

QUALITY AUDIT STANDARD QAS3001-B MEASUREMENT PROTOCOLS

0.4g one-shot bottles of polydisperse glass-bead transfer standard, Part No.CRM0016.

Suitable for: Hydro MV, Hydro SM

Hydro 2000S, Hydro 2000S+, Hydro 2000SM, Autosampler 2000 with Hydro 2000S using 2 bottles per test

STP2520

www.malvern.com

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Introduction

Malvern's QAS3001B Quality Audit Standard (bottle part number CRM0016) has been produced to provide users of Malvern particle size analysers with a one-shot, polydisperse transfer standard that enables them to check the performance of their sample dispersion units on a regular basis.

Compliance with International Standards

QAS3001B complies with the recommendations of ISO13320, USP <429> and EP 2.9.31 relating to the validation of laser diffraction systems. The glass bead particles present within QAS3001B are spherical, cover a decade in size and have precisely defined optical properties.

In addition, the standard is used in conjunction with a clear measurement procedure, as outlined in this datasheet. As such, QAS3001B provides a reliable means of checking and documenting the consistent operation of a laser diffraction system, as part of FDA or other international laboratory accreditation schemes (e.g. ISO, NAMAS, and IAF).

Sample Variability

Polydisperse particle sizing standards are prone to segregation during transit, which can lead to sampling errors. To overcome this, Malvern's Quality Audit Standards are produced by Whitehouse Scientific Ltd., who have used an extremely efficient riffle-splitting process to ensure that each one-shot sample is representative of the entire batch.

Random sampling of QAS3001B bottles has shown that the relative standard deviation for the median (Dv50) particle size is of the order of 0.2%. This confirms that, as long as the entire contents of the bottle are used during a measurement in accordance with the instructions included on this datasheet, reproducible results can be obtained.

Shelf Life and Batch Numbering

Malvern's Quality Audit Standards are made of inert glass beads and are stored in sealed containers. For this reason they have an indefinite shelf life. It has also been possible to provide many years of continuous supply from a single, large master batch. As a result, the only batch number for QAS3001B is 02.

Traceability

The pass/fail specifications set for Malvern's Quality Audit Standards have been developed via a fully documented programme of testing using reference laser diffraction systems which have been verified using NIST-traceable polystyrene latex standards. As such, although these standards are transfer standards, they are indirectly traceable to NIST.

Establishing Pass/Fail criteria and measurement procedures

An on-going programme of dispersion unit testing is carried out by Malvern in order to characterize each Quality Audit Standard and establish the pass/fail criteria referenced on this datasheet. As testing continues, Malvern constantly assesses the average measurement values obtained over the entire population of dispersion units. As the population increases, slight adjustments to the pass/fail criteria may be required in order to ensure that these accurately reflect the expected performance of all units. Changes may also be made to the measurement procedure in order to ensure robust measurements can be made.

Given the above, it is important that the latest version of this datasheet is used, especially when carrying out an annual system OQ or PV. In case of doubt, the latest version number (MRK794-nn) can be verified by visiting Malvern's website. If there is any disagreement between the datasheet and the latest OQ procedure, the OQ certificate and specification should be considered to take precedence over the datasheet.

Expected Results

QAS3001B has been designed for use with the following dispersion units:

Mastersizer 3000	Hydro MV, Hydro SM
Mastersizer 2000	Hydro 2000SM, Hydro 2000S, Hydro 2000S+, Hydro 2000S with Autosampler 2000
Spraytec	Wet Dispersion Unit (STP2520)

Note: Specifications for the **Mastersizer S** dispersion units are provided in an earlier version of this document (MRK0794-09). Please contact your local Malvern representative if you wish to obtain a copy of this document.

Mastersizer 2000

The specifications for the Mastersizer 2000 dispersion units are set at $\pm 3\%$ for the Dv50 and $\pm 5\%$ for the Dv10 and Dv90.

	Dv10 / μm	Dv50 / μm	Dv90 / μm
Lower Limit	34.735	58.779	83.944
Target Value	36.563	60.597	88.362
Upper Limit	38.391	62.415	92.780

Mastersizer 3000

The specifications for the Mastersizer 3000 dispersion units are set at $\pm 2.5\%$ for the Dv50, $\pm 3\%$ for the Dv10 and $\pm 4\%$ Dv90.

