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COMMON FORMAT FOR Risk Assessment

(In accordance with Annex III of the Cartagena Protocol on Biosafety)

Risk assessment details	
1. Country Taking Decision:	South Africa
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LMO information	
4. Name and identity of the living modified organism:	MON 89034 × TC1507 × NK603 × DAS-40278-9 was obtained by conventional breeding of four single event products: MON 89034; TC1507, NK603 and DAS-40278-9. The maize contains <i>cry1A.105</i> , <i>cry2Ab2</i> , <i>cry1F</i> , <i>pat</i> , CP4 <i>epsps</i> and <i>aad-1</i> genes conferring resistance against certain lepidopteran target pests and tolerance to glufosinate-ammonium, glyphosate-based and 2,4-D herbicides.
5. Unique identification of the living modified organism:	MON-89034-3×DAS-01507-1×MON-00603-6×DAS-40278-9
6. Transformation event:	MON 89034 × TC1507 × NK603 × DAS-40278-9
7. Introduced or Modified Traits:	Chemical tolerance - Herbicide tolerance Pest resistance - Insect resistance
8. Techniques used for modification:	No new genetic modification has been introduced in MON 89034 × TC1507 × NK603 × DAS-40278-9 maize, since it was produced through a traditional breeding cross between MON 89034, TC1507, NK603 and DAS-40278-9 maize. The individual components were developed as follows: MON89034: plasmid carried by <i>Agrobacterium tumefaciens</i> , TC1507 and NK603: biolistic methods and DAS-40278-9 by direct Whiskers-mediated transformation

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9. Description of gene modification:	<p>No new genetic modification has been introduced in MON 89034 × TC1507 × NK603 × DAS-40278-9 maize, since it was produced through a traditional breeding cross between MON 89034, TC1507, NK603 and DAS-40278-9 maize.</p> <p>MON 89034 was developed through <i>Agrobacterium</i>-mediated transformation of maize to produce the <i>Bt</i> insecticidal proteins Cry1A.105 and Cry2Ab2 using the binary plasmid vector, PV-ZMIR245.</p> <p>1507 maize was obtained by insertion of a linear DNA fragment (insert PHI8999A), containing the plant optimised <i>cry1F</i> and <i>pat</i> coding sequences and the necessary regulatory components, into maize cells using the particle acceleration method. Maize TC1507 maize expresses the Cry1F and PAT proteins.</p> <p>NK603 was also generated by particle acceleration technology using the DNA fragment PV-ZMGT32L containing a 5-enolpyruvylshikimate-3-phosphate synthase (<i>epsps</i>) gene from <i>Agrobacterium</i> sp. strain CP4 (<i>cp4 epsps</i>)</p> <p>DAS-40278-9 maize was developed using direct Whiskers-mediated transformation to stably incorporate the <i>aad-1</i> gene from the soil bacterium, <i>Sphingobium herbicidovorans</i>, into maize.</p>
Characteristics of modification	
10. Vector characteristics (Annex III.9(c)):	<p>No vector was used in the production of MON 89034 × TC1507 × NK603 × DAS-40278-9 maize. Traditional breeding methods were used in the traditional crossing between progeny of MON 89034, TC1507, NK603 and DAS-40278-9 maize, to generate MON 89034 × TC1507 × NK603 × DAS-40278-9 maize.</p>

