

281-24-236 x 3006-210-23 x MON 88913

cotton

WideStrike[®] Flex cotton

Fact-sheet for operators

2021

281-24-236 x 3006-210-23 x MON 88913 cotton

WideStrike® Flex cotton

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The placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 x 3006-210-23 x MON 88913 (also referred to as WideStrike® Flex cotton), developed by a conventional cross between 281-24-236 x 3006-210-23 cotton (known as WideStrike® Insect Protection cotton) and MON 88913 cotton (known as Genuity® Roundup Ready® Flex cotton¹), 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) 2017/1211².

The authorisation decision for 281-24-236 x 3006-210-23 x MON 88913 cotton is published at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017D1211&from=EN>

The following products are authorised:

- (a) Food and food ingredients containing, consisting of, or produced from 281-24-236 x 3006-210-23 x MON 88913 cotton
- (b) Feed containing, consisting of, or produced from 281-24-236 x 3006-210-23 x MON 88913 cotton
- (c) 281-24-236 x 3006-210-23 x MON 88913 cotton in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation

General Characteristics of 281-24-236 x 3006-210-23 x MON 88913 cotton

281-24-236 x 3006-210-23 x MON 88913 cotton has been developed to express the Cry1F and Cry1Ac proteins which provide protection against certain lepidopteran insect pests, the phosphinothricin acetyltransferase (PAT) protein which confers tolerance to glufosinate ammonium herbicides, and the modified CP4 5-enolpyruvyl-shikimate-3-phosphate synthase (CP4 EPSPS) protein conferring tolerance to glyphosate herbicides.

The 281-24-236 x 3006-210-23 x MON88913 cotton has been obtained by conventional breeding cross between two genetically modified cotton lines:

- the two-event stack 281-24-236 x 3006-210-23 cotton expressing the Cry1F and Cry1Ac proteins and the PAT protein, which confer protection against certain lepidopteran insect pests and tolerance to glufosinate ammonium herbicides, respectively; and
- MON 88913 cotton expressing the modified CP4 EPSPS protein conferring tolerance to glyphosate herbicides.

¹ Genuity and Roundup Ready are registered trademarks of Monsanto technology LLC

² Commission Implementing Decision (EU) 2017/1211 of 4 July 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 x 3006-210-23 x MON 88913, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

Further reading materials can be found in <https://phytogencottonseed.com/traits>

Safety of the 281-24-236 x 3006-210-23 x MON 88913 cotton

In March 2009, Dow AgroSciences Europe³ submitted an application for the placing on the market of 281-24-236 x 3006-210-23 x MON 88913 cotton for food and feed uses, import and processing in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2009-68). On 9 March 2016, 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 the three-event stack cotton is as safe and as nutritious as its conventional counterpart in the context of its scope”* (EFSA, 2016)⁴.

“Considering the introduced traits, the outcome of the comparative analysis, the routes of exposure and the limited exposure levels, the GMO Panel concluded that this three-event stack cotton would not raise safety concerns in the event of accidental release of viable GM cotton seeds into the environment” (EFSA, 2016).

The EFSA GMO panel scientific opinion is available at:

<https://www.efsa.europa.eu/en/efsajournal/pub/4430>

Monitoring Conditions for 281-24-236 x 3006-210-23 x MON 88913 cotton

As indicated in the positive EFSA GMO Panel opinion on 281-24-236 x 3006-210-23 x MON 88913 cotton, *“the three-event stack cotton is as safe and as nutritious as its conventional counterpart”* (EFSA, 2016). Therefore, post-market monitoring of food/feed derived from 281-24-236 x 3006-210-23 x MON 88913 cotton is not necessary, as confirmed by the EFSA GMO Panel (EFSA, 2016) and in the Commission authorisation decision for 281-24-236 x 3006-21023 x MON 88913 cotton (EC, 2017).