	Dv10 / μm	Dv50 / μm	Dv90 / μm
Lower Limit	35.597	60.054	85.928
Target Value	36.698	61.594	89.508
Upper Limit	37.799	63.134	93.088

Spraytec

The Spraytec software does not provide an equivalent of the 'Monomodal' or 'Single Mode' analysis models offered with the Mastersizer systems. For this reason, the target values are different, especially for the Dv90:

	Dv10 / μm	Dv50 / μm	Dv90 / μm
Lower Limit	35.255	58.179	90.753
Target Value	37.111	59.978	95.529
Upper Limit	38.967	61.777	100.305

Material Safety Data Sheet [MSDS]

<p>1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY/UNDERTAKING Product Name: Malvern Quality Audit standards EINECS Number: 65987-17-3 Product Code: 2660460 Synonyms: GLASS BEADS Use/description of product: Soda Lime Glass Company: Whitehouse Scientific Ltd. Whitechurch Road, Waverton, Chester, CH3 7PB, England Tel: +44 (0) 1244 332626 Fax: +44 (0) 1244 335098 email: info@whitehousescientific.com</p>	<p>2. COMPOSITION / INFORMATION ON INGREDIENTS Hazardous Ingredients: SODA LIME GLASS 100.000% EINECS: 2660460 CAS: 65997-17-3</p> <p>3. HAZARDS IDENTIFICATION Main Hazards: No significant hazard.</p>	<p>4. FIRST AID MEASURES (SYMPTOMS) Skin contact: There may be mild irritation at the site of contact. Eye contact: There may be irritation and redness. Inhalation: No Symptoms. Ingestion: Exposure may cause coughing or wheezing.</p> <p>4. FIRST AID MEASURES (ACTIONS) Skin contact: Wash immediately with plenty of soap and water. Eye contact: Flush with running water for at least 15 minutes. Also rinse under the eyelids. If irritation persists, consult a specialist.</p>	<p>5. FIRE FIGHTING MEASURES Extinguishing Media: Non-flammable substance, not applicable. Suitable extinguishing media for the surrounding fire should be used. Protection of fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.</p> <p>6. ACCIDENTAL RELEASE MEASURES Personal Precautions: Refer to section 8 below for personal protection details. Environmental Precautions: Material can create slippery conditions underfoot. Clean-Up Procedure: Avoid creating dust.</p>	<p>7. HANDLING AND STORAGE Handling Requirements: Ensure that there is sufficient ventilation of the area. Avoid direct contact with the substance. Avoid the formation or spread of dust in the air. Storage Conditions: Store in cool, well ventilated area. Keep bottles tightly closed.</p> <p>8. EXPOSURE CONTROLS / PERSONAL PROTECTION Hazardous Ingredients: SODA LIME GLASS TWA (8hr exposure limit): 5mg/m3 (OES) Engineering Methods: Ensure that there is exhaust ventilation of the area.</p>	<p>9. PHYSICAL AND CHEMICAL PROPERTIES State: Solid. Colour: White. Odour: Odourless. Melting Point/Range°C: Approximately 730°C Relative Density: 2.6 g/cm3 (20°C)</p> <p>10. STABILITY AND REACTIVITY Stability: Stable under normal conditions.</p> <p>11. TOXICOLOGICAL INFORMATION Chronic Toxicity: Overexposure to dust may cause irritation of eye and throat. Routes of Exposure: No data available.</p> <p>12. ECOLOGICAL INFORMATION Mobility: No data available. Persistence and degradability: No data available. Bioaccumulative Potential: No data available.</p> <p>13. DISPOSAL CONSIDERATIONS Disposal Operations: Contact waste disposal services. Disposal of Packaging: Contact waste disposal services. NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.</p>	<p>14. TRANSPORTATION INFORMATION ADR RID UN No.: Shipping Name: "NOT SUBJECT TO ADR" IMDG / IMO UN No.: IATA / ICAO UN No.:</p> <p>15. REGULATORY INFORMATION Hazard Symbols: No significant hazard. Note: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions which complete these regulations. Refer to all applicable national, international and local regulations or provisions.</p> <p>16. OTHER INFORMATION Other Information: Complies with Directives (2001/58/EC), (1999/45/EC), (91/155/EEC), (67/548/EEC) as amended and Chemicals (hazard information and packaging for supply) 2002 (CHIP3) Regulation, EH40.</p> <p>Legal Disclaimer: The information contained in this safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and does not constitute a warranty. The user's attention is drawn to the fact that the user should refer to the specific material designated and may not be valid for such material used in combination with any other materials or in any process unless specified in the text.</p>
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