Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

Your Goal is Zero Positives. So is ours.

Granulated and Ready-to-Use Culture Media for Secure Media Fill Trials

When performing media fill trials, you shouldn't have to worry about your culture media compromising your validated process. Every batch of irradiated media is tested to ensure quality. Our granulated media has excellent cold filtration properties to avoid clogged filters. Our media is triple-wrapped and cleanroom ready.

Superior quality and reliability

- Choice of compositions: standard Tryptic Soy Broth or non-animal peptone broth
- Flexible formats: granulated culture media in 500 g or 5 kg triple-wrapped drums; ready-to-use liquid in 10 L bags; and customization available upon request
- Validated sterilization and irradiation processes
- Mycoplasma and BSE/TSE free
- Triple-wrapped for safe transfer to cleanrooms
- Proven growth performance exceeding EP and USP standards

MERCK

Aim for Accuracy with Reliable Culture Media

True safety

Accurate and convenient media fill trials

False results due to low-quality culture media are a major concern in media fill trials. With the robust validated process of our high-quality broths, you can eliminate media-related positives from your aseptic process simulation. Our stringent sterilization and irradiation processes ensures the removal of viable yeasts, molds, spores and mycoplasma.

Our granulated and liquid media are both available as either Tryptic Soy Broth (TSB) or non-animal Vegetable Peptone Broth (VPB). Simply choose the format that suits your needs:

- **Dehydrated culture media:** Gamma-irradiated; highly soluble and filterable in low-dust granulated form; triple-wrapped for secure cleanroom use
- **Ready-to-use liquid broth:** Sterilized by autoclave, our ready-to use liquid media is supplied triple-wrapped in gas-impermeable bags for aseptic connections; direct link to production vessels and delivery systems

Top standards

Internationally compliant quality — BSE/TSE Free

Whether vegetable or animal-based, every batch of our culture media is produced and tested in compliance with stringent international standards. For additional security, we source all bovine ingredients exclusively from countries classified by the OIE as negligible risk countries to ensure the BSE/TSE Free media.

- EU Note for Guidance (EMA/410/01 Rev. 03) aimed at minimizing the risk of infection from animal spongiform encephalopathy via pharmaceutical products
- FDA standards for validation of aseptic preparations
- All culture media with bovine peptones already comply with the future EU Directive on minimizing the risk of BSE from products of animal origin

Total confidence

Comprehensive documentation

We supply detailed documentation for every culture medium we supply to support your GMP aseptic process and simplify audits.

- **BSE/TSE certificates** provide full traceability of all animal-derived material and facilitate compliance with requirements
- **Quality agreements with suppliers** ensure the consistent quality of our products
- **Certificates of Analysis** include detailed information about each product, such as actual results obtained from quality control testing

Granulated Culture Media

Minimal dust, maximum security and performance

Our granulated culture media has been carefully formulated to ensure pharmaceutical manufacturers can perform efficient media fill trials with minimal risks.

- Reduced dust spread during preparation lowers health risks and prevents environmental contamination. Less dust on equipment also eases handling and cleaning.
- Excellent solubility significantly reduces preparation time and effort.
- Optimized cold filtration properties, from raw materials to final product, help prolong filter life and reduce replacements, saving time and costs.
- Gamma-irradiated at a high dose of 48–76 kGy to reduce microbial cross-contamination and risk of false positives due to irradiation survivals.

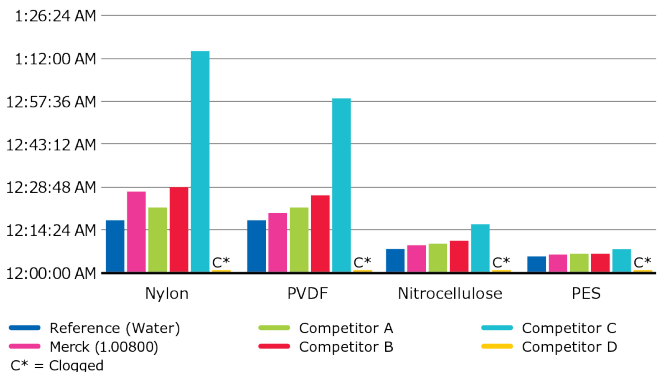
Optimized cold-filtration avoids clogs and costs

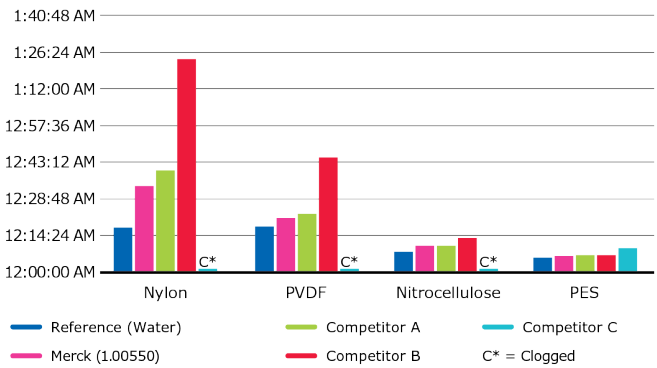
Most aseptic filling processes involve a sterile filtration step, which is typically part of the process simulation with culture media. The large amounts of liquid running through the filters make this step both time-consuming and expensive. This is of particular concern when problems such as clogs occur.

