



DATE: 20 May 2025

Product Identifier

RM Number: 8675

RM Name: NISTCHO, Clonal CHO-K1 Cell Line Producing cNISTmAb

Under the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) 29 CFR 1910.1200, this Reference Material (RM) is NOT classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, pyrophoric gas, or hazard not otherwise classified. There are no hazard pictograms, hazard statements or signal word associated with it. Safety Data Sheet information is not required. This document may be used in conjunction with your hazard communication program. Biological hazards are exempted per 1910.1200(b)(6)(xii).

Description: PURCHASER'S USE OF RM 8675 IS STRICTLY LIMITED TO NON-COMMERCIAL RESEARCH USE. Additionally, RM 8675 AND ANY MATERIALS DERIVED FROM RM 8675 MAY NOT BE USED IN HUMANS OR ANIMALS, INCLUDING FOR ANY DIAGNOSTIC, PROGNOSTIC, CLINICAL OR TREATMENT PURPOSES. This RM is intended to provide a publicly accessible, industry relevant monoclonal antibody expressing cell line for biomanufacturing research and development. This RM can be used for a variety of purposes that may include assessing the performance of bioprocess measurement systems and bioprocess technologies associated with monoclonal antibody production or use in biomanufacturing educational and training programs. A unit of RM 8675 consists of one vial cryopreserved, Chinese hamster ovary K1 subtype (*Critellus griseus*; CHO-K1) lineage cell suspension with nominal volume of 1.0 mL, nominal cell number of 1×10^7 cells and a time-in-culture post-clonal isolation of nine passages. The cryopreservation matrix consists of EX-CELL CD CHO Fusion culture medium supplemented with seven volume percent (7 % v/v) dimethylsulfoxide. When in culture, cell suspensions propagated from RM 8675 are expected to produce a non-originator, humanized, IgG1 κ monoclonal antibody, cNISTmAb, having the same primary amino acid sequence as the NISTmAb monoclonal antibody (RM 8671). The CHOZN GS-/- host cell line was used to develop the NISTCHO cell line. Clonality of the cell line was established by limiting dilution and confirmed using optical photomicroscopy. The development of RM 8675 was conducted with materials and reagents free of animal origin.

Additional Notes for Biomaterials: RM 8675 is a Biosafety Level 1 material and should be handled according to applicable federal, state, and/or local regulations and according to the policies and procedures of the recipient's organization. See the Reference Material Information Sheet for additional storage and use instructions.

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