

# CERTIFICATE OF ANALYSIS

ERM<sup>®</sup>-BF427c

MAIZE SEED POWDER		
	Certified value	Uncertainty <sup>3)</sup>
98140 maize mass fraction <sup>1)</sup>	20.0 g/kg <sup>2)</sup>	0.8 g/kg
98140 maize DNA copy number ratio <sup>4)</sup>	1.75 % <sup>5)</sup>	0.13 %
<p>1) Mass fraction of 98140 maize, based on the masses of mixed dried genetically modified 98140 maize seed powder and dried non-modified maize seed powder, and their respective water content.</p> <p>2) The certified value is traceable to the International System of Units (SI).</p> <p>3) The certified uncertainty is the expanded uncertainty with a coverage factor <math>k = 2</math>, corresponding to a level of confidence of about 95 %, estimated in accordance with the ISO/IEC Guide 98-3, Guide to the Expression of Uncertainty in Measurement (GUM:1995), ISO, 2008.</p> <p>4) The copy number ratio of 98140 maize is defined by the 98140 maize real-time Polymerase Chain Reaction quantification method validated by the European Union Reference Laboratory for GM Food and Feed (EURL-GMFF, available on <a href="http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm">http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm</a>) and calibrated with the 98140 plasmid DNA Certified Reference Material ERM<sup>®</sup>-AD427.</p> <p>5) The certified DNA copy number ratio is the unweighted mean of 20 accepted data sets. It is traceable to the International System of Units (SI).</p>		

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is 100 mg.

## NOTE

European Reference Material ERM<sup>®</sup>-BF427c was originally produced and certified under the responsibility of the Institute for Reference Materials and Measurements of the European Commission's Joint Research Centre according to the principles laid down in the technical guidelines of the European Reference Materials<sup>®</sup> co-operation agreement between BAM-IRMM-LGC. Information on these guidelines is available on the internet (<http://www.erm-crm.org>).

Accepted as an ERM<sup>®</sup>, Geel, January 2009  
Latest revision June 2011

**INFORMATION ONLY**

Prof. Dr. Hendrik Emons  
European Commission  
Joint Research Centre  
Institute for Reference Materials and Measurements  
Retieseweg 111  
B-2440 Geel, Belgium

## DESCRIPTION OF THE MATERIAL

ERM-BF427c is a powder mixture produced from whole seeds of a non-modified maize and the genetically modified maize 98140, both delivered by Pioneer Hi-Bred International Inc. (Johnston, IA, US). According to the information provided by Pioneer the genetically modified donor for the heterozygous 98140 maize was the female parent. In accordance with European Commission Regulation (EC) No 65/2004, the maize 98140 event received the unique identifier maize DP-Ø9814Ø-6.

The CRM is available in glass bottles containing approximately 1 g of maize powder closed under argon atmosphere. ERM-BF427c is part of a set of four maize powder CRMs containing different mass fractions (< 0.4, 5.0, 20.0 and 100 g/kg) of GM maize 98140. This set of maize powder CRMs was first certified in December 2009 for its mass fraction. In 2011, ERM-BF427c was certified additionally for its DNA copy number ratio.

## ANALYTICAL METHODS USED FOR CERTIFICATION

The gravimetric preparation of ERM-BF427c was verified by real-time Polymerase Chain Reaction.

The certified DNA copy number ratio value has been established using the maize 98140 event-specific real-time Polymerase Chain Reaction method validated by the EURL-GMFF targeting the 5' insert-to-plant junction (available on <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>) and a single copy target of the *high mobility group (hmg)* gene. Measurements were calibrated with the plasmid DNA ERM-AD427.

