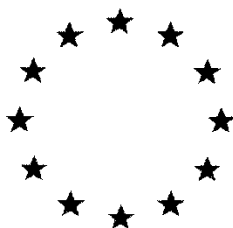


European Commission



**Combined Draft (Renewal) Assessment Report prepared according to
Regulation (EC) N° 1107/2009
and
Proposal for Harmonised Classification and Labelling (CLH Report)
according to Regulation (EC) N° 1272/2008**

GIBBERELLINS (GA4, GA7)

Volume 3 – B.2 (AS)

Rapporteur Member State: Slovenia
Co-Rapporteur Member State: Slovakia

Version History

When	What
2019/April	Initial DRAR including co-RMS suggestions

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Introduction

This document has been prepared to evaluate the European Gibberellins Task Force (Valent Biosciences Corporation (Sumitomo Chemical Agro Europe), Fine Agrochemicals Ltd, Globachem NV) application for EU renewal of the Annex I inclusion of active substance gibberellins (GA4, GA7). The document supplements and updates the corresponding Annex B section of the Draft Assessment Report produced during the first review of gibberellins (2005 - 2011).

Gibberelin has been identified as a presumed low-risk active substance in the Commission working document on the AIR-IV renewal programme (SANTE-2016-10616-rev 8). The EU Gibberellin Task Force (EGTF) proposes that Gibberelin is a low risk active substance according to Regulation (EC) 1107/2009 as amended by Commission Regulation 2017/1432.

In this report studies submitted for the first inclusion of gibberellins in Annex I to Directive 91/414/EEC and for the renewal of the approval of gibberellins have been evaluated.

Previous EU assessment

The dossier to support the first inclusion of gibberellins in Annex I to Directive 91/414/EEC was submitted to Hungary as the Rapporteur Member State in June 2005. The Draft Assessment Report is dated July 2006. Final Addendum to Draft Assessment Report, containing all individually submitted addenda on gibberellins, was compiled by EFSA in October 2011.

Structure of this document

Summaries of available data and overall assessments of each sub-section, as well as the exposure assessments, generally are not included in this document. Instead these parts of the assessment are included in Vol. 1, Level 2. The reason behind this structure is to avoid repetition and facilitate revisions of the assessment. As a result, this Annex B only contains the presentation and evaluation of individual study reports on the active substance.

In each section of this document, the following headings (a-b)) occur:

a) Previous evaluation (2005-2011)

Under this heading study reports submitted for the first inclusion of gibberellins in Annex I to Directive 91/414/EEC are summarised. These studies have been re-evaluated for the purpose of the renewal in the light of current scientific and technical knowledge. The endpoints from the studies were also re-assessed and if considered relevant, re-calculated. However, full details from each study have not been repeated in this DRAR - therefore this DRAR is not a "stand-alone document" and for full reference sometimes the reader needs to consult the DAR (2005-2011).

b) Evaluation of additional data for the purpose of renewal of Annex I inclusion

Under this heading studies submitted prior to Annex I inclusion, but no evaluation of such material was presented in the form of Addenda to the DAR and studies that were submitted to support the application for renewal of Annex I inclusion are evaluated, i.e. new studies.

B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. MELTING POINT AND BOILING POINT						
Melting, freezing or solidification point B.2.1/01	OECD 102, EEC A.1	99% w/w Lot no. D104	Melting point: 205.5 – 231.0 °C. At 210 °C the test item changed colour from white to orange indicating thermal decomposition.	Acceptable The exact melting point could not be determined	Y	Comb 1997 (DAR 2006 Revised DAR 2011)
	Calculation (adapted Stein and Brown method)	Not applicable	Melting point GA4: 204.62 °C GA7: 205.33 °C (weighted value)	Calculated value	N	Ville 2005 (DAR 2006 Revised DAR 2011)
	OECD 102, USP 23 for class I (741)	92.5% w/w (GA4 – 60.4%) Lot no. 81-351-CD	Four additional batches were tested and gave similar ranges. Melting point: 205.6 – 224.5 °C.	acceptable	Y	Rojas 1996 (DAR 2006 Revised DAR 2011)
Boiling point B.2.1/02	-	-	A boiling point determination is not applicable as the test item was found to thermally decompose prior to boiling.	acceptable	-	-
Decomposition / Sublimation temperature B.2.1/03	OECD 102, USP 23 for class I (741)	92.5% w/w (GA4 – 60.4%) Lot no. 81-351-CD	The decomposition temperature is above 224.5 °C.	acceptable	Y	Rojas 1996 (DAR 2006 Revised DAR 2011)

