Instructions for Use

CIM® Octa Oligo dT18 0.05 mL Monolithic Column (C12 Linker) (2 µm channels)

CIM Convective Interaction Media®
BIA-128.1219-2

SARTORIUS

Contents

1. About These Instructions for Use

These instructions are part of the device. They apply to the device product number indicated on the cover page.

2. Safety

⚠WARNING
Denotes a hazard that may result in death or severe injury if it is not avoided.

⚠CAUTION
Denotes a hazard that may result in moderate or minor injury if it is not avoided.

NOTICE
Denotes a hazard that may result in property damage if it is not avoided.

2.1. Intended Use

CIM® Octa Monoliths are miniaturized eight-in-line columns, designed for automatic and parallel chromatographic screening of process development parameters. The columns are used with a robotic liquid handling workstation with a needle. Inside CIM® Octa columns are CIM® monoliths with homogeneous channel size and surface chemistry. The properties of the stationary phase are directly comparable to CIM® preparative chromatographic columns, making CIM® Octa a robust tool in early process development stages.

2.2. Safety Note

Follow the guidelines in this Instructions for Use. Improper use may result in malfunction, personal injury, or damage of the product or material. Follow safety instructions, wear gloves, safety glasses, and a lab coat during operation.

3. Technical Data

Column chemistry	Oligo dT18 coupled to CDI-activated matrix, C12 Linker
Channel radius	1050 nm (950 nm – 1150 nm)
Support matrix	Poly(glycidyl methacrylate -co- ethylene dimethacrylate)
Monolith dimensions	Diameter: 5 mm; length: 2.5 mm; bed volume (CV): 0.05 mL
Column format	Row of eight-in-line columns, material: polypropylene (PP) and polyethylene (HDPE)
Operating parameters	Flow rate between 30-270 cm/h | 2 - 18 CV/min | 100 - 900 µl/min

Maximum pressure	0.8 MPa, 8.0 bar, 116 psi
Operating temperature	4 °C (39 °F) to 30 °C (86 °F)
Chemical stability	All commonly used aqueous buffers, sodium hydroxide (short term up to 0.5 M, see cleaning guidelines), 6 M guanidine hydrochloride, 12 M guanidine thiocyanate, 10 M urea, 20 % ethanol.
Recommended pH	Working range 2-10, Cleaning in place 2–13
Storage conditions	2 °C (36 °F) to 25 °C (77 °F); 20 % ethanol
Shelf life	3 years

4. Installation

Remove the product from its shipping box or crate and place on a flat surface. Carefully inspect the product for any damage that may have occurred during shipping. Immediately report any such damage to your vendor and the courier. The product is shipped in the designated storage solution at ambient temperature and should be stored upon receiving as stated under Technical Data.

NOTICE
Do not store the product below 0 °C (32 °F).

5. Getting Started

The CIM® Octa columns require a fully automated robotic system and are operated with a needle. CIM® Octa columns are supplied as a row of eight-in-line columns. Each row of columns comes with a holder for easier handling. Each individual column is removable from the holder. Operating parameters can be found under Technical Data. Before use, remove the top and bottom cover seals. Place the columns in the array plate to a tight fit and start the process by removing storage solution.

5.1. General Recommendations

The following are general guidelines to consider when working with chromatography. The guidelines may not apply to specific column chemistry or sample properties.

- Treat loading material appropriately (e.g. pre-treat, filter, concentrate / dilute, etc.). For more details, please refer to the Guideline 'Pre-treatment of complex biological samples before column purification and regeneration procedures for columns with increased back pressure' (biaseparations.com/en/library/guidelines).
- Always use freshly prepared mobile phases, filtered through 0.2 µm filter, compatible with mobile phases.
- Air bubbles will not disturb the stationary phase and can be washed out of the column. However, drying the monolith risks damaging the stationary phase.
- Surfactants can improve recoveries in virus purification. Non-ionic surfactants will not interact with ion exchange chromatography media. Non-UV-absorbing (at working wavelengths) surfactants will improve the baseline signal.
- Ensure all components of the system used are compatible with the working solutions (e.g. sodium hydroxide, organic solvents, high salt concentrations, etc).

NOTICE
Always ensure mobile phases are compatible before mixing them or applying consecutively on the column. Examples of in-compatible buffers are: magnesium ion-containing buffers and sodium hydroxide (forms precipitate), acetonitrile and sodium hydroxide (forms ammonia and acetate), ammonium acetate and sodium hydroxide (potential formation of explosive atmosphere). Wash the column with water or another compatible solution when using two incompatible solutions consecutively.

6. Operating the Column

6.1. Equilibration

The column should be equilibrated before use. Equilibration mobile phase should be of same or similar composition to the sample.

1. Wash the column with 10 CV of water to prevent mixing of incompatible buffers.
2. Wash the column with at least 10 CV of elution mobile phase.
3. Wash the column with at least 10 CV of binding mobile phase.

7. Cleaning | Maintenance

Cleaning and maintenance of the column may improve its lifetime and increase reproducibility. Sample properties should be taken into account for column cleaning.

7.1. Cleaning in Place (CIP)

Column cleaning is recommended between purification runs or cycles. A reduced flow rate is suggested for column cleaning to extend contact time with the cleaning and neutralisation-equilibration solutions (between 0.1 and 0.5 CV/min).

⚠CAUTION
Remain below the maximum pressure specified in Technical Data.

⚠CAUTION
Ensure compatibility between the current column solution and cleaning solutions (see examples in General Recommendations).

1. If needed wash the column with 10 CV of water to prevent mixing of incompatible buffers.
2. Wash the column with at least 10 CV of 0.5 M NaOH. A contact time of up to 30 min is recommended.
3. Wash the column with 10 CV of water.
4. Wash the column with at least 10 CV of a neutralisation-equilibration solution. A buffer (e.g. Tris pH 7) with high salt

concentration is recommended (e.g. binding mobile phase). A solution of 1 M ammonium acetate may be used. **Note:** Collect ammonium acetate solution in a separate waste container to avoid mixing with NaOH.

To improve cleaning, extend the contact time with cleaning solution or implement cleaning steps specific to the contaminants present in the sample.

8. Storage

Clean and equilibrate the column before storage. The column can be stored in working buffers overnight.

NOTICE
NaOH-ethanol mixtures at any concentration form ethoxide anions that are highly destructive to biomolecules, and ligands on chromatography media. Neutralise the column environment before introducing ethanol.

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1. Wash the column with 10 CV deionised water.
2. Wash the column with 10 CV of storage solution. **Note:** Reduce the flow rate when using viscous solvents (such as ethanol) to avoid a pressure increase.
3. Seal the column with bottom and upper seal and store at the temperature specified in Technical Data. If there is a possibility of biological contamination from the sample it is recommended to store the column between 2 °C (36 °F) and 8 °C (46 °F).

9. Troubleshooting

Problems arising during the analysis are usually related to the device, sample, mobile phase, or the instrumentation. It is advisable to use an elimination approach to exclude possible causes. Please refer to our troubleshooting guide (biaseparations.com/en/library/guidelines).

10. Decommissioning | Transportation

If there is reason to return the product, complete a Return Form (biaseparations.com/en/terms-conditions) and contact help.bia@sartorius.com.

Contaminated samples used during the process that could cause biological or chemical hazards are potentially hazardous substances. If the product has come into contact with hazardous substances, steps must be taken to ensure proper decontamination and declaration.

Procedure
Decontaminate the product. The operator of the product is responsible for adhering to local government regulations on the proper decontamination and declaration for transport and disposal.

11. Ordering Information

Transferring the workflow to a different scale or format (analytical, screening) is simple with CIM®. Contact your local support to find the appropriate products.

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The information and figures contained in these instructions correspond to the version date specified below.
Sartorius reserves the right to make changes to the technology, features, specifications and design of the equipment without notice.
Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote the other gender as well.

Last updated

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