

PRODUCT SAFETY DATA INFORMATION

Date: 16 December 2020

Data Sheet Number: PSDS GPS-00183

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers GeneDisc® Plates

Example Product name(s): GeneDisc Pathogenic *E. coli* O157 06 (See Appendix 1)

Example Part Number(s): GECO157106006 (See Appendix 1)

The articles detailed above are intended for user protection detection and quantification of DNA by real-time PCR.

For further information on Pall products, please visit Pall at <https://www.pall.com/en/about-pall.html>

This product can expose you to chemicals including DEHP, which is a known in the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov

However, GeneDisc plates placed on the market in the State of California by Pall are not intended for 'consumer' sale, and are for professional or industrial use only. Therefore, the only anticipated exposure to these items would be through 'occupational exposure' which does not require mandatory labelling of all articles.

In line with the 'Questions and Answers for business' (dated August 2017) on the labelling requirements – Q41 - an SDS may be used to convey warnings for occupational exposure, but Pall has alternatively elected to use this PSDS document to convey that information. Should you have any questions related to the information provided by Pall or a specific product enquiry please do not hesitate to contact your local Pall Customer Services department.

SECTION 2 - Hazards Identification

Product definition: Article.

These products are is not classified as hazardous according to REACH Regulation 1907/2006, or European CLP/GHS Regulation 1272/2008.

GHS Signal word: No signal word applicable

Hazard statements: No known significant effects or critical hazards

Special packaging requirements: Not applicable.

PRODUCT SAFETY DATA INFORMATION

Date: 16 December 2020

Data Sheet Number: PSDS GPS-00183

SECTION 3 - Materials of Construction

3.1 The product detailed in Section 1 are comprised of the following materials:

Material Name	CAS Number	Percentage Composition
Polycarbonate	CAS: 25037-45-0	≤60
Polypropylene	CAS: 9003-07-0	≤40
PCR reagents	Pall proprietary	< 1%

plus packaging comprised of the following materials:

Material Name	CAS Number	Percentage Composition
Polyethylene bagging	CAS: 9002-88-4	1.7%
Cardboard box	n/a	30%
Instruction for use	n/a	5%
Certificate of conformity	n/a	1.25%

These products are not known to contain BADGE, NOGE, or BFDGE.

Trace additives will not be present in the plastic components.

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the article.

BPA may be present but is not known to be present in the finished articles above 0.1%.

There are no current REACH SVHC substances known to be present in the finished articles above 0.1%.

There are no current ROHS2 Directive (2011/65/EU) and amendment (2015/863) substances of concern (including Lead, Cadmium, Mercury, Hexavalent Chromium, Polybrominated biphenyl (PBB), Polybrominated diphenyl ether (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Benzyl Butyl Phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP)) known to be present in the materials employed in excess of the limits laid down, based on information from our suppliers and knowledge of substances used within Pall the manufacturing facility.

Pall product does not employ natural rubber latex, or latex derivatives in their construction.

These products (see appendix 1) do not contain animal materials (i.e. animal parts, tissues, or body fluids). However, to assist our customers in performing a TSE/BSE risk assessment, we are pleased to provide the following information:

Pall filters for laboratory applications may utilise components which are fabricated from plastic resins containing animal-derived additives at trace levels such as tallow-derived substances. Please be advised that tallow-derived additives are not considered specified BSE risk materials according to the current revision of

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PRODUCT SAFETY DATA INFORMATION

Date: 16 December 2020

Data Sheet Number: PSDS GPS-00183

the U.S. Code of Federal Regulations, Title 21 of part 189.5. Furthermore, the CPMP's *Note for guidance on minimising the risk of transmitting animal spongiform encephalopathies via human and veterinary medicinal products* (EMA410/01 rev 3) gives specific consideration to tallow derivatives and state they are unlikely to be infectious due to the rigorous processing steps used during their manufacture (an example of which is transesterification, or hydrolysis, at not less than 200°C under pressure for not less than 20 minutes).

SECTION 4 - First Aid Measures

4.1 First aid measures

Always address any contaminants present on the filter as the result of use.

Eye Contact:	Unlikely mode of exposure - Eye injury could result from physical impact. Get medical attention immediately.
Inhalation:	Inhalation is not considered a likely route of exposure for these articles as supplied by Pall.
Skin Contact:	Wash with soap and water. If irritation persists, get medical attention.>
Ingestion:	Unlikely mode of exposure - However if ingestion occurs, seek medical attention
Protection of first-aiders:	No action shall be taken involving any personal risk or without suitable training.