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 281-24-236 x 3006-210-23 x MON 88913 cotton. Therefore, case-specific monitoring of 281-24-236 x 3006-210-23 x MON 88913 cotton is not necessary, as confirmed by the EFSA GMO panel in its scientific opinion (EFSA, 2016). As specified by Commission decision (EC, 2017), a post-market environmental monitoring plan for 281-24-236 x 3006-210-23 x MON 88913 cotton 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 281-24-236 x 3006-210-23 x MON 88913 cotton, if any.

As stated by the EFSA GMO Panel in its scientific opinion on 281-24-236 x 3006-210-23 x MON 88913 cotton for food and feed uses, import and processing *“The post-market environmental*

³ hereafter referred to as Dow AgroSciences

⁴ EFSA, 2016. Scientific opinion on an application by Dow AgroSciences LLC (EFSA-GMO-NL-2009-68) for the placing on the market of cotton 281-24-236 x 3006-210-23 x MON 88913 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. EFSA Journal 2016; 14(4):4430, 21pp. doi:10.2903/j.efsa.2016.4430

monitoring plans provided by the applicant are in line with the scope of the three-event stack cotton” (EFSA, 2016).

The monitoring takes place in cooperation with monitoring networks of trade associations representing operators importing, handling and processing viable cotton commodity, which report back to 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 281-24-236 x 3006-210-23 x MON 88913 cotton has been published on the EU register for genetically modified food and feed:
http://ec.europa.eu/food/dyna/gm_register/Monitoring%20plan%20cotton%20281-24-236x3006-210-23xMON88913.pdf

Conditions for traceability and labelling for 281-24-236 x 3006-210-23 x MON 88913 cotton

Operators importing, handling and processing 281-24-236 x 3006-210-23 x MON 88913 cotton 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) 2017/1211 for 281-24-236 x 3006-210-23 x MON 88913 cotton.

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 cotton.

The words ‘not for cultivation’ shall appear on the label of and in documents accompanying products containing or consisting of 281-24-236 x 3006-210-23 x MON 88913 cotton, with the exception of foods and food ingredients.

The unique identifier assigned to 281-24-236 x 3006-210-23 x MON 88913 cotton is DAS-24236-5×DAS-21Ø23-5×MON-88913-8.

Methods for detection and reference material for 281-24-236 x 3006-210-23 x MON 88913 cotton

Validated 281-24-236 x 3006-210-23 x MON 88913 cotton detection method

The detection, sampling and identification methods for 281-24-236 x 3006-210-23 x MON 88913 cotton consist of the same detection, sampling and identification methods available for 281-24-236, 3006-210-23 and MON 88913 cottons, which have been validated by the Joint Research Centre (JRC) of the Community Reference Laboratory for GM Food and Feed.

In accordance with Regulation (EC) No 1829/2003 and in line with the above-mentioned application for authorisation of 281-24-236 x 3006-210-23 x MON 88913 cotton, Dow AgroSciences provided the JRC European Union Reference Laboratory (JRC-EURL) with a PCR detection method that consists of the validated event-specific real-time PCR method for the quantification of 281-24-236, 3006-210-23 and MON 88913 cottons, for verification. The

detection method has been validated by EURL on 22 March 2016 and is publicly available from the JRC-EURL website:

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

281-24-236 x 3006-210-23 x MON 88913 cotton certified reference material

The Certified Reference Materials (CRM) for 281-24-236 x 3006-210-23 x MON 88913 cotton consist of the CRMs for 281-24-236 x 3006-210-23 cotton produced by the Joint Research Centre's GMO Reference Unit and for MON 88913 produced by the American Oil Chemists Society (AOCS). The corresponding CRM set ERM®-BF422 for 281-24-

236 x 3006-210-23 can be obtained via the JRC website:

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

AOCS 0906-D and AOCS 0804-A for MON 88913 can be obtained via AOCS website:

<https://www.aocs.org/crm>

Contact points for Operators

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

CroLife Europe is the primary address for reporting general surveillance activities or any unanticipated adverse effects, and is skilled to provide adequate response. In addition, CroLife 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 CroLife Europe at: <https://www.ecpa.eu/product-info>

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

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1000 Bruxelles

Belgium

Email address: CortevaEUBiotech@corteva.com