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11. Insert or inserts (Annex III.9(d)):	MON 89034 × TC1507 × NK603 × DAS-40278-9 maize was obtained by traditional breeding of four single events: MON 89034, TC1507, NK603 and DAS-40278-9 maize. The transferred nucleic acid in each of the individual events is inserted at a single locus and are stably transmitted over generations. The inserts in MON 89034 function to provide protection against lepidopteran insect pests; those in TC1507 provide protection against lepidopteran insect pests and glufosinate- ammonium; that in NK603 imparts tolerance to glyphosate, while that in DAS-40278-9 degrades the herbicide 2,4-dichlorophenoxyacetic acid (2,4-D).
Recipient organism or parental organisms (Annex III.9(a)):	
12. Taxonomic name/status of recipient organism or parental organisms:	Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta; Spermatophyta; Magnoliophyta; Liliopsida; Poales; Poaceae
13. Common name of recipient organism or parental organisms:	Maize; corn
14. Point of collection or acquisition of recipient or parental organisms:	Commercially available maize products MON89034, NK603, TC1507 and DAS-40278-9
15. Characteristics of recipient organism or parental organisms related to biosafety:	Maize is a well-known crop plant worldwide. Maize is extensively cultivated in South Africa and has a history of safe use. Maize grain and forage, or derived products of maize, are not considered to have toxic effects on humans, animals and other organisms.
16. Centre(s) of origin of recipient organism or parental organisms:	It is believed that maize originated in south central Mexico, specifically in the Pacific slope of the modern Mexican states of Oaxaca, Tehuacán, and the Valley of Mexico. Specific geographic coordinates are unknown
17. Centres of genetic diversity, if known, of recipient organism or parental organisms:	Centers of genetic diversity of maize are the same as its Centre of origin.

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18. Habitats where the recipient organism or parental organisms may persist or proliferate:	Maize does not persist or proliferate outside of agriculture in South Africa. There are no known populations in any natural habitat in the country.
Donor organism or organisms (Annex III.9(b)):	
19. Taxonomic name/status of donor organism(s)	<p>MON 89034 × TC1507 × NK603 × DAS-40278-9 maize was obtained by traditional breeding of four single events: MON 89034, TC1507, NK603 and DAS-40278-9 maize. Donor organisms for the four individual events were:</p> <p><u>Donor organism (s) MON 89034</u> <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> (Bacteria; Firmicutes; Bacilli; Bacillales; Bacillaceae; Bacillus)</p> <p><u>Donor organism (s) TC1507</u> <i>Bacillus thuringiensis</i> var. <i>aizawai</i> (Bacteria; Firmicutes; Bacilli; Bacillales; Bacillaceae; Bacillus)</p> <p><i>Streptomyces viridochromogenes</i> (Bacteria; Actinobacteria; Actinobacteria; Actinomycetales; Streptomycetaceae; Streptomyces)</p> <p><u>Donor organism (s) NK603</u> <i>Agrobacterium tumefaciens</i> strain CP4 (Bacteria; Proteobacteria; Alphaproteobacteria; Rhizobiales; Rhizobiaceae; Rhizobium/Agrobacterium group; Agrobacterium)</p> <p><u>Donor organism (s) DAS-40278-9</u> <i>Sphingobium herbicidovorans</i> (Bacteria; Proteobacteria; Alphaproteobacteria; Sphingomonadales; Sphingomonadaceae; Sphingobium)</p>

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20. Common name of donor organism(s):	<p><u>Donor organism (s) MON 89034</u></p> <p>Bt</p> <p><u>Donor organism (s) TC1507</u></p> <p>Bt</p> <p><i>Streptomyces viridochromogenes</i></p> <p><u>Donor organism (s) NK603</u></p> <p><i>Agrobacterium tumefaciens</i></p> <p><u>Donor organism (s) DAS-40278-9</u></p> <p><i>Sphingobium herbicidovorans</i></p>
21. Point of collection or acquisition of donor organism(s):	<p>None of the donor organisms was collected from a specific geographic location. The genes, promoters, or transcription terminator elements were acquired from commercial suppliers or from research collaborators.</p>
22. Characteristics of donor organism(s) related to biosafety:	<p><i>Bacillus thuringiensis</i> is a common soil bacterium found worldwide. It is not a pathogen of plants, humans, or higher animals, but it normally produces proteins that are toxic to insects.</p> <p><i>Streptomyces viridochromogenes</i> is ubiquitous in the soil. It exhibits very slight antimicrobial activity, is inhibited by streptomycin, and there have been no reports of adverse effects on humans, animals, or plants.</p> <p><i>Agrobacterium tumefaciens</i> is a bacterium that is found in soils worldwide. It infects plants but does not infect humans or animals.</p> <p><i>Sphingobium herbicidovorans</i> is a gram-negative soil bacterium. Sphingomonads are widely distributed in nature and have been isolated from land and water habitats, as well as from plant root systems, clinical specimens, etc. There are no reports of <i>S. herbicidovorans</i> being implicated as a human pathogen, producing any allergens or adversely affecting livestock or the environment.</p>
Intended use and receiving environment	

