

3M™ Novec™ Engineered Fluids

Non-flammable fluids for pharmaceutical and chemical processing

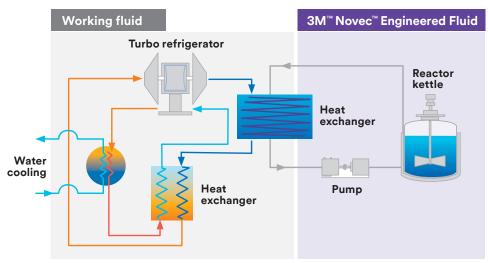
Cool solutions that are easy to handle and safer for workers

Lyophilization, or freeze-drying, is a low pressure, low temperature vacuum freeze-drying process widely used in the manufacturing of pharmaceuticals and biologics. Temperatures may vary from -55°C (-67°F) to 121°C (249.8°F) during sterilization and operation.

IMA Life installed a freeze dryer utilizing 3M™ Novec™ Engineered Fluid to help a large pharmaceutical company manufacture vaccines at extremely low temperatures while reducing the risk of fire and explosion.

Traditionally, materials like chlorofluorocarbons (CFCs), trichloroethylene (TCE), methylene chloride or silicone oils are used as heat transfer fluids to maintain temperatures in pharmaceutical and chemical processing.





Primary Cooling

Secondary Cooling

Unfortunately, these "traditional" fluids have a number of limitations. Some are combustible and may be fire hazards. Others are unacceptable because of their high toxicity and potential to harm workers. Still others are restricted in their use due to unfavorable environmental profiles.

A new generation of fluids

The unique low temperature properties of 3M™ Novec™ Engineered Fluids allow them to provide excellent heat transfer performance, helping ensure uniform product quality in a variety of processes.

Just as important, Novec fluids are designed with health, safety and sustainability in mind — meaning these unique materials optimize heat transfer performance without compromising worker safety or environmental sustainability.

These heat transfer fluids are non-flammable, have low toxicity, zero ozone depletion potential, short atmospheric lifetimes and low global warming potentials. In addition, they do not contribute to the formation of photochemical smog. 3M™ Novec™ 7100, 7200 and 7500 Engineered Fluids have been exempted from the

U.S. EPA definition for volatile organic compounds (VOC). Novec fluids are non-flammable and are not regulated for transport, storage or use.

Performance under pressure

Freeze drying, or lyophilization, involves removal of solvent in such a way that the active pharmaceutical ingredient is not compromised.

This is done by using temperature controlled shelves whose temperature can vary from -55°C to 80°C during processing. Careful temperature control across the operating range is critical for a successful batch of freeze dried product.

Several Novec fluids have been qualified for use in lyophilizers.

3M™ Novec™ 7500 Engineered Fluid, with a boiling point of 130°C, is well-suited for production or pilot-scale lyophilizers that are steam-sterilized.

3M™ Novec™ 7100 Engineered Fluid and 3M™ Novec™ 7200 Engineered Fluid both have very low viscosities, but their lower boiling points make them more suited for R&D lyophilizers or any steam-sterilized unit that can tolerate higher vapor pressure.

The fluids typically used to cool jacketed reactor vessels suffer similar limitations to those used in

Table 1.		3M™ Novec™ Engineered Fluids			
		7000	7100	7200	7500
Boiling Point	°C	34	61	76	128
Pour Point	°C	-122	-135	-138	-100
Kinematic viscosity @ 25°C	cSt	0.32	0.38	0.41	0.77
Kinematic viscosity @ -80°C	cSt	2	4	5	43

lyophilizers. An additional constraint is added by the ever-increasing demand for lower temperatures. More and more frequently, these processes require temperatures of -100°C and lower. Very few fluids are useful at these temperature extremes.

When using silicone oil in reactor cooling applications at temperatures lower than -80°C to -90°C, for example, it becomes difficult to maintain turbulent flow with manageable pressure drops and pumping power.¹ 3M™ Novec™ Engineered Fluids, in comparison, function well at temperatures as low as -120°C with good heat-transfer coefficients and pumping power demands. Novec 7100 and Novec 7200 fluids have been used in processes well below -80°C, and 3M™ Novec™ 7000 Engineered Fluid has been successfully used below -115°C.

Safer and easier handling

The use of combustible heat transfer fluids such as silicone oils creates regulatory challenges that can be eliminated by switching to 3M Novec fluids. For example, areas with equipment using flammable fluids must have an "H-2" fire rating (per NFPA and IBC).² For two-story operations, this coverage must extend to the condenser area and the floor between the chamber and condenser must be sealed. Blow-out panels are also required.

In addition to the costs associated with building spaces that meet fire rating and explosion resistance requirements, converting existing facilities often poses architectural challenges and may not be feasible in some cases. Unlike silicone oils, used in this application, Novec fluids do not have a flash point and therefore do not present a fire or

explosion hazard, even at the high temperatures encountered during the sterilization phase of the freeze drying process. This makes them safer for workers to handle and eliminates the need for explosion proofing.

Support you can trust

Finally, when you choose 3M™ Novec™ Engineered Fluids for your pharmaceutical and chemical processing applications, you get more than a product, you get the technical and customer support of a global partner.

Our team of experienced professionals will help you select the right Novec fluid for your application and its unique requirements. We will work with you every step of the way to help ensure your process is performing at its full potential.

Responsible fluid disposal

As part of 3M's commitment to product stewardship and customer service, the <u>3M Used Fluid Disposal Program</u> provides pickup of used 3M fluids in the United States, including 3M™ Novec™ Engineered Fluids. This program is provided through Clean Harbors Environmental Services to help ensure that your used 3M fluids will be managed properly and responsibly.

Committed to the future

While it's difficult to forecast the exact nature of legislation, it's a good bet that it will continue to evolve in favor of environmental stewardship. 3M Novec fluids are well positioned to meet regulations today and into the foreseeable future. 3M is committed to improving our technologies with continuous new product research and development.

Contact us

If you have any questions about Novec fluids for use in pharmaceutical and chemical processing, please contact your local 3M representative, or call 3M Electronics Materials Solutions Division, 800 810 8513.

¹ Tuma, Phillip. Hydrofluoroethers as Low-Temperature Heat-Transfer Fluids in the Pharmaceutical Industry. Pharmaceutical Technology®. March 2000.

² International Fire Code®. International Code Council. 2015.

For additional information

For information on additional 3M fluids, coatings and other chemical products, visit our web site at: www.3m.com/Novec

Smart. Safe. Sustainable.

The 3M™ Novec™ Brand Family

The Novec brand is the hallmark for a variety of proprietary 3M products. Although each has its own unique formula and performance properties, all Novec products are designed in common to address the need for smart, safe and sustainable solutions in industry-specific applications. These include precision and electronics cleaning, heat transfer, fire protection, protective coatings, immersion cooling, advanced insulation media replacement solutions and several specialty chemical applications.

3M™ Novec™ Engineered Fluids ■ 3M™ Novec™ Aerosol Cleaners ■ 3M™ Novec™ 1230 Fire Protection Fluid ■ 3M™ Novec™ Electronic Grade Coatings ■ 3M™ Novec™ Electronic Surfactants ■ 3M™ Novec™ Insulating Gases

Safety Data Sheet: Consult Safety Data Sheet prior to use.

Regulatory: For regulatory information about this product, contact your 3M representative.

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