

QUALITY AUDIT STANDARD QAS3002 MEASUREMENT PROTOCOLS

2.5g one-shot bottles of polydisperse glass-bead transfer standard, Part No.CRM0014.

Suitable for:

Hydro LV, Hydro EV, Aero S, Aero M, DIF2012, QSpec MU, Hydro 2000 MU, Hydro 2000G, Scirocco 2000, Scirocco 2000 M, MAM2460, MAM2461.

Autosampler 2000 with Hydro 2000G using 2 bottles per test.

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Introduction

Malvern's QAS3002 Quality Audit Standard (bottle part number CRM0014) 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

QAS3002 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 QAS3002 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, QAS3002 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 use an extremely efficient riffle-splitting process to ensure that each one-shot sample is representative of the entire batch.

Random sampling of QAS3002 bottles has shown that the relative standard deviation for the median (Dv50) particle size is of the order of 0.3%. 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 QAS3002 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 ongoing 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 ((MRK665-11)) 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

QAS3002 has been designed for use with the following dispersion units:

Mastersizer 3000	Hydro LV, Hydro EV, Aero S (all venturis), Aero M (Standard Venturis only)
Mastersizer 2000	Hydro 2000G, Hydro 2000G with autosampler, Hydro 2000MU, Scirocco 2000, Scirocco 2000M
Mastersizer S	DIF2012, QSpec MU, MAM2460, MAM2461, MAM2461C

DIF2012, Hydro 2000G, Hydro 2000G with autosampler, Hydro 2000MU and QSpec MU dispersion units

The specifications for the Mastersizer 2000 and Mastersizer S wet dispersion units are set at ± 3% for the Dv50 and ± 5% for the Dv10 and Dv90.

	Dv10 / µm	Dv50 / µm	Dv90 / µm
Lower Limit	35.326	59.995	85.473
Target Value	37.185	61.850	89.972
Upper Limit	39.044	63.706	94.471

MAM2460, MAM2461, MAM2461C, Scirocco 2000, Scirocco 2000M dispersion units

The specifications for the Mastersizer 2000 and Mastersizer S dry dispersion units are set at ± 3% for the Dv50 and ± 5% for the Dv10 and Dv90.

	Dv10 / µm	Dv50 / µm	Dv90 / µm
Lower Limit	36.631	61.360	85.515
Target Value	38.559	63.258	90.016
Upper Limit	40.487	65.156	94.517

Hydro LV and Hydro EV dispersion units

The specifications for the Mastersizer 3000 wet dispersion units are set at ± 2.5% for the Dv50, ±3% for the Dv10 and ±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

Aero S & Aero M dispersion units

The specifications for both the Mastersizer 3000 Aero S and Aero M dry dispersion units are set at ± 2.5% for the Dv50, ±3% for the Dv10 and ±4% Dv90.

For the stainless steel and ceramic versions of the Aero S and Aero M standard venturi disperser, the specifications are as follows:

	Dv10 / µm	Dv50 / µm	Dv90 / µm
Lower Limit	36.388	60.625	85.786
Target Value	37.513	62.179	89.360
Upper Limit	38.638	63.733	92.934

The specifications for the stainless steel and ceramic versions of the Aero S (only) high-energy venturi disperser are as follows:

	Dv10 / µm	Dv50 / µm	Dv90 / µm
Lower Limit	37.512	61.682	86.672
Target Value	38.672	63.264	90.283
Upper Limit	39.832	64.846	93.894

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. Clean-Up Procedure: Material can create slippery conditions underfoot. 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 TWAs (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 eyes 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 UN No.: UN Name: 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 or any other specific material designated and may not be valid for the specific material used in combination with any other materials or in any process unless specified in the text.</p>
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