We take every measure to ensure the reliable cold-filtration properties of our granulated culture media. Filtration tests are performed at every stage and for every batch:

- Qualification of raw materials
- Control of incoming peptones
- Pre-batch samples and in-process testing
- End product testing

Filterability Study





	Nylon	PVDF	Nitrocellulose	PES
Reference (Water)	00:17:38	00:17:40	00:08:07	00:05:29
Merck	00:27:06	00:20:14	00:09:23	00:06:09
Competitor A	00:21:49	00:21:54	00:09:58	00:06:30
Competitor B	00:28:44	00:25:52	00:10:51	00:06:26
Competitor C	01:14:14	00:58:33	00:16:27	00:08:00
Competitor D	clogged	clogged	clogged	clogged

Figure 1: Filterability Comparison Tryptic Soy Broth (TSB)

	Nylon	PVDF	Nitrocellulose	PES
Reference (Water)	00:17:38	00:17:40	00:08:07	00:05:29
Merck	00:33:54	00:21:17	00:10:13	00:06:09
Competitor A	00:39:56	00:22:52	00:10:26	00:06:32
Competitor B	01:23:32	00:44:51	00:13:27	00:06:40
Competitor C	clogged	clogged	clogged	00:09:16

Figure 2: Filterability Comparison Vegetable Peptone Broth (VPB)

More data about the study is available in a comprehensive application note. To obtain a copy, please contact your sales representative, or visit: **SigmaAldrich.com/MediaFills**

Filters used in study

Ordering No.	Material	Manufacturer	Pore Size
GNWP04700	Nylon Membrane	Merck	0.20 µm
GVWP04700	Durapore® Polyvinylidene Fluoride (PVDF)	Merck	0.22 µm
GSWP04700	Nitrocellulose Membrane	Merck	0.22 µm
GPWP04700	Millipore Express® Plus Polyethersulfone (PES)	Merck	0.22 µm

Ready-to-Use Liquid Media

Pre-filtered and ready to go

Our ready-to-use culture media include Tryptic Soy Broth (TSB) prepared according to European and US pharmacopeias. Alternatively, you can choose our Vegetable Peptone Broth (VPB). These liquid broths are moist heat sterilized, and then undergo a two-step pre-filtration process consisting of a particulate filter to avoid clogging, and a 0.2 µm filter for sterilization. The media is supplied in 10 liter bags that are triple-wrapped and gamma-irradiated at 9–20 kGy for enhanced safety. Larger volumes are also available upon request.

Gas-impermeable bags for greater safety and convenience

The self-collapsing bags include an 80 cm long tube with an MPC connector (male insert 3/8”), which enables direct connection to the filling line. An injection port with a septum allows the supplementation of the broth medium, for example with neutralizers, antibiotics inactivators, or growth supplements.

Connection of bag with: inlet tubing, outlet tubing, and injection port (from left to right)

Handle at top of bag for convenient use

10 L bag containing TSB in transport box

Ordering Information

Ordering No	Description	Granulated	Ready-to-use	Package Size
1008000500	Tryptic Soy Broth Irradiated	•		500 g
1008005000	Tryptic Soy Broth Irradiated	•		5 kg
1463160001	Tryptic Soy Broth (in self-collapsing, single-use bag)		•	10 L
1005500500	Tryptic Soy Broth Non-animal, irradiated	•		500 g
1005505000	Tryptic Soy Broth Non-animal, irradiated	•		5 kg
1463320001	Vegetable Peptone Broth (in self-collapsing, single use bag)		•	10 L
1087205000	Thioglycolate Broth Non-animal, irradiated	•		5 kg

Please contact your local sales representative for customized solutions.

See the benefits in action

Watch our video to learn more about our granulated culture media.

SigmaAldrich.com/MediaFills

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Frankfurter Strasse 250, 64293
Darmstadt, Germany

To place an order or receive technical assistance

Order/Customer Service: **SigmaAldrich.com/order**
Technical Service: **SigmaAldrich.com/techservice**
Safety-related Informatione: **SigmaAldrich.com/safetycenter**

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