

Renewal Assessment Report



*Draft Renewal Assessment Report prepared according to the Commission
Regulation (EC) N° 1107/2009*

Trinexapac-ethyl

Volume 3 – B.1 Identity

Rev.0

March 2017

**Rapporteur Member State : Lithuania
Co-Rapporteur Member State : Latvia**

Version History

When	What
October 2003	Initial DAR Draft Assessment Report (DAR) – prepared by RMS NL in the context of the application for first inclusion of the a.s. in Annex I to Council Directive 91/414/EEC
2017-03-31	Draft Renewal Assessment Report (DRAR) – prepared by RMS LT in the context of the application for renewal of approval of the a.s. according to Reg (EU) No 844/2012. <i>Note: The DRAR is a stand-alone document containing the evaluations in the original DAR dated October 2003, as well as the new assessments. The revision of the initial DAR has been done in accordance with SANCO guidance document SANCO/10180/2013 rev.1 (March 2013), with changes to the original text – resulting from assessment of new studies (or reconsideration of old studies or studies that were not yet previously peer-reviewed) being highlighted by yellow shading.</i>

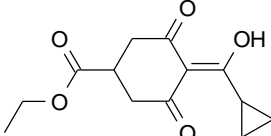
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B.1. IDENTITY**B.1.1. IDENTITY OF THE ACTIVE SUBSTANCE**

B.1.1.1. Name and address of applicant(s) for the renewal of the active substances approval	
<u>Applicant on behalf of the EU Task Force of trinexapac-ethyl</u>	
Syngenta Crop Protection AG European Product Registration B8.4.29 Scharzwaldallee 2015 CH-4058 Basel Switzerland	Contact: Christian Warmers Tel.: +41 (0) 61 32 38044 Fax: +41 (0) 61 32 36155 Email: christian.warmers@syngenta.com
Other Task Force members (in alphabetical order)	
ADAMA Agriculture B.V. Arnhemseweg 87 NL-3832 GK Leusden The Netherlands	Contact: Marion Gagniarre Tel.: Fax.: Email: Marion.gagniarre@adama.com
formerly	
Adama Agriculture BV Eurofins Regulatory AG Weidenweg 15 CH-4310 Rheinfelden Switzerland	
Cheminova A/S Thyborønvej 78, DK-7673 Harboøre, Denmark	Contact: Dr. Stuart Leslie Regulatory affairs Tel.: +44 1423 857 862 Fax.: - Email: stuart.leslie@fmc.com (formerly: stuart.leslie@cheminova.com)
Helm AG Nordkanalstrasse 28 20097 Hamburg Germany	Contact: Dr. Diana Nakunst Tel.: +49 40 2375-1384 Fax: +49 40 2375 29 0373 Email: d.nakunst@helmag.com
B.1.1.2. Common name proposed or ISO-accepted and synonyms	Trinexapac-ethyl
B.1.1.3. Chemical name (IUPAC and CA nomenclature)	
IUPAC	4-(cyclopropyl-hydroxymethylene)-3,5-dioxo- cyclohexanecarboxylic acid ethylester or ethyl (RS)-4-cyclopropyl(hydroxyl)methylene-3,5-dioxo- cyclohexanecarboxylate

Commented [WCC1]: Marion Gagniarre confirmed a new address for ADAMA Agriculture B.V.

CA	4-(cyclopropyl-hydroxymethylene)-3,5-dioxo-cyclohexanecarboxylic acid ethylester or ethyl 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylate
B.1.1.4. Manufacturer's development code number	CGA 163935 The code given above by the notifier Syngenta was already used at the first Annex I inclusion.
B.1.1.5. CAS, EEC and CIPAC numbers	
CAS	95266-40-3
EEC	none allocated
CIPAC	732.202
B.1.1.6. Molecular and structural formula, molecular mass	
Molecular formula	C ₁₃ H ₁₆ O ₅
Structural formula	
Molecular mass	252.3 g/mol
B.1.1.7. Method of manufacture (synthesis pathway) of the active substance	CONFIDENTIAL information – See Vol. 4.
B.1.1.8. Specification of purity of the active substance in g/kg	Min. 950 g/kg
B.1.1.9. Identity and content of additives (such as stabilisers) and impurities	
<i>B.1.1.9.1. Additives</i>	CONFIDENTIAL information – See Vol. 4.
<i>B.1.1.9.2. Significant impurities</i>	CONFIDENTIAL information – See Vol. 4.
<i>B.1.1.9.3. Relevant impurities</i>	Open
B.1.1.10. Analytical profile of batches	CONFIDENTIAL information – See Vol. 4.

B.1.2. REFERENCES RELIED ON

None