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23. Intended use of the LMO (Annex III 9(g)):	For all uses as for any other maize, excluding cultivation.
24. Receiving environment (Annex III.9(h)):	This is not an application for release of MON 89034 × TC1507 × NK603 × DAS-40278-9 into the environment of South Africa.
Risk assessment summary	
25. Detection/Identification method of the LMO (Annex III.9(f)):	Since no novel genetic modification has been introduced in the production of MON 89034 × TC1507 × NK603 × DAS-40278-9 maize—produced by conventional breeding methods between MON 89034, TC1507, NK603 and DAS-40278-9 maize—, MON 89034 × TC1507 × NK603 × DAS-40278-9 is detectable using the existing detection methods for: MON 89034, TC1507, NK603 and DAS-40278-9 maize.
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	The scope of this application does not include cultivation of MON 89034 × TC1507 × NK603 × DAS-40278-9 maize seed products in South Africa. Any exposure to the environment will be limited to any unintended release of MON 89034 × TC1507 × NK603 × DAS-40278-9 maize, which could occur via accidental spillage during loading/unloading of the vessels, trains and trucks carrying the load of commodity grain including MON 89034 × TC1507 × NK603 × DAS-40278-9 maize destined for processing into animal feed or human food products. However, this limited exposure is highly unlikely to give rise to any adverse effect and, if necessary, any spillage could be easily controlled by the application of current agricultural practices used for the control of volunteer maize plants, such as the application of non-selective herbicide with the exception of glufosinate-ammonium, glyphosate and 2,4-D. Furthermore, maize is a poor competitor and cannot persist as a weed. Environmental conditions at the sites of handling are unlikely to be conducive to germination, growth and reproduction of maize grain that is incidentally released.
27. Evaluation of the consequences (Annex III.8(c)):	The possible consequences of environmental exposure are negligible
28. Overall risk (Annex III.8(d)):	The overall risk posed by this GMO is negligible

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29. Recommendation (Annex III.8(e)):	<p>The scope of this application does not include cultivation of MON 89034 × TC1507 × NK603 × DAS-40278-9 maize seed products in South Africa. Therefore any exposure to the environment will be limited to any unintended release of MON 89034 × TC1507 × NK603 × DAS-40278-9 maize, which could occur via accidental spillage during loading/unloading of the vessels, trains and trucks carrying the load of commodity grain including MON 89034 × TC1507 × NK603 × DAS-40278-9 maize destined for processing into animal feed or human food products. However, this limited exposure is highly unlikely to give rise to any adverse effect and, if necessary, any spillage could be easily controlled by the application of current agricultural practices used for the control of volunteer maize plants, such as the application of non-selective herbicide with the exception of glufosinate-ammonium, glyphosate and 2,4-D.</p> <p>Therefore, application of established routine surveillance practices (e.g. the monitoring of agricultural cultivars or plant protection products) for the general surveillance of the occurrence of unanticipated adverse effects to conventional agricultural practice is not necessary for MON 89034 × TC1507 × NK603 × DAS-40278-9 maize.</p> <p>However, general surveillance might assist in confirming the safety of MON 89034 × TC1507 × NK603 × DAS-40278-9 maize with a view to safeguarding against any unanticipated effects.</p>
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	No actions are required at this time
Additional information	
31. Availability of detailed risk assessment information:	All data relating to this risk assessment have been presented in this dossier
32. Any other relevant information:	To the best of our knowledge, all relevant information has been supplied in this dossier.

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33. Attach document:	<i>Not applicable to applicant</i> <Specific types of entry: option to choose a file from the local source and 'upload' a copy to the BCH server>
34. Notes:	<Text entry>
