

Certified Reference Material

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Certificate of Analysis

AOCS 0523-B, KWS20-1 sugar beet seed OECD Unique ID KB-KWS2Ø1-6

| Certified Presence | Certified Value | Measurement Uncertainty | Test Method |
|-------------------------------|-----------------|----------------------------|----------------------------------|
| KWS20-1 sugar beet present | 1000 g/kg | -62 g/kg | event-specific real- time PCR |

Description: This is the first batch of KWS20-1 sugar beet CRM prepared by AOCS for KWS SAAT SE & Co. KGaA. It was produced in December 2023. The certified value is based on a sample purity of 100% (96 out of 96 leaves tested positive for KWS20-1). With 95% confidence, the true value is \geq 938 g/kg. The measurement uncertainty is the expanded uncertainty with a coverage factor of 2 and confidence level of 95%. This material is for limited purposes only: see "Intended Use" and "Terms and Conditions".

This certificate is valid through: July 2025

This validity may be extended when further evidence of stability becomes available. Customers will be notified by AOCS if a stability issue arises at AOCS Headquarters.

Introduced: 2 April 2025

Technical Services Manager Fiona Liu

Chief Executive Officer Patrick J. Donnelly

AOCS Mission: AOCS advances the science and technology of oils, fats, proteins, surfactants and related materials, enriching the lives of people everywhere.

Characterization

Product Description AOCS 0523-B has been prepared by AOCS from sugar beet seed delivered by KWS SAAT SE & Co. KGaA. AOCS 0523-B is available in 27-mL glass headspace vials containing approximately 10 g of material. The KWS20-1 sugar beet seed used in the preparation of AOCS 0523-B is hemizygous hybrid seed. The hybrid seed represents a cross between a female, non-modified line and a male, KWS20-1 line, which resulted from several cycles of self-pollination respectively.

Homogeneity The homogeneity of AOCS 0523-B is related to the purity of the seeds. 96 seeds were geminated, and one leaf was collected from each of the 96 plants. 96 out of 96 individual plant leaves tested positive for the KWS20-1 sugar beet event by event-specific qualitative PCR. Based on the sample purity of 100%, as determined using SeedCalc8, the batch was expected to be homogeneous.

To further confirm homogeneity, ten vials of AOCS 0523-B were evaluated to determine the within-unit and between-unit property value. The property value is defined as the ratio between copies of the event specific target (KWS20-1) and copies of a taxon-specific reference target (glutamine synthetase, GS). Variability of this ratio within CRM vials and between CRM vials is reported as the within-unit relative standard deviation (RSD_w), and the between-unit relative standard deviation (RSD_b). The results summarized below confirm the homogeneity of AOCS 0523-B.

| CRM | RSD _w [%] | RSD₀ [%] | U*bu,rel [%] |
|-------------|----------------------|-------------------|--------------|
| AOCS 0523-B | 5.8 | n.c. ¹ | 2.8 |

 1 n.c: RSD_b cannot be calculated as MS_{between} < MS_{within}. In this situation, maximum hidden inhomogeneity (u*_{bu,rel}) is provided as an alternative. MS is mean square for RSD calculation. See report for more information.

In addition, ten packaged samples, 10 g each, were tested using event-specific qualitative PCR methods developed and validated by KWS SAAT SE & Co. KGaA. Test results received from Eurofins GeneScan GmbH, Freiburg, Germany (an ISO 17025 Accredited laboratory) for qualitative, event-specific analysis were all consistent with the reported presence of the KWS20-1 trait.

Stability AOCS Certified Reference Materials are assessed for transport (short-term) and long-term stability and tested for stability on an annual or biennial basis, depending on the type of homogeneity testing that is required, and certificates may be extended based on the outcome of this testing. Customers may request extended certificates, but they are informed that results are based on samples that are obtained from AOCS' inventory. AOCS cannot guarantee the integrity of samples outside of our control.

Analytical Method Used for Certification

The Certified value is based on the purity of the KWS20-1 material used in the production of this CRM. Eurofins GeneScan GmbH, Freiburg, Germany (an ISO 17025 Accredited laboratory) performed event-specific qualitative PCR for KWS20-1 to validate the presence of the KWS20-1 trait and event-specific quantitative PCR for KWS20-1 to determine the copy number ratio between the event-specific targets and the taxon-specific targets for the assessment of homogeneity. Purity, homogeneity and stability results were used to determine the expanded measurement uncertainty of the certified value.

