American Oil and Chemists' Society
Certified Reference Materials
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CERTIFICATE OF ANALYSIS

AOCS 0804-D2 | MON 15985 | Cotton | Powder

OECD Unique ID MON-15985-7

Certified Presence	Certified Value	Measurement Uncertainty	Test Method
MON 15985 cotton present	1000 g/kg	- 22 g/kg	event-specific real-time PCR

Description: This is the second batch of MON 15985 cotton CRM prepared by AOCS for Bayer CropScience. It was produced in July 2020. The certified value is based on a sample purity of 100% (719 out of 719 seeds tested positive for MON 15985). With 95% confidence, the true value is ≥ 978 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 2027

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: 25-AUG-20
Revised: 22-JUN-21, 28-JUL-22, 10-JUL-23, 03-JUL-24, 18-JUL-25, 02-JUL-26

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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 0804-D2 has been prepared by AOCS from cotton seed. AOCS 0804-D2 is available in 27-mL glass headspace vials containing approximately 10 g of material. Users are informed that this reference material has been produced from seed of MON 15985 cotton delivered by Bayer CropScience. The MON 15985 cotton seed used to prepare AOCS 0804-D2 was homozygous resulting from several cycles of self-pollination of the MON 15985 line.

Homogeneity The homogeneity of AOCS 0804-D2 is related to the purity of the seeds. 719 out of 719 seeds tested positive for the MON 15985 cotton event by event-specific PCR. Based on the sample purity of 100%, as determined using SeedCalc8, the batch was considered to be homogeneous.

In addition, ten packaged samples, 10 g each, were tested using event-specific qualitative PCR methods developed and validated by Bayer CropScience. Test results received from Eurofins-GeneScan, New Orleans, LA (an ISO 17025-accredited laboratory) for qualitative, event-specific analysis were all consistent with the reported presence of the MON 15985 trait.

Stability AOCS Certified Reference Materials are assessed for transport (short-term) and long-term stability and tested for stability on an annual basis 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 MON 15985 material used in production of this CRM. Eurofins-GeneScan, New Orleans, LA (an ISO 17025-accredited laboratory) performed event-specific real-time PCR for MON 15985 to validate the presence of the MON 15985 trait. Purity 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 0804-D2, 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 headsapce 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 **minimum 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 MON 15985 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 0804-D2 certification report is available online and a paper copy will be supplied upon request.

Terms and Conditions (i–ix)

i. The CRM AOCS 0804-D2 shall be used solely 1) in assays for (a) detecting the presence of MON 15985, or (b) quantification of MON 15985; or 2) for determining whether an assay cross-reacts with CRM AOCS 0804-D2. CRM AOCS 0804-D2 shall be used for no other purpose. Specifically, the CRM may not be used to develop a detection method for MON 15985 nor trait(s) present therein. No other rights are conveyed by the sale of the CRM 0804-D2 to any purchaser, including any rights to any pending or granted Bayer CropScience Patents or other Bayer CropScience Intellectual Property that may protect the CRM or MON 15985 or trait(s) present therein or a detection method for MON 15985.

ii. Neither the CRM AOCS 0804-D2 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 0804-D2, nor any extract or portion thereof, shall be used for human or animal consumption or human or animal trials.

iv. Neither the CRM AOCS 0804-D2 nor MON 15985 DNA, nor any part of either of these, shall be used for transformation or breeding.

v. No characterization or derivation of MON 15985, of the trait or traits present in CRM AOCS 0804-D2, or of the CRM AOCS 0804-D2 shall be performed, except as allowed for in section (i).

vi. All assay activities undertaken using the CRM AOCS 0804-D2 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 0804-D2 or residues thereof, such material or residue must be treated in a manner that degrades MON 15985 in the CRM material, such as by autoclaving.

viii. CRM AOCS 0804-D2 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 0804-D2 IS PROVIDED FOR THE PURPOSE OF IDENTIFYING, DETECTING AND QUANTIFYING MON 15985 AND FOR NO OTHER PURPOSE. AOCS HAS TESTED CRM 0804-D2 WITHIN THE PAST 12 MONTHS AND STATES THAT IT HAS DETERMINED IT TO BE OF SUFFICIENT QUALITY AND FIT FOR THE PURPOSES STATED HEREIN. NO BAYER CROPSCIENCE WARRANTY IS PROVIDED WHETHER EXPRESS OR IMPLIED, IN RELATION TO THE CRM AOCS 0804-D2 AND BAYER CROPSCIENCE MATERIALS. BAYER CROPSCIENCE MAKES NO REPRESENTATION OR WARRANTY THAT THE USE OF THE CRM AOCS 0804-D2, WHETHER BEFORE, OR AFTER THE EFFECTIVE DATE OF THE APPLICABLE CERTIFICATE, WILL NOT INFRINGE ANY PATENT OR OTHER PROPERTY RIGHTS.