

Sender
The Netherlands

Date
13 April 2017

Ctgb: Dr. ir. L.P. van Duijn, director;
Ministry of Economic Affairs:

Dr. 5.1.2.e Woo , 5.1.2.e WOO

Notification according to art. 44(4) of Regulation (EC) No 1107/2009

Please note that the following authorisation has been withdrawn or amended in accordance with Article 44(4) of Regulation (EC) No 1107/2009

Member State	The Netherlands
Trade name of Plant Protection Product	Clinic Ace
Authorisation Number	14446 N
Use	herbicide
Names and contents of active substances	glyphosate 360 g/L
Type of formulation	SL
Authorisation holder	Nufarm Deutschland GmbH
Application number (EU database) [not applicable yet]	not applicable yet
Action taken	Withdrawal of authorisation
Date of decision	November 11, 2016
Details of the decision	<p>The European Commission has decided by Commission Implementing Regulation (EU) 2016/1313 (d.d. 1 August 2016) that per August 22, 2016, plant protection products may not contain the co-formulant POE-tallowamine:</p> <p><i>'In the light of current scientific and technical knowledge it is appropriate to amend the conditions of use of the active substance in particular by excluding the co-formulant POE-</i></p>

	<i>tallowamine (CAS No 61791-26-2) from the use in plant protection products containing glyphosate.'</i>
Reasons for the decision	POE-tallowamine is more toxic compared to glyphosate. The NOAELs and LOAELs are lower (repeated dose toxicity, effects on fertility and developmental toxicity) and POE-tallowamine may cause DNA damage at high doses which are cytotoxic.
Notes	The authorisation holder was given the opportunity to submit comments. A grace period was granted that consisted of four months for sale which is subsequently followed by five months for use.

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Naming convention: MS_PP.doc (MS = ISO country code, PP = product trade name)