Warnings and Precautions

This product is for laboratory use only and is not for consumption. The user of this CRM should follow safety requirements and rules issued by voluntary organizations and government agencies expert in the field of laboratory safety.

Intended Use

This CRM, AOCS 0523-B, is intended for use as quality control material or calibrant in methods for the detection, identification, and/or quantification of biotechnology-derived events.

Instructions for Use

Upon receipt the product should be stored in a sealed container in the dark and at ambient or cooler conditions. The product may have settled during shipment, therefore, thoroughly mix the CRM before use to ensure homogeneity.

If the user of this CRM intends to use it multiple times, proper protocols must be followed to ensure that the sample retains its integrity. Use a clean laboratory spatula to remove the intended sample amount. After the sample has been removed, flush the headspace of the vial with nitrogen gas, then replace the rubber stopper. Place a new 20 mm tear-off aluminum unlined seal on top of the rubber stopper and crimp it to the vial by using a crimping tool. Store the CRM in the dark and at ambient or cooler conditions and repeat this process for all subsequent uses.

Sample size:

The recommended **sample intake** suitable for DNA extraction and real time PCR is 1 g.

Protocols have been followed to ensure that this CRM has the presence of the KWS20-1 trait. Please follow all instructions on this certificate to prevent contamination and be sure to store the CRM under the proper conditions.

Note: The AOCS 0523-B certification report is available online and a paper copy will be supplied upon request.

Terms and Conditions (i- ix)

- i. The CRM AOCS 0523-B shall be used solely 1) in assays for (a) detecting the presence of KWS20-1, or (b) quantification of KWS20-1; or 2) for determining whether an assay cross-reacts with CRM AOCS 0523-B. CRM AOCS 0523-B shall be used for no other purpose. Specifically, the CRM may not be used to develop a detection method for KWS20-1 nor trait(s) present therein. No other rights are conveyed by the sale of the CRM 0523-B to any purchaser, including any rights to any pending or granted KWS SAAT SE & Co. KGaA Patents or other KWS SAAT SE & Co. KGaA Intellectual Property that may protect the CRM or KWS20-1 or trait(s) present therein or a detection method for KWS20-1.
- ii. Neither the CRM AOCS 0523-B, nor any extract or portion thereof shall be resold or redistributed by any purchaser, unless the resale or redistribution is required by national law in force in the purchaser's country.
- iii. Neither the CRM AOCS 0523-B, nor any extract or portion thereof, shall be used for human or animal consumption or human or animal trials.
- iv. Neither the CRM AOCS 0523-B, nor KWS20-1 DNA, nor any part of either of these, shall be used for transformation or breeding.
- v. No characterization or derivation of KWS20-1, of the trait or traits present in CRM AOCS 0523-B, or of the CRM AOCS 0523-B shall be performed, except as allowed for in section (i).
- vi. All assay activities undertaken using the CRM AOCS 0523-B shall be conducted in strict compliance with all Applicable Laws governing such activities and shall comply with conditions of all permits and authorizations which may be required for such activities; and such activities shall be strictly limited to assays in contained facilities, for example, laboratories.
- vii. Prior to disposal of any used or excess CRM AOCS 0523-B or residues thereof, such material or residue must be treated in a manner that degrades KWS20-1 in the CRM, such as by autoclaving.

- viii. CRM AOCS 0523-B shall not be exported nor re-exported in violation of any Applicable Laws or without securing any necessary export or import clearances or permits.
- ix. THE CRM 0523-B IS PROVIDED FOR THE PURPOSE OF IDENTIFYING, DETECTING AND QUANTIFYING KWS20-1 AND FOR NO OTHER PURPOSE. AOCS HAS TESTED CRM 0523-B WITHIN THE PAST 24 MONTHS AND STATES THAT IT HAS DETERMINED IT TO BE OF SUFFICIENT QUALITY AND FIT FOR THE PURPOSES STATED HEREIN. NO KWS SAAT SE & Co. KGaA WARRANTY IS PROVIDED WHETHER EXPRESS OR IMPLIED, IN RELATION TO THE CRM AOCS 0523-B AND KWS SAAT SE & Co. KGaA MATERIALS. KWS SAAT SE & Co. KGaA MAKE NO REPRESENTATION OR WARRANTY THAT THE USE OF THE CRM AOCS 0523-B, WHETHER BEFORE, OR AFTER THE EFFECTIVE DATE OF THE APPLICABLE CERTIFICATE, WILL NOT INFRINGE ANY PATENT OR OTHER PROPERTY RIGHTS.