COMMON FORMAT FOR Risk Assessment

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

	Risk assessment details	
1.	Country Taking Decision:	South Africa
2.	Title:	Application for a commodity clearance of genetically modified DP-Ø73496-4, known as DP73496 canola
3.	Contact details:	DuPont Pioneer. P.O Box 8010 Centurion, 0046 On behalf of DuPont Pioneer and other affiliated companies. Tel: +27 (0)12 – 683 5700 Fax:+(0)12 – 663 4190
	LMO information	
4.	Name and identity of the living modified organism:	The LMO is DP73496 canola and was produced via biolistic transformation of canola microspores with a gel-purified DNA fragment (PHP28181A) derived from *Hin*d III–*Not* I-digested plasmid PHP28181. The transformation resulted in the introduction of the *gat4621* gene cassette into canola genome, which results in the production of the GAT4621 glyphosate acetyltransferase. Expression of the GAT4621 protein in DP73496 canola confers herbicide-tolerance via acetylation of the glyphosate to the non-phytotoxic product N-acetylglyphosate.
5.	Unique identification of the living modified organism:	DP-Ø73496-4
6.	Transformation event:	DP73496 canola
7.	Introduced or Modified Traits:	Herbicide tolerant
8.	Techniques used for modification:	Recombinant DNA techniques

9.	Description of gene modification:	Expression of the GAT4621 enzyme in DP73496 canola confers herbicide-tolerance via acetylation of the glyphosate to the non-phytotoxic product N-acetylglyphosate. The *gat4621* gene is a variant of three *gat* genes isolated from the common soil bacterium *Bacillus licheniformis*. *B. licheniformis* is widespread in the environment; therefore, animals and humans are regularly exposed without adverse consequences to this organism and its components including the GAT protein. GAT proteins are members of the GCN 5-related family of N-acetyltransferases (also known as the GNAT family). The GNAT superfamily is one of the largest enzyme superfamilies recognized to date with over 10,000 representatives from plants, animals and microbes. The GAT4621 protein is 75-78% identical and 90-91% similar at the amino acid level to each of the three native GAT enzymes from which it was derived. In DP74396 canola, the expression of the *gat4621* gene is driven by *Arabidopsis thaliana* ubiquitin promoter (*UBQ10*), including a 5' untranslated region (UTR) and intron (Noris *et al.,* 1993). The terminator for *gat4621* gene is the 3' terminator sequence from the proteinase inhibitor II gene (*pinII* terminator) of *Solanum tuberosum* (An *et al.,* 1989; Keil *et al*., 1986).
	Characteristics of modification	
10.	Vector characteristics (Annex III.9(c)):	No vector was used in producing DP73496 canola
11.	Insert or inserts (Annex III.9(d)):	Please refer to 4 and 9 above
	Recipient organism or parental organisms (Annex III.9(a)):	
12.	Taxonomic name/status of recipient organism or parental organisms:	Family name: Brassicaceae Genus: *Brassica* Species: *Brassica napus L.* Common name: Oilseed rape, Canola
13.	Common name of recipient organism or parental organisms:	Oilseed rape, Canola
14.	Point of collection or acquisition of recipient or parental organisms:	USA

15.	Characteristics of recipient organism or parental organisms related to biosafety:	Canola is a non-dormant annual crop and seeds are the only survival structures. Natural regeneration of canola from vegetative tissue or vegetative reproduction is not known to occur (CFIA, 1994). Additionally, canola has not been reported to be an invasive weed in South Africa and no information is available on the potential for reproductive compatibility between *B. napus* and indigenous relatives in South Africa (McGeogh *et al.,* 2009). Crucially, feral canola has not been reported to become invasive outside cultivated and ruderal habitats (Devos *et al.*, 2012). In 1985 the U.S. Food and Drug Administration (FDA) declared canola "Generally Recognized as Safe" (GRAS) (www.agmrc.org).
16.	Centre(s) of origin of recipient organism or parental organisms:	Genetic origins include Asia and the Mediterranean
17.	Centres of genetic diversity, if known, of recipient organism or parental organisms:	Please refer to 16 above
18.	Habitats where the recipient organism or parental organisms may persist or proliferate:	Canola is a cool-season crop that is widely adapted and performs well in various soil types with adequate moisture and fertilization.
	Donor organism or organisms (Annex III.9(b)):	
19.	Taxonomic name/status of donor organism(s)	The *gat4621* gene is a variant of three *gat* genes isolated from the common soil bacterium *Bacillus licheniformis*
20.	Common name of donor organism(s):	*Bacillus licheniformis*
21.	Point of collection or acquisition of donor organism(s):	USA
22.	Characteristics of donor organism(s) related to biosafety:	*B. licheniformis* is widespread in the environment and animals and humans are regularly exposed without adverse consequences to this organism and its components including the GAT protein.
	Intended use and receiving environment	

23. Intended use of the LMO (Annex III 9(g)):	Food, feed and industrial use
24. Receiving environment (Annex III.9(h)):	Commodity import of DP73496 canola will be part of the general import of canola and will take place at the same locations dealing with import of other commercial canola into South Africa.
Risk assessment summary	
25. Detection/Identification method of the LMO (Annex III.9(f)):	The introduced genes can be identified using PCR techniques.
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	No adverse effects to human and animal health or the environment are anticipated from the proposed commodity clearance. The toxicological, allergenicity, agronomic, and compositional assessments have found DP73496 canola to be equivalent to conventional canola.
27. Evaluation of the consequences (Annex III.8(c)):	Please refer to 26 above
28. Overall risk (Annex III.8(d)):	Please refer to 26 above
29. Recommendation (Annex III.8(e)):	There are no anticipated risks to human and animal health or the environment due to the proposed commodity clearance. It is recommended that DP73496 canola can be managed as per applicable commodity clearance regulations in South Africa.
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	Not applicable
Additional information	
31. Availability of detailed risk assessment information:	Please refer to DuPont Pioneer's application to the RSA authorities.
32. Any other relevant information:	Not applicable
33. Attach document:	The affidavit is attached. No other applicable documents are attached to the Risk Assessment
34. Notes:	Not applicable.