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	OECD 102, EEC A.1	99% w/w Lot no. D104	The colour of the samples changed from white to orange at 210°C, indicating thermal decomposition. See also B.2.1/01 above.	acceptable	Y	Comb (1997) (DAR 2006 Revised DAR 2011)
B.2.2. VAPOUR PRESSURE, VOLATILITY						
Vapour pressure B.2.2/01	OECD 104, EEC A.4 (vapour pressure balance)	99% w/w Lot no. D104	1.0 x 10 ⁻⁵ Pa at 25 °C (recommended, mean value). 7.68 x 10 ⁻⁶ Pa at 20 °C (calculated from data measurements between 134 and 200 °C).	acceptable This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.	Y	Comb 1997 (DAR 2006 Revised DAR 2011)
	OECD 104, EEC A.4 (gas saturation method)	90.8% w/w (GA7 – 24.97%, GA4 – 65.83%) Lot no. 33-263-CD-00	Direct measurements at 22.1 ± 0.1 °C: GA4: 0.16 Pa GA7: 0.067 Pa At 50 °C: GA4: 0.55 Pa GA7: 0.18 Pa	acceptable This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.	Y	Purghart 2000a (DAR 2006 Revised DAR 2011)

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	Calculation (modified grain method)	Not listed	1.0 x 10 ⁻⁶ Pa at 25 °C using a vapour pressure balance.	acceptable This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.	N	Agritox Data Base (DAR 2006 Revised DAR 2011)
	Calculation	Not applicable	Estimated using Bond SAR method: GA4: 4.90 x 10 ⁻¹⁴ GA7: 4.31 x 10 ⁻¹⁴ Calculation using EPI values – GA4: 1.706 x 10 ⁻¹⁵ GA7: 9.531 x 10 ⁻¹⁶ This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.	Non acceptable, large difference between calculated and measured values.	N	Ville 2005 (DAR 2006 Revised DAR 2011)
Volatility (Henry's Law constant) B.2.2/02	Calculation	99% w/w Lot no. D104	Henry's law constant = 2.0 × 10 ⁻⁵ Pa m ³ mol ⁻¹ (20 °C) Values used for calculation: vapour pressure 7.68 × 10 ⁶ Pa at 20 °C, water solubility 126.8 mg L ⁻¹ at 20 °C.	Acceptable This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been	N/A	Comb 1997 (DAR 2006 Revised DAR 2011)

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
				changed.		
	Calculation	Not listed	Henry's law constant = $2.0 \times 10^{-5} \text{ Pa m}^3 \text{ mol}^{-1}$	Acceptable This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.	N/A	Agritox Data Base (DAR 2006 Revised DAR 2011)
	Calculation	N/A	Henry's law constant GA4 $0.155 \text{ Pa m}^3 \text{ mol}^{-1}$ GA7 $0.065 \text{ Pa m}^3 \text{ mol}^{-1}$. Values used for calculation: vapour pressure 0.16 Pa at 20°C , water solubility 1.3 mol m^{-3} at 20°C .	Acceptable This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.	N/A	Curl 2005a (DAR 2006 Revised DAR 2011)
B.2.3. APPEARANCE (PHYSICAL STATE, COLOUR)						
Physical state and colour B.2.3/01	Visual (Munsell colour system) / Organoleptic.	99% w/w Lot no. D104	Pure: White powder at 25°C with no detectable odour. Technical: White, free flowing powder with a faintly acidic smell.	Acceptable This study was evaluated in the original DAR and	Y	Comb 1997 (DAR 2006 Revised

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
				has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.		DAR 2011)
	Visual / Organoleptic	Not listed	Solid, white, odourless crystals.	Acceptable Taken from MSDS