4.2 Key symptoms and effects

No known significant effects or critical hazards related to the materials of construction of the plate as supplied.

SECTION 5 - Fire Fighting Measures

5.1 Extinguishing media

Select an extinguish medium suitable for surrounding / working environment.

Not Known

5.2 Specific Hazards

No specific fire or explosion hazard

Hazardous thermal decomposition products: Decomposition products may include the following materials:
carbon dioxide carbon monoxide,

PRODUCT SAFETY DATA INFORMATION

Date: 16 December 2020

Data Sheet Number: PSDS GPS-00183

5.3 Advice to Fire Fighters

Special precaution required. Fire-fighters should wear appropriate protective equipment, including self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

No special precaution is required:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode

SECTION 6 - Accidental Release Measures

No special measures are required.

6.1 Personal precautions, protective equipment and emergency procedures

No special measures are required.

For used plate always address any contaminants present on the plate as the result of use.

6.2 Environmental precautions

For unused plates, place in designated waste container appropriate to the materials of construction listed in Section 3 and dispose of in accordance with local regulations via a licensed waste disposal contractor.

For used plates, using clear-up, containment and appropriate PPE measures related to the users product being filtered / tested and the materials of construction detailed in Section 3.

6.3 Spillage containment and cleaning up

Use suitable equipment to collect the plate and place in a designated, labelled waste container.

Care should be taken to consider the nature of any contamination on the plate as the result of use and suitable PPE employed for handling that form of waste.

Dispose of waste via a licensed waste disposal contractor.

SECTION 7 – Handling and Storage

7.1 Handling

Put on appropriate personal protective equipment for the working environment (See Section 8). Consult details of product being filtered for specific advice. Avoid activities that can damage the product.

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PRODUCT SAFETY DATA INFORMATION

Date: 16 December 2020

Data Sheet Number: PSDS GPS-00183

Follow good hygiene practices. Eating, drinking and smoking are generally prohibited in areas where this product is handled, stored or processed.

Wear gloves to prevent contamination of the product and maintain cleanliness of the unused plate.

7.2 Storage

In the received condition, special protective equipment is not needed during handling and normal use of these product. However, gloves are recommended to prevent contamination of the plate and maintain cleanliness. Handling of used plates must take into account the nature of potential contaminants.

The article is supplied dry, without the presence of any preserving fluid.

Store in a cool, clean environment.

Handle with care to avoid damage or abrading.

Do not expose to direct sunlight or other radiation or direct weather conditions.

Store in original shipping bag or boxing. Once the outer packaging is opened GeneDisc Plates must be stored in a sealed plastic bag at 4°C. Consult individual instructions for use information for shelf life.

Pall recommends a visual inspection prior to use. Do not use if the product or packaging is damaged (please contact Pall for further advice).

Please also consult the Pall instructions for use information on the product prior to use.

SECTION 8 - Exposure Controls/Personal Protection

8.1 Control parameters

Occupational Exposure limits: Not known

Recommended monitoring procedures: Not known

8.2 Exposure controls

There are no special ventilation requirements for the article as supplied in the new and unused condition.

Hygiene Measures: No special measures required.

Hand protection: Disposable gloves are recommended to ensure products remains clean during installation and post use as required by the users local risk assessments.

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PRODUCT SAFETY DATA INFORMATION

Date: 16 December 2020

Data Sheet Number: PSDS GPS-00183

Environmental Exposure Controls: No special measures required. Consider nature of product being tested.

After the filter has been used additional exposure controls care should be taken in line with the nature of any contaminant on the filter as a result of its use.

SECTION 9 - Physical and Chemical Properties

Appearance:	GeneDisc plate
Physical state:	Solid
Colour:	White and blue printed label on colourless polymer moulded support material wells
Solubility:	Not Applicable
Auto-ignition temperature:	Polycarbonate 580 °C, Polypropylene 388 °C
Sensitive to shock:	Mechanical / thermal shock can result in damage to the plates

SECTION 10 – Stability and Reactivity

Reactivity:	Stable under the recommended conditions of use and storage.
Chemical Stability:	Stable under recommended conditions of use and storage.
Hazardous Polymerisation:	Under recommended conditions of storage and use, hazardous reactions will not occur
Other hazardous reactions:	Consult details of product being filtered for specific advice. Under normal conditions of storage and use, no hazardous reactions will occur.
Conditions to Avoid:	Avoid conditions that soften, swell or adversely affect the plate or its materials of construction. Do not allow fluids to freeze on the filter.
Incompatible Materials:	Reactive or incompatible with the following materials: Strong oxidizing materials
Decomposition Products:	Under recommended conditions of use or storage, no hazardous decomposition products will be produced.