## PARTICIPANTS

- Agencia Española de Seguridad Alimentaria - Centro Nacional de Alimentación, Madrid, ES<sup>1</sup> (ENAC 178/LE397)
- Danish Plant Directorate, Laboratory for Diagnoses in Plants, Food and Feed, Lyngby, DK<sup>1</sup> (DANAK, 330)
- Danmarks Tekniske Universitet, DTU - New Technical University of Denmark, Fødevareinstituttet, Søborg, DK<sup>1</sup> (DANAK, 350)
- Ente Nazionale Delle Sementi Elette ENSE, Tavazzano, IT
- Eurofins Genescan GmbH, Freiburg, DE<sup>1</sup> (DACH, DAC-PL-0526-07-03)
- European Commission, Joint Research Centre, Institute for Health and Customer Protection (IHCP), Ispra, IT<sup>1</sup> (DACH, DAC-PL-0459-06-00)
- European Commission, Joint Research Centre, Institute for Reference Materials and Measurements (IRMM), Geel, BE<sup>1</sup> (BELAC, 268-TEST)
- Groupe d'études et de contrôle des variétés et des semences GEVES (BioGEVES), Surgeres, FR<sup>1</sup> (COFRAC, 1-1540)
- Hainaut Vigilance Sanitaire, Institut Provincial d'Information et d'Analyses Sanitaires, Mons, BE<sup>1</sup> (BELAC, 068-test)
- Institut für Hygiene und Umwelt, Behörde für Umwelt und Gesundheit, Hamburg, DE<sup>1</sup> (DACH, DAC-PL-0137-01-10)
- Instituut voor Landbouw- en Visserijonderzoek (ILVO), Dept. of Animal Product Quality and Transformation Technology, Merelbeke, BE<sup>1</sup> (BELAC, 033-TEST)
- Korea Research Institute of Standards and Science (KRISS) - Organic and Bio Analysis Group, Daejeon, KR<sup>1</sup>
- Lebensmittel- und Veterinäruntersuchungsamt des Landes Schleswig-Holstein (LVUA), Landeslabor Schleswig-Holstein, Neumünster, DE<sup>1</sup> (AKS, AKS-P-10101-EU)
- Livsmedelsverket - National Food Administration, Biology Division, Uppsala, SE<sup>1</sup> (SWEDAC, 1457)
- Nacionalinis maisto ir veterinarijos rizikos vertinimo institutas (NMVRVI), Vilnius, LT<sup>1</sup> (DAP, DAP-PL-3328.99)
- Nacionalni Inštitut za Biologijo - National Institute of Biology (NIB), Ljubljana, SI<sup>1</sup> (Slovenska akreditacija, LP-028)
- Nederlandse Organisatie voor toegepast-natuurwetenschappelijk Onderzoek (TNO), TNO quality of life - Food & Biotechnology Innovations - GMO foods, Zeist, NL<sup>1</sup> (Dutch Accreditation Council RvA, L027)
- Nestlé Research Center, Lausanne, CH<sup>1</sup> (SAS, STS 188)
- Tullilaboratorio - Finnish Customs Laboratory, Espoo, FI<sup>1</sup> (FINAS, T006)
- Umweltbundesamt Wien, Wien, AT<sup>1</sup> (Federal Ministry of Economics and Labour, 200)

## SAFETY INFORMATION

The usual laboratory safety precautions apply. The CRM does not contain viable seeds.

---

<sup>1</sup> The laboratory holds ISO/IEC 17025 accreditation for DNA-based GMO measurements (accreditation body and registration number are mentioned).

## INSTRUCTIONS FOR USE

The material ERM-BF427c, certified for its maize 98140 mass fraction, is intended to be used for calibration or quality control of methods for the detection of genetically modified food and feed containing GM maize 98140 expressing the measurement results in mass fractions.

The material ERM-BF427c, certified for the DNA copy number ratio, is intended to be used for quality control of measurements of the maize 98140 DNA copy number ratio in genetically modified food and feed ingredients. Experiments should be performed exclusively in conjunction with the ERM-AD427 calibrant and the maize 98140 event-specific detection method as described in the accompanying certification report.

The CRM powder is hygroscopic. Users are therefore advised to close bottles immediately after taking a sample.

## STORAGE

Bottles should be stored dry and in the dark at a maximum temperature of 4 °C. However, the European Commission cannot be held responsible for changes that happen during storage of the material at the customer's premises. We recommend using samples once opened as soon as possible.

## LEGAL NOTICE

Neither the European Commission, its contractors nor any person acting on their behalf:

- (a) make any warranty or representation, express or implied, that the use of any information, material, apparatus, method or process disclosed in this document does not infringe any privately owned intellectual property rights; or
- (b) assume any liability with respect to, or for damages resulting from, the use of any information, material, apparatus, method or process disclosed in this document save for loss or damage arising solely and directly from the negligence of the Institute for Reference Materials and Measurements of the European Commission's Joint Research Centre.

## NOTE

Two detailed technical reports are available on [www.irmm.jrc.be](http://www.irmm.jrc.be). The first report (published in 2009) describes the processing and certification of ERM-BF427c for its maize 98140 mass fraction. The second report (published in 2010) describes the certification of ERM-BF427c for its maize 98140 DNA copy number ratio. Paper copies can be obtained from the Institute for Reference Materials and Measurements on request.