

MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations

MIR162xDAS-40278-9,
MON89034x1507xMIR162,
MON89034xMIR162xDAS-40278-9,
1507xMIR162xDAS-40278-9,
MIR162xNK603xDAS-40278-9,
MON89034x1507xMIR162xDAS-40278-9,
MON89034x1507xNK603xDAS40278-9,
MON89034xMIR162xNK603xDAS-40278-9,
1507xMIR162xNK603xDAS-40278-9

Fact-sheet for operators

2023



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MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations MIR162xDAS-40278-9, MON89034x1507xMIR162, MON 89034xMIR162x DAS-40278-9, 1507xMIR162xDAS-40278-9, MIR162xNK603xDAS-40278-9, MON89034x1507xMIR162xDAS-40278-9, MON 89034x1507xNK603xDAS40278-9, MON89034xMIR162xNK603xDAS-40278-9, 1507xMIR162xNK603xDAS-40278-9

Commission implementing decision (EU) 2023/2133¹ of 13 October 2023 authorised the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034x1507xMIR162xNK603xDAS-40278-9² and its sub-combinations MIR162xDAS-40278-9, MON89034x1507xMIR162, MON 89034xMIR162x DAS-40278-9, 1507xMIR162xDAS-40278-9, MIR162xNK603xDAS-40278-9, MON89034x1507xMIR162xDAS-40278-9, MON 89034x1507xNK603xDAS40278-9, MON89034xMIR162xNK603xDAS-40278-9, 1507xMIR162xNK603xDAS-40278-9³, pursuant to Regulation (EC) No 1829/2003⁴ of the European Parliament and of the Council.

The following products are authorised by Commission implementing decision (EU) 2023/2133:

- (a) food and food ingredients containing, consisting of or produced from MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations covered by this authorisation
- (b) Feed containing, consisting of, or produced from MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations covered by this authorisation
- (c) Products containing or consisting of MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations covered by this authorisation for uses other than those provided for in points (a) and (b), with the exception of cultivation.

It shall be noted that among the twenty five sub-combinations of the single events constituting MON89034x1507xMIR162xNK603xDAS-40278-9 maize, sixteen of those sub-combinations were already authorized as follows: MON 89034x1507, authorised by Commission Implementing Decision 2013/650/EU⁵; MON 89034xMIR162, MON 89034xNK603, MIR162xNK603, MON 89034xMIR162xNK603, authorised by Commission

¹ EC, 2023. Commission Implementing Decision (EU) 2023/2133 of 13 October 2023 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 and nine sub-combinations, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202302133&qid=1699949767883

² Also known as PowerCore® Ultra Enlist® Corn in the commercial context.

³ Hereafter referred to as MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations covered by this authorisation

⁴ EC, 2003. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003R1829>

⁵ EC, 2013. Commission Implementing Decision 2013/650/EU of 6 November 2013 authorising the placing on the market of products containing, consisting of, or produced from genetically modified (GM) maize MON 89034 × 1507 × MON88017 × 59122 (MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7), four related GM maize combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89034-3 × DAS-01507-1 × MON-88017-3), MON89034 × 1507 × 59122 (MON-89034-3 × DAS-01507-1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89034-3 × MON-88017-3 × DAS-59122-7), 1507 × MON 88017 × 59122 (DAS-01507-1 × MON-88017-3 × DAS-59122-7)) and four related GM maize combining two different single GM events (MON89034 × 1507 (MON-89034-3 × DAS-01507-1), MON89034 × 59122 (MON-89034-3 × DAS-59122-7), 1507 × MON88017 (DAS-01507-1 × MON-88017-3), MON 88017 × 59122 (MON-88017-3 × DAS-59122-7)) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013D0650>

Implementing Decision (EU) 2021/60⁶; MON 89034xDAS-40278-9, 1507xDAS-40278-9, MON 89034x1507xDAS-40278-9, authorised by Commission Implementing Decision (EU) 2019/2086⁷; NK603xDAS-40278-9, MON 89034xNK603xDAS-40278-9, 1507xNK603xDAS-40278-9, MON 89034x1507xNK603xDAS-40278-9, authorised by Commission Implementing Decision (EU) 2019/2085⁸; 1507xMIR162, authorised by Commission Implementing Decision (EU) 2019/1305⁹; 1507xNK603, authorised by Commission Implementing Decision (EU) 2019/1306¹⁰; MON 89034x1507xNK603, authorised by Commission Implementing Decision 2013/648/EU¹¹; 1507xMIR162xNK603, authorised by Commission Implementing Decision (EU) 2021/1388¹². Therefore, the placing on the market of all sub-combinations of MON89034x1507xMIR162xNK603xDAS-40278-9 maize is authorised in the European Union.

General Characteristics

MON89034x1507xMIR162xNK603xDAS-40278-9 maize has been obtained by traditional breeding between genetically modified MON89034, 1507, MIR162, NK603 and DAS-40278-9 maize single events. No new genetic modifications were introduced to obtain MON89034x1507xMIR162xNK603xDAS-40278-9 maize nor any of its sub-combinations.