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PRODUCT SAFETY DATA INFORMATION

Date: 16 December 2020

Data Sheet Number: PSDS GPS-00183

SECTION 11 - Toxicological Information

The information in this section contains generic advice and guidance in respect of the unused filter as supplied. Consult SDS details of the product being filtered for specific advice and recommendations.

11.1 Acute Toxicity

Irritation/Corrosion/Sensitisation: No known concern to unused filter as supplied

Mutagenicity / Carcinogenicity / Reproductive Toxicity / Teratogenicity: No known concern for the materials of construction of the plate as supplied (new and unused)

Aspiration Hazard: Not applicable

Potential acute health effects: No known significant effects or critical hazards

11.2 Chronic health effects

No known significant effects or critical hazards for the unused filter as supplied.

Carcinogenicity: No specific test data available, no evidence for hazardous properties

SECTION 12 - Ecological Information

Pall filters are not expected to degrade in contact with soil or water under ambient conditions.

SECTION 13 - Disposal Information

The information in this section contains generic advice and guidance.

Product

Methods of disposal:

Consideration must be given to the nature of any contaminant resulting from its use.

The generation of waste should be avoided or minimized wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

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PRODUCT SAFETY DATA INFORMATION

Date: 16 December 2020

Data Sheet Number: PSDS GPS-00183

Disposal/handling of the used and unused plates should be in-line with national legislation and local regulatory requirements for the materials present. Due consideration must also be made to the nature of the contaminants on the plates as the result of use.

Hazardous Waste: To the best of our knowledge, this product if unused is not regarded as hazardous waste as defined by the EU Directive 91/689/EEC and amendments.

Used filter cartridges should be disposed of as clinical waste due to the nature of the contaminants on the filters as a result of use. Therefore, used filters may be classified as hazardous – clinical waste.

Packaging

Bagging: Plastic (polyethylene)

Box: Cardboard

The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled where suitable arrangements and facilities exist. Incineration or land-fill should only be considered where re-cycling is not feasible.

SECTION 14 - Transport Information

The clean and un-used filter, supplied in its original packaging, is not classified as dangerous goods under ADR, RID, IMDG or IATA regulations.

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Notice to Reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above Pall Corporation, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any materials is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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PRODUCT SAFETY DATA INFORMATION

Date: 16 December 2020

Data Sheet Number: PSDS GPS-00183

APPENDIX 1:

Here are some examples of product name and part numbers

Part Number	Product name
GBSPOBC303012	GeneDisc Beer Spoilage Bacteria 3 samples
GBSPOBC306006	GeneDisc Beer Spoilage Bacteria 6 samples
GTABSPO106006	GeneDisc plate Spoilage TAB
GYEASCR106006	GeneDisc Plate for Yeast Screening 06
GYEASID106006	GeneDisc Plate for Yeast ID 06
GECOSLM206006	GeneDisc Pathogenic <i>E. coli</i> O157 & <i>Salmonella spp</i> 06
GECOSLM212006	GeneDisc Pathogenic <i>E. coli</i> O157 & <i>Salmonella spp</i> 12
GLISDUO106006	GeneDisc <i>Listeria</i> DUO 06
GLISDUO112006	GENEDISC <i>LISTERIA</i> DUO 12
GLISMON206006	GENEDISC <i>LISTERIA MONOCYTOGENES</i> 06
GLISMON212006	GeneDisc <i>Listeria monocytogenes</i> 12
GLISTID106006	GENEDISC <i>LISTERIA</i> ID 06
GSLMSPP206006	GENEDISC <i>SALMONELLA SPP</i> 06
GSLMSPP212006	GENEDISC <i>SALMONELLA SPP</i> 12
GSTECSL206006	GeneDisc ShigaToxic <i>E. coli</i> & <i>Salmonella spp</i> 06
GSTECSL212006	GeneDisc ShigaToxic <i>E. coli</i> & <i>Salmonella spp</i> 12
GSTEHEC112006	GeneDisc ShigaToxic <i>E. coli</i> 12
GCAMPSL103012	GeneDisc plate <i>Campylobacter</i> & <i>Salmonella</i> v2 03
GCAMPSL106006	GeneDisc plate <i>Campylobacter</i> & <i>Salmonella</i> v2 06
GCAMPSL112006	GeneDisc plate <i>Campylobacter</i> & <i>Salmonella</i> v2 12

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