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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:	Republic of South Africa.
2. Title:	Application for Commodity Clearance of DAS-40278-9 in the Republic of South Africa.
3. Contact details:	Dow AgroSciences South Africa, P.O. Box 76129 Lynnwoodridge, Pretoria 0040, South Africa. Telephone: (+27) 12 361 8120; Fax (+27) 12 361 8126.
LMO information	
4. Name and identity of the living modified organism:	The LMO is DAS-40278-9. DAS 40278-9 was generated from the publicly available maize line, Hi-II. Hi-II is a derivative of the A188 and B73 inbred maize lines, which are publicly available lines developed by the University of Minnesota and Iowa State University, respectively.
5. Unique identification of the living modified organism:	DAS-40278-9
6. Transformation event:	DAS-40278-9
7. Introduced or Modified Traits:	<b>Chemical tolerance</b> - Herbicide tolerance.
8. Techniques used for modification:	Whiskers-mediated transformation.
9. Description of gene modification:	DAS-40278-9 maize was developed by inserting a linear <i>Fsp</i> I fragment from plasmid pDAS1740 using direct Whiskers-mediated transformation to stably incorporate the <i>aad-1</i> gene from the soil bacterium, <i>Sphingobium herbicidovorans</i> , into maize. DAS-40278-9 produces the AAD-1 protein which degrades the herbicide 2,4-dichlorophenoxyacetic acid (2,4-D) into herbicidally-inactive 2,4-dichlorophenol (DCP). Additionally, AAD-1 converts certain aryloxyphenoxypropionate (AOPP) herbicides (such as quizalofop) into their corresponding inactive phenols.
Characteristics of modification	

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10. Vector characteristics (Annex III.9(c)):	<p>The recipient maize line Hi-II was transformed using direct insertion of the DNA <i>Fsp</i> I fragment, carrying the <i>aad-1</i> expression cassette for insertion into the plant genome, from plasmid pDAS1740.</p> <p>The <i>aad-1</i> expression cassette contained in the pDAS1740/<i>Fsp</i> I fragment was designed to express the plant-optimized aryloxyalkanoate dioxygenase (<i>aad-1</i>) gene that encodes the AAD-1 protein. The <i>aad-1</i> gene was isolated from <i>Sphingobium herbicidovorans</i> and the synthetic version of the gene had the G+C codon optimized, to a level more typical for plant expression. The insertion of the <i>aad-1</i> gene into maize plants confers tolerance to 2,4-D and AOPP ("fop") herbicides. The <i>aad-1</i> gene encodes a protein of 296 amino acids that has a molecular weight of approximately 33 kDa.</p>
11. Insert or inserts (Annex III.9(d)):	<p>The transgene insert in maize event DAS-40278-9 is a single, intact copy of the <i>aad-1</i> expression cassette from plasmid pDAS1740. The event is stably integrated and inherited across and within breeding generations, and no plasmid backbone sequences are present in DAS-40278-9 maize.</p>
Recipient organism or parental organisms (Annex III.9(a)):	
12. Taxonomic name/status of recipient organism or parental organisms:	<p>Common name: Maize, Family: Graminae, Genus: Zea, Species: mays (2n=20)</p>
13. Common name of recipient organism or parental organisms:	<p>Maize</p>
14. Point of collection or acquisition of recipient or parental organisms:	<p>Privately owned germplasm.</p>
15. Characteristics of recipient organism or parental organisms related to biosafety:	<p>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.</p>
16. Centre(s) of origin of recipient organism or parental organisms:	<p>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.</p>
17. Centres of genetic diversity, if known, of recipient organism or parental organisms:	<p>Centers of genetic diversity of maize are the same as its centre of origin.</p>

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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)	<i>Sphingobium herbicidovorans</i> (Bacteria; Proteobacteria; Alphaproteobacteria; Sphingomonadales; Sphingomonadaceae; <i>Sphingobium</i> )
20. Common name of donor organism(s):	Bacteria
21. Point of collection or acquisition of donor organism(s):	Bacteria are ubiquitous in nature.
22. Characteristics of donor organism(s) related to biosafety:	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. Out of the ~20 recognized species of <i>Sphingobium</i> , only one, <i>S. yanoikuyae</i> has been isolated from a clinical environment. Other related genera however, are known to cause infrequent infections which are generally limited in virulence. Because of their ubiquity and adaptability, sphingomonads are often found in clinical settings, but usually not associated with infection. There are reports of sphingomonads producing antigenic glycolipids that may have use as therapeutics. Due to their biodegradative and biosynthetic capabilities, other related sphingomonads have been used for a wide range of biotechnological applications, including bioremediation of environmental contaminants and production of extracellular polymers such as sphingans which are used extensively in the food.
Intended use and receiving environment	
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 DAS-40278-9 into the environment of South Africa.
Risk assessment summary	
25. Detection/Identification method of the LMO (Annex III.9(f)):	Detection methods to confirm the molecular identity of DAS-40278-9 maize as well as certified reference materials have been developed (see <a href="http://www.sumobrain.com/patents/wipo/Detection-aad-1-event-das/WO2011022471A1.pdf">http://www.sumobrain.com/patents/wipo/Detection-aad-1-event-das/WO2011022471A1.pdf</a> ).

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26.Evaluation of the likelihood of adverse effects (Annex III.8(b)):	The scope of this application does not include cultivation of of DAS-40278-9 maize in South Africa. Any exposure to the environment will be limited to any unintended release of 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 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. 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)):	<p>In the unlikely event that some grain containing DAS-40278-9 (from grain imports) may end up in the environment of South Africa before being milled, the impact would be negligible as data supported a conclusion that DAS-40278-9 is substantially equivalent to conventional maize; maize plants cannot survive without human intervention.</p> <p>Furthermore, South Africa is not the centre of origin for <i>Zea mays</i> and there are no wild relatives in South Africa with which maize can outcross and if the grain was to be used as seed for planting, it would represent a F2 generation of which the growth, development and yield is extremely variable and predominantly weak.</p>
28.Overall risk (Annex III.8(d)):	The overall risk posed by this GMO is negligible.
29.Recommendation (Annex III.8(e)):	The overall risk is negligible. No recommendations other than procedures that may apply to conventional maize are applicable.
30.Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	There is no uncertainty regarding the risk profile.
<b>Additional information</b>	
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.
33.Attach document:	<p><i>Not applicable to applicant</i></p> <p>&lt;Specific types of entry: option to choose a file from the local source and 'upload' a copy to the BCH server&gt;</p>

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