Therefore, MON89034x1507xMIR162xNK603xDAS-40278-9 maize expresses the newly expressed proteins from the single events:

- MON89034 maize expresses the Cry1A.105 and Cry2Ab2 proteins, which confer protection against certain lepidopteran pests.
- 1507 expresses the Cry1F protein, which confers protection against certain lepidopteran pests and the PAT protein, which confers tolerance to glufosinate ammonium-based herbicides.
- MIR162 maize expresses the Vip3Aa20 protein, which confers protection against certain lepidopteran pests. In addition, the PMI protein was used as a selection marker in the genetic modification process.

⁶ EC, 2021. Commission Implementing Decision (EU) 2021/60 of 22 January 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and NK603, and repealing Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021D0060>

⁷ EC, 2019. Commission Implementing Decision (EU) 2019/2086 of 28 November 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D2086>

⁸ EC, 2019. Commission Implementing Decision (EU) 2019/2085 of 28 November 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D2085>

⁹ EC, 2019. Commission Implementing Decision (EU) 2019/1305 of 26 July 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × 1507 × GA21 and sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1305>

¹⁰ EC, 2019. Commission Implementing Decision (EU) 2019/1306 of 26 July 2019 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize 1507 × NK603 (DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1306&qid=1699973140253>

¹¹ EC, 2013. 2013/648/EU: Commission Implementing Decision of 6 November 2013 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × 1507 × NK603 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013D0648>

¹² EC, 2021. Commission Implementing Decision (EU) 2021/1388 of 17 August 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 1507 × MIR162 × MON810 × NK603 and genetically modified maize combining two or three of the single events 1507, MIR162, MON810 and NK603, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021D1388>

- NK603 expresses the CP4 EPSPS and CP4 EPSPS L214P proteins, which confer tolerance to glyphosate-containing herbicides
- DAS-40278-9 maize expresses the AAD-1 protein, which confers tolerance to 2,4-D and AOPP herbicides.

MON89034x1507xMIR162xNK603xDAS-40278-9 maize therefore confers i.) herbicide tolerance to glufosinate, glyphosate, 2,4-D and AOPP herbicides, due to the presence of the PAT, CP4 EPSPS and AAD-1 proteins, respectively and ii.) control of certain lepidopteran pests based on the presence of the Cry1A.105, Cry2Ab2, Cry1F and Vip3Aa20 proteins, conferring multiple modes of action for insect protection. Trait pyramids such as MON89034x1507xMIR162xNK603xDAS-40278-9 maize provide greater potential durability compared to products expressing a single mode of action, because each mode of action controls insects that are partially or completely resistant to the other mode of action.

Similarly, the different sub-combinations of MON89034x1507xMIR162xNK603xDAS-40278-9 maize have the characteristics conferred by the respective sub-combinations of single events.

Safety

In May 2018, Dow AgroSciences Europe on behalf of Dow AgroSciences LLC¹³ submitted to the competent authority of the Netherlands an application for the placing on the market of MON89034x1507xMIR162xNK603xDAS-40278-9 maize and all its sub-combinations for food and feed uses, import and processing in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2018-151).

On 4 July 2022, the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms (GMO) adopted a positive scientific opinion in which it concluded:

“The GMO Panel concludes that maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 and its subcombinations, as described in this application, are as safe as the comparator and the selected non-GM reference varieties with respect to potential effects on human and animal health and the environment.”¹⁴

Monitoring Conditions

As indicated in the positive EFSA GMO Panel opinion, MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations are as safe and as nutritious as its non-GM comparator¹⁴. Therefore, post-market monitoring of food/feed derived from MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations is not necessary, as confirmed by the EFSA GMO Panel opinion¹⁴ and the Commission authorisation decision¹.

Furthermore, no potential adverse effects to human and animal health or the environment have been identified in the environmental risk assessment from the uses of MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations. Therefore, no case-specific monitoring of MON89034x1507xMIR162xNK603xDAS-40278-9

¹³ As of January 4th, 2021 Dow AgroSciences LLC changed its name to Corteva Agriscience LLC.

¹⁴ EFSA GMO Panel, 2022. Scientific Opinion on the assessment of genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 for food and feed uses, under regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2018-151). EFSA Journal 2022; 20(8):7451, 44 pp. <https://doi.org/10.2903/j.efsa.2022.7451>

maize and its sub-combinations is necessary, as confirmed by the EFSA GMO panel in its scientific opinion¹⁴.

As specified by Commission decision (EU) 2023/2133¹, a post-market environmental monitoring (PMEM) plan for MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations covered by this authorisation is in place and consists of a general surveillance plan, not based on a particular hypothesis, to report observed unanticipated adverse effects on human and animal health or the environment arising from handling or use of viable MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations covered by this authorisation, if any.

As stated by the EFSA GMO Panel in its scientific opinion on MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations for food and feed uses, import and processing: *“The GMO Panel considers that the scope of the PMEM plan provided by the applicant is consistent with the intended uses of five-event stack maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9. The GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan. The PMEM plan and reporting intervals are in line with the intended uses of the five-event stack maize and its subcombinations.”*¹⁴

The monitoring takes place in cooperation with monitoring networks of trade associations representing operators importing, handling and processing viable maize commodity, which report back to CropLife Europe. The result of the monitoring activities is reported back to the European Commission by Corteva Agriscience on an annual basis.

