SAFC®
Pharma & Biopharma Raw Material Solutions

Data Sheet

50% Glucose (w/v) – HTST treated

To reduce viral risks in your process

Glucose, a commonly used feed in the biopharmaceutical industry, poses a viral risk due to its attractiveness to rodents. Therefore, it is crucial to manage glucose effectively as part of your overall virus risk mitigation strategy in your upstream process. One highly effective method for virus inactivation is HTST pasteurization. This process involves rapidly heating the material to a predetermined temperature (>100 °C) and holding it at that temperature for a specified time to inactivate any adventitious viral agents that may be present. We offer ready-to-use, sterile-filtered, HTST treated glucose solutions in single-use bags protecting you from costly viral contamination incidents.

Features and Benefits

- Catalog version available in 1 L and 20 L pack sizes
- Ready-to-use catalog products to satisfy small volume demands or facilitate scale-up if required
- Customized offerings are available at smaller and larger scales and at various concentrations
- Animal component-free material
- Outsourcing HTST treated glucose can support efficiency gains in your process
- Forms a vital part of your viral risk mitigation strategy

Customers seeking efficiency gains can now streamline their operations by outsourcing and receiving ready-to-use HTST-treated Glucose solutions rather than investing resources in developing and implementing an in-house process.

In-house or outsource?

Establishing an in-house process to HTST treat media and glucose has challenges and risks:

- The design and installation of an in-line HTST process requires a high upfront capital cost.
- Dedicated resource and knowledge is needed to optimize the process parameters to achieve viral inactivation while ensuring product quality is not affected.
- Operating an in-house pasteurization process creates a single-point failure and potentially a process bottleneck if the equipment is not sized and run appropriately.

The most effective risk mitigation strategy would be to only use HTST pre-treated high risk raw materials on site, as it would ensure the lowest possible probability of a viral contamination event. Outsourcing this process step therefore becomes an attractive alternative and can help mitigate process risk.

MilliporeSigma

Pre-treated HTST treated glucose

- Our deep understanding of HTST treatment has allowed us to develop a robust and very effective process that delivers greater than 6 log inactivation of virus – helping you to mitigate risk in your process.
- HTST pre-treated glucose is available for both clinical and commercial scale operations – providing you flexibility of scale.
- Outsourcing this raw material treatment step saves significant upfront capital expenditure, and allows valuable resources to be devoted to other critical processes.
- Shipping of HTST Glucose in single-use bags has successfully undergone rigorous ISTA ship testing, allowing delivery of raw materials in a convenient, ready-to-use format.

Process excellence and control

To deliver a process that provides sufficient inactivation against a broad range of viruses, the HTST process needs to be precisely controlled. The fully automated HTST process we offer tracks critical process parameters to ensure that material is subjected to the predetermined pasteurization set-points. High quality in-line process control and monitoring allow real-time process analysis and adjustment, and this allows us to deliver reliable pasteurization performance each time.

Performance

We have undertaken lab-scale virus inactivation trials which have been designed to be representative of the industrial pasteurization processes, both at pilot and commercial scale. The analytical trials subjected a worst case virus, Minute Virus of Mice (MVM), a mammalian parvovirus that is very resistant to physicochemical methods of inactivation, to a series of HTST processing conditions to determine the viral Log Reduction Value (LRV) of different pasteurization temperatures and residence times.

Hold Temperture	Hold Time (s)	Log Reduction Value (LRV)		
		Run 1	Run 2	Run 3
90 °C	10	1.9	2.1	2.1
	40	2.6	3.3	3.7
102 °C	10	**≥6.9**	**≥6.7**	**≥6.4**
	40	**≥6.9**	**≥6.7**	**≥6.4**
105 °C	10	**≥6.9**	**≥6.7**	**≥6.4**
	40	**≥6.9**	**≥6.7**	**≥6.4**

These results demonstrate that HTST is an effective viral inactivation technology for treatment of cell culture feeds, complementing other virus mitigation approaches to minimize the risk of introducing adventitious agents into the bioreactor.

Storage

HTST treated glucose must be stored at 15 to 30 °C.

Shelf Life

24 months shelf life. Do not use after expiration date.

Intended Use

For research or further manufacturing uses only. Not intended for direct use in humans or animals.

Quality Segment

MQ500

Ordering Information

	Material Number	Pack Size
50% Glucose (w/v) – HTST	**58955C-1BC**	1 L
	58955C-20BC	20 L

Custom Product

Please contact your local representative for more information on a customized version of this product. We offer a range of concentrations and volumes to meet your specific needs.

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To place an order or receive technical assistance

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