

DAS-40278-9 maize
Enlist™ maize
Fact-sheet for operators

2021



DAS-40278-9 maize **Fact-sheet for operators**

The placing on the market of products containing, consisting of, or produced from genetically modified maize DAS-40278-9, also referred to as Enlist™ maize, was authorised, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by the European Commission on 4 July 2017 under Commission implementing decision (EU) 2017/1212 (EC, 2017)¹.

The authorisation decision for DAS-40278-9 maize is published at:

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017D1212&from=EN>

The following products are authorised:

- (a) Food and food ingredients containing, consisting of, or produced from DAS-40278-9 maize
- (b) Feed containing, consisting of, or produced from DAS-40278-9 maize
- (c) DAS-40278-9 maize in products containing it or consisting of it for any other use than those provided in points (a) and (b), with the exception of cultivation

General Characteristics of DAS-40278-9 maize

DAS-40278-9 maize was developed to express the aryloxyalkanoate dioxygenase-1 (AAD-1) protein which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) herbicides.

For further reading, please visit the following sites: <https://www.enlist.com/en/traits.html>

Safety of the DAS-40278-9 maize

In November 2010, Dow AgroSciences submitted an application for the placing on the market of DAS-40278-9 maize for food and feed uses, import and processing in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2010-89). On 26 October 2016, the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms (GMO) adopted a positive scientific opinion in which it concluded : *“the EFSA GMO Panel considers that the information available for maize DAS-40278-9 addresses the scientific comments raised by Members States and that maize DAS-40278-9, as described in this application, is as safe as the non-GM comparator and non-GM maize reference varieties with respect to potential effects on human and animal health and the environment in the context of the scope of the application (EFSA, 2016)².*

¹ EC, 2017. Commission Implementing Decision (EU) 2017/1212 of 4 July 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DAS-40278-9, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed

² EFSA, 2016. Scientific opinion on an application by Dow AgroSciences LLC (EFSA-GMO-NL-2010-89) for placing on the market the genetically modified herbicide-tolerant maize DAS-40278-9 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. *EFSA Journal* 2016; 14(12):4633, 25pp. doi:10.2903/j.efsa.2016.4633

The EFSA GMO panel scientific opinion is available at:
<https://www.efsa.europa.eu/en/efsajournal/pub/4633>

Monitoring Conditions for DAS-40278-9 maize

As indicated in the positive EFSA GMO Panel opinion on DAS-40278-9 maize, “*Maize DAS-40278-9 is as nutritious as non-GM commercial varieties*” (EFSA, 2016). Therefore, post-market monitoring of DAS-40278-9 maize food/feed is not necessary, as confirmed by the EFSA GMO Panel (EFSA, 2016) and in the Commission authorisation decision for DAS-40278-9 maize (EC, 2017)³.

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 DAS-40278-9 maize. Therefore, no case-specific monitoring of DAS-40278-9 maize is necessary, as confirmed by the EFSA GMO panel in its scientific opinion (EFSA, 2016). As specified by Commission decision (EC, 2017)³, a post-market environmental monitoring (PMEM) plan for DAS-40278-9 maize 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 DAS-40278-9 maize, if any.

As stated by the EFSA GMO Panel in its scientific opinion on DAS-40278-9 maize for food and feed uses, import and processing “*The scope of the PMEM plan provided by the applicant and the reporting intervals are in line with the intended uses of maize DAS-40278-9*” (EFSA, 2016).

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 the CropLife Europe. The result of the monitoring activities is reported back to the European Commission by Dow AgroSciences on an annual basis.

The post-market environmental monitoring plan for DAS-40278-9 maize has been published on the EU register for genetically modified food and feed:

http://ec.europa.eu/food/dyna/gm_register/Monitoring%20plan%20maize%20DAS-40278-9.pdf

Conditions for traceability and labelling for DAS-40278-9 maize

Operators importing, handling and processing DAS-40278-9 maize grain and derived foods and feeds in the EU shall comply with the conditions for traceability and labelling outlined in Regulations (EC) No 1829/2003 and 1830/2003 and in Commission Implementing Decision (EU) 2017/1212 for DAS-40278-9 maize.

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 DAS-40278-9 maize with the exception of foods and food ingredients containing, consisting of, or produced from DAS-40278-9 maize.

The unique identifier assigned to DAS-40278-9 maize is DAS-40278-9.

Methods for detection and reference material for DAS-40278-9 maize

Validated DAS-40278-9 maize detection method

In accordance with Regulation (EC) No 1829/2003 and in line with the above-mentioned application for authorisation of the DAS-40278-9 maize, a validated event-specific detection method for the quantification of DAS-40278-9 maize event has been published by the European Union Reference Laboratory (EURL) of the Joint Research Centre (JRC). The validated detection method is publicly available from the JRC-EURL website:

<http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>

DAS-40278-9 maize certified reference material

In accordance with Regulation (EC) No 1829/2003 and in line with the above application for authorisation of DAS-40278-9 maize, certified reference material is available at the Joint Research Centre's GMO Reference Unit. The corresponding certified reference material set ERM®-BF433 can be obtained via the JRC website:

<https://crm.jrc.ec.europa.eu/e/92/Catalogue-price-list-pdf>

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: www.ecpa.eu/product-info

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

Corteva Agriscience

Rue Montoyer 25

1000 Bruxelles

Belgium

Email address: CortevaEUBiotech@corteva.com