The post-market environmental monitoring plan for MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its subcombinations covered by this authorisation has been published on the EU register for genetically modified food and feed¹⁵.

Conditions for traceability and labelling

Operators importing, handling and processing grain and foods and feeds derived from MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations covered by this authorisation in the EU shall comply with the conditions for traceability and labelling outlined in Regulations (EC) No 1829/2003⁴ and 1830/2003¹⁶ and in Commission decision (EU) 2023/2133¹.

For the purposes of the specific labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be maize.

The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying products containing or consisting of MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations covered by this authorisation with the exception of foods and food ingredients containing, consisting of, or produced from MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations covered by this authorisation.

¹⁵ <https://ec.europa.eu/food/food-feed-portal/screen/gmo/search>

¹⁶ EC, 2003. Regulation (EC) No1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

The unique identifiers assigned to MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations covered by this authorisation are listed in Table 1.

Table 1: MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations covered by Commission decision (EU) 2023/2133¹:

Maize	Unique identifier
MON89034x1507xMIR162xNK603xDAS-40278-9	MON-89Ø34-3x DAS-Ø15Ø7-1x SYN-IR162-4xMON-ØØ6Ø3-6xDAS-4Ø278-9
MON 89034x1507xMIR162xDAS-40278-9	MON-89Ø34-3xDAS-Ø15Ø7-1xSYN-IR162-4xDAS-4Ø278-9
MON 89034x1507xNK603xDAS-40278-9	MON-89Ø34-3xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6xDAS-4Ø278-9
MON 89034xMIR162xNK603xDAS-40278-9	MON-89Ø34-3xSYN-IR162-4xMON-ØØ6Ø3-6xDAS-4Ø278-9
1507xMIR162xNK603xDAS-40278-9	DAS-Ø15Ø7-1xSYN-IR162-4xMON-ØØ6Ø3-6xDAS-4Ø278-9
MON 89034x1507xMIR162	MON-89Ø34-3xDAS-Ø15Ø7-1xSYN-IR162-4
MON 89034xMIR162xDAS-40278-9	MON-89Ø34-3xSYN-IR162-4xDAS-4Ø278-9
1507xMIR162xDAS-40278-9	DAS-Ø15Ø7-1xSYN-IR162-4xDAS-4Ø278-9
MIR162xNK603xDAS-40278-9	SYN-IR162-4xMON-ØØ6Ø3-6xDAS-4Ø278-9
MIR162xDAS-40278-9	SYN-IR162-4xDAS-4Ø278-9

Methods for detection and reference material

Validated detection method

The detection, sampling and identification methods for MON89034x1507xMIR162xNK603xDAS-40278-9 maize consist of the same detection, sampling and identification methods available for MON89034, 1507, MIR162, NK603 and DAS-40278-9 maize, which have been validated by the Joint Research Centre (JRC) of the European Union Reference Laboratory (EURL). In accordance with Regulation (EC) No 1829/2003 and in line with the above-mentioned application for authorisation of MON89034x1507xMIR162xNK603xDAS-40278-9 maize and its sub-combinations, the applicant provided the JRC-EURL with a detection method that consists of the validated event-specific PCR method for the quantification of MON89034, 1507, MIR162, NK603 and DAS-40278-9 maize, for verification. The detection method has been validated by EURL in November 2020 and is publicly available from the JRC-EURL website¹⁷.

Certified reference material

The Certified Reference Materials (CRM) for the individual events comprising MON89034x1507xMIR162xNK603xDAS-40278-9 maize consist of the CRMs for MON89034, 1507, MIR162, NK603 and DAS-40278-9 maize. The certified reference materials for MON 89034 (AOCS 0906-E2) is accessible via the American Oil Chemists' Society¹⁸. The certified reference materials for 1507 (ERM®-BF418), MIR162 (ERM®-

¹⁷ European Union Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF). Method validations. <https://gmo-crl.jrc.ec.europa.eu/method-validations>

¹⁸ <https://www.aocs.org/crm>

BF446), NK603 (ERM[®]-BF415) and DAS-40278-9 (ERM[®]-BF433) maize are accessible via the JRC of the European Commission¹⁹.

Contact points for Operators

As there are other technology providers for GM maize and shipments entering the European harbours may be commingled, an industry wide approach has been developed. Therefore, CropLife Europe is the central communication point for the GM plant technology providers.

CropLife Europe is the primary address for reporting general surveillance activities or any unanticipated adverse effects and is skilled to provide adequate response. In addition, CropLife Europe will transfer the messages to the relevant industry partner if further action is required.

Operators are requested to report, if possible, via their branch representative, any unanticipated adverse effect to CropLife Europe at: <https://croplifeeurope.eu/product-information/>

If required, additional comments or questions can also be addressed to:

Corteva Agriscience
Rue Montoyer, 25
1000 Brussels
Belgium
Email address: CortevaEUBiotech@corteva.com

¹⁹ <https://crm.jrc.ec.europa.eu/>