PART II

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
2.	Title:	Application for a general release of genetically modified DAS-40278-9 maize.
3.	Contact details:	Dow AgroSciences Southern Africa (Pty) Ltd., CBI Deleted information
	LMO information	
4.	Name and identity of the living modified organism:	DAS-40278-9 maize was modified by the insertion of aryloxyalkanoate dioxygenase-1 (*aad*-1) gene. DAS-40278-9 maize was developed using direct Whiskers-mediated transformation method and expresses AAD-1 protein conferring tolerance to 2,4-D herbicides.
5.	Unique identification of the living modified organism:	DAS-4Ø278-9
6.	Transformation event:	DAS-40278-9
7.	Introduced or Modified Traits:	**Chemical tolerance** - Herbicide tolerance **Pest resistance** - N/A
8.	Techniques used for modification:	DAS-40278-9 was developed using direct Whiskers-mediated transformation with a purified *Fsp* I restriction fragment of plasmid pDAS1740 (also known as pDAB3812) to stably incorporate the *aad*-1 gene into maize genome.
9.	Description of gene modification:	DAS-40278-9 maize was modified by insertion of aryloxyalkanoate dioxygenase-1 *(aad*-1) gene obtained from the soil bacterium, *Sphingobium herbicidovorans.* DAS-40278-9 was developed using direct Whiskers-mediated transformation with a purified *Fsp* I restriction fragment of plasmid pDAS1740 (also known as pDAB3812) to stably incorporate the *aad*-1 gene into maize genome.

Characteristics of modification	
10. Vector characteristics (Annex III.9(c)):	No vector was used in the production of DAS-40278-9 maize. Direct Whiskers-mediated transformation with a purified *Fsp* I restriction fragment of plasmid pDAS1740 (also known as pDAB3812) was used to generate DAS-40278-9 maize.
11. Insert or inserts (Annex III.9(d)):	Please refer to section 9 above.

Recipient organism or parental organisms (Annex III.9(a)):		
12. Taxonomic name/status of recipient organism or parental organisms:	Family name:	Gramineae (Poaceae)
	Genus:	*Zea*
	Species:	*Zea mays* L.
13. Common name of recipient organism or parental organisms:	Maize; Corn	
14. Point of collection or acquisition of recipient or parental organisms:	USA.	
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.	
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.	
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)	DAS-40278-9 maize was modified by the insertion of aryloxyalkanoate dioxygenase-1 (*aad*-1) gene obtained from the soil bacterium, *Sphingobium herbicidovorans.* <u>Inserted gene donor organisms were:</u> *Sphingobium herbicidovorans* <u>Regulatory elements donors:</u> *Zea mays*
20. Common name of donor organism(s):	<u>Donor organism (s) for DAS-40278-9 maize</u> *Shingobium herbicidovorans*
21. Point of collection or acquisition of donor organism(s):	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. DAS-40278-9 maize has previously been approved for trial release in South Africa.
22. Characteristics of donor organism(s) related to biosafety:	*Sphingobium herbicidovorans* is a member of the sphingomonads, a widely distributed bacterial group in nature which has been isolated from land and water habitats, as well as from plant root systems. Due to their biodegradative and biosynthetic capabilities, the sphingomonads have been used for a wide range of biotechnological applications such as bioremediation of environmental contaminants and production of extracellular polymers such as sphingans which are used extensively in the food industry.
Intended use and receiving environment	
23. Intended use of the LMO (Annex III 9(g)):	General Release of DAS-40278-9 maize.
24. Receiving environment (Annex III.9(h)):	Maize agricultural lands of South Africa.
Risk assessment summary	
25. Detection/Identification method of the LMO (Annex III.9(f)):	DAS-40278-9 maize is detectable using the event specific PCR detection method for detection of DAS-40278-9 DNA and Southern blot detection.
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	As indicated in the body of the application, DAS-40278-9 maize is as safe as conventional maize. Therefore, there are no anticipated adverse effects to human and animal health or the environment.

27. Evaluation of the consequences (Annex III.8(c)):	Studies confirmed that except for the specifically introduced herbicide tolerance trait, DAS-40278-9 maize is agronomically comparable to conventional maize. DAS-40278-9 maize would therefore not be able to survive in the environment without the same agricultural practices required to ensure a sustainable maize crop.
28. Overall risk (Annex III.8(d)):	The overall risk posed by this GM maize is negligible.
29. Recommendation (Annex III.8(e)):	No risks have been identified and therefore other than the containment parameters and permit conditions that might apply through the permit conditions, no additional actions need to be taken.
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	The potential risks identified are negligible, hence no additional actions are required except compliance with the conditions contained in the permit.
Additional information	
31. Availability of detailed risk assessment information:	Information relating to the risk assessment of DAS-40278-9 maize has been presented in this application as well as in previous applications that have been approved by the Executive Council.
32. Any other relevant information:	Not applicable.
33. Attach document:	Not applicable to applicant.
34. Notes:	Not applicable.