylene / polyethylene	"	possible weak paraffinic	155 - 170	"	"	"	"
Capsule Vent Seals	Silicone Rubber	"	"	approx. 250	"	"	"	"
Filling Bell	Polycarbonate	"	"	approx. 155	"	"	"	"

10. Stability and reactivity

Component	Material of Construction	Stability	Reaction with water	Other known hazards	Avoid contact with:				
					Water	Acids	Bases	Oxidisers	Combustibles
Filtration Media	Polypropylene	Stable at normal temperature and pressure	None	Can react with oxidising materials	N	N	N	Y	N
Upstream Support	Polypropylene	"	"	"	"	"	"	"	"
Downstream Support	Polypropylene	"	"	"	"	"	"	"	"
Inner Support Core	Polypropylene / polyethylene	"	"	"	"	"	"	"	"
Outer Protection Cage	Polypropylene / polyethylene	"	"	"	"	"	"	"	"
Endcaps	Polypropylene / polyethylene	"	"	"	"	"	"	"	"
Endcap Insert	316 Stainless Steel	"	"	None	N	N	N	N	N
Standard O-Rings	Silicone Rubber	"	"	Can react violently with calcium metal, metal acetylides and oxidising materials. May react on heating with metal hexafluorides and carbonates.	N	N	N	Y	N
Capsule Body	Polypropylene / polyethylene	"	"	Can react with oxidising materials	"	"	"	"	"
Capsule Vent Seals	Silicone Rubber	"	"	Can react violently with calcium metal, metal acetylides and oxidising materials. May react on heating with metal hexafluorides and carbonates.	"	"	"	"	"
Filling Bell	Polycarbonate	Thermally stable at normal use temperature. Avoid temperatures above 425C. Product can decompose at elevated temperatures.	Absorption - 24hrs 0.15%	Can react with oxidising materials	"	"	"	"	"

11. Toxicological information

All materials used in the construction of PEPLYN PLUS products that have product contact have met the requirements of the current USP Biological Reactivity Tests, In Vivo to Plastics Class VI-121°C. All jointed surfaces are assembled by the use of heat sealing technology. No resins or binders are used in the manufacture of the filter and no surfactants are added to aid wetting.

An independent research establishment has assessed the biological safety associated with the use of PEPLYN PLUS filters designed for processing pharmaceutical products. The materials used in the construction of PEPLYN PLUS products meet the requirements of the current USP <88> Biological Reactivity tests at Plastics Class VI – 121°C.

- **Carcinogenicity:** No components are listed as carcinogenic by IARC, NIOSH, NTP or OSHA
- **Endocrine Disrupters:** To the best of our knowledge, none of the components are suspected endocrine disrupters

Exposure limits

	OSHA PEL	ACGIH TLV	NIOSH REL
All components:	None listed	None listed	None listed

12. Ecological information

- **Mobility:** None
- **Bioaccumulation:** None
- **Persistence / degradability:** Very low UV degradability.
- **Ecotoxicity:** No indication that this material is being a risk to the environment.
- **Aquatic toxicity:** Insoluble non-toxic solid material (no water hazard).

13. Disposal considerations

None of the components of these devices are listed as hazardous wastes. The liquid processes through these devices may leave residual materials, which are subject to hazardous waste regulations, and would, therefore, subject the used devices to applicable disposal regulations. Waste devices should be disposed of in a manner consistent with federal, state, and local legislation and regulations.

European Union:

When ready for disposal, these devices should be considered according to the European Waste catalogue (replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste) as part of the following category: 20 01 39: municipal wastes (household waste and similar commercial, industrial and institutional wastes) including separately collection fractions (except 15 01) - plastics (unless contaminated).

General disposal considerations:

Where facilities exist, domnick hunter limited encourages the recycling of these products. domnick hunter will cooperate with customers and their disposal facilities by providing as much information on active compounds and materials of construction as possible, consistent with the need to safeguard company proprietary information. The user should consult with their regulatory personnel before placing these products into the conventional solid waste stream.

14. Transport information

The transport of these devices is not regulated by USDOT, ICAO/IATA, ADR, IMO or HSE (UK) as hazardous material or dangerous goods. However, once used, these devices may contain residual materials that are regulated materials. The user should determine the applicability of current regulations before shipping used devices.

15. Regulatory information

United States

All component parts of these devices are listed on the USEPA Toxic Substances Control Act (TSCA) Inventory or are covered by the polymer exemption of the Act.

European Union:

European labeling in accordance with applicable EC Directives:

- Hazard symbols: N/A
- Risk Phrases: N/A
- Safety Phrases: N/A

United Kingdom:

- The Control of Substances Hazardous to Health Regulations 2002 Rating: L
- Chemicals (Hazard Information and Packaging for Supply) Regulations 2002: N/A

Canada:

As manufactured articles, these devices are exempt from WHMIS classification.

16. Other Information

© Parker Hannifin Limited. All rights reserved. The information set forth herein has been gathered from standard reference materials and/or supplier test data and is to the best knowledge and belief of domnick hunter, Process Filtration accurate and reliable. Such information is offered solely for your consideration, investigation and verification, and it is not suggested or guaranteed that the hazard precautions or procedures mentioned are the only ones which exist. Parker Domnick Hunter, Process Filtration makes no warranties, expressed or implied, with respect to the use of such information or the use of the specific material identified herein in combination with any other material or process, and assumes no responsibility therefor.