



## 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 2022.

**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.

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