



## Regulatory Data Sheet

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This Regulatory Data Sheet is provided as a courtesy in response to a customer request.

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## 3M™ Betapure™ AU Series Filter Cartridge - C11 Grade

### Product Identification Numbers

AU01C11NG, AU05C11NG, AU09C11NG, AU19C11NG, AU20C11BA, AU20C11FA, AU20C11FK, AU29C11NG, AU30C11BA, AU30C11CC, AU30C11FA, AU30C11NG, AU40C11CA, 70-0200-3125-1, 70-0200-3178-0, 70-0200-3235-8, 70-0200-3257-2, 70-0200-3258-0, 70-0201-2751-3, 70-0201-3792-6, 70-0201-5307-1, 70-0201-6789-9, 70-0201-9853-0, 70-0202-4301-3, 70-0202-9220-0, 70-0203-5134-5, 7010381688, 7010411120, 7000125429, 7000029245, 7010381514, 7010380277, 7100205640, 7000125444, 7010314591, 7010381238, 7010381952, 7000050957, 7010410973

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RDSs are available at [www.3M.com](http://www.3M.com)

## Regulations and Industry Standards

### SDS (US OSHA)

This product is an article and therefore is not subject to the requirements of the US Occupational Safety and Health Administration's (OSHA) Hazardous Communications Standard 29 CFR 1910.1200(b)(6)(v) to provide a Safety Data Sheet (SDS).

### California Proposition 65

This product is an industrial product manufactured outside of California. It has not been assessed for consumer sale or use. Contact the manufacturer if more information is needed for your use.

### Drug Master File

A Drug Master File for this product is available upon request. Please contact the manufacturer for more information or to obtain a Letter of Authorization (LOA).

### EU Food Allergens

This product complies with Regulation (EU) 1169/2011 on the provision of food information to consumers, as there is no intentionally added component identified in Annex II of this regulation. Specifically, none of the following are intentionally added: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seeds, sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/L expressed as sulphur dioxide, lupin, mollusks, and/or derivatives thereof.

**EU REACH**

This product, including any article that the product is composed of, does not contain at greater than 0.1% by weight a Substance of Very High Concern (SVHC) substance identified according to Article 59 of REACH. This declaration reflects the substances on the candidate SVHC list, effective January 2024.

**EU RoHS**

This product does not exceed the maximum concentration values (MCVs) set under EU Directive 2011/65/EU (RoHS recast/RoHS 2), as stated in Annex II to that directive. This means that each of the homogenous materials within this product does not exceed the following MCVs: (a) 0.1% (by weight) for lead, mercury, hexavalent chromium, polybrominated biphenyls or polybrominated diphenyl ethers; and (b) 0.01% (by weight) for cadmium.

**MEM Elution Cytotoxicity Testing**

Representative samples of this product have been tested and found to meet the requirements of the ISO10993-5 elution test and are considered non-cytotoxic under the standard.

**TSCA 8(a) Nanomaterial Reporting**

This product does not contain nanoparticles subject to reporting under TSCA Section 8(a). Under the “Chemical Substances When Manufactured or Processed as Nanoscale Materials: TSCA Reporting and Recordkeeping Requirements” rule, a reportable nanoparticle is defined as having at least one dimension in the size range of 1 – 100 nm and is manufactured or processed to exhibit unique and novel properties because of its size.

**USP <232>/<233> and ICH Q3D Elemental Impurities**

Data on USP<232>/<233> and ICH Q3D Elemental Impurities is not currently available for this product.

**USP<88> Class VI Biological Reactivity Tests for Plastics**

Representative samples of this product have been tested and found to meet the requirements of the USP<88> guidelines for plastics Class VI at a minimum of 70°C.

**Definitions**

*Note: all Definitions take Disclaimers into account and apply to the “Chemicals and/or Compounds of Interest” and/or “Per and poly-fluoroalkyl Substances (PFAS)” sections only*

Terms	Definitions
Contains*	Present based on composition information disclosed by 3M suppliers, analytical testing, or both.
Not known to contain*	1. Analytical measurement for presence is not currently available; 2. If measurement is possible, a) The material has not been identified or disclosed to 3M and b) The material has not been specifically quantified or detected; OR c) Based on information from raw material suppliers, possible presence as an impurity or by-product at or below regulatory thresholds (e.g., 0.1 or 0.01 %)
Intentionally added**	Desired in the final product to provide a specific characteristic, appearance, or quality and/or to perform a specific function.
Not intentionally added**	By-product(s), impurity(ies) and/or unintended artifact(s) resulting from the formulation and/or manufacture of a material.
By-product***	A chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.
Impurity***	A chemical substance which is unintentionally present with another chemical substance (e.g., residuals, catalysts, process solvents).

*\*Terms apply to the Chemicals and/or Compounds of Interest Section only (if section is present)*

*\*\*Terms apply to the PFAS Section only (if section is present)*

*\*\*\*Terms apply to both the Chemicals and/or Compounds of Interest and PFAS Sections (if section(s) are present)*

Disclaimers: The information provided in this document related to material content represents the Manufacturer's knowledge and belief, which may be based in whole or in part on information provided by suppliers to the Manufacturer. This is intended to answer commonly asked questions about the Manufacturer's products and is not intended to be a comprehensive listing of all substances that may be of interest or that may be regulated in this or other products of the Manufacturer, nor is it intended to be a comprehensive summary of any and all regulations that may apply to this product. Where substances are listed, their listing does not infer or constitute a judgment as to their safety, environmental or health impacts. Information is supplied upon the condition that the persons receiving the same will make their own determination as to its suitability for their purposes prior to use. Customers are encouraged to consult with legal and regulatory experts to determine applicable regulations in light of intended use of the product.

Limitation of Remedies and Liability: In the event any Product is proven not to conform with the information in this document, then to the extent permitted by law, the Manufacturer's entire liability and Buyer's exclusive remedy, will be at the Manufacturer's option either: (i) replacement of Product with a conforming product, or (ii) refund of the purchase price paid by Buyer for each non-conforming Product, within a reasonable time after written notification of said non-conformance and return of said Product to the Manufacturer. The Manufacturer shall not under any circumstances be liable for direct, incidental, special, or consequential damages (including but not limited to loss of profits, revenue, or business) related to or arising out of this certification, including, the use, misuse or inability to use the Product. Unless stated otherwise in writing, the foregoing language cannot be waived, modified, or supplemented in any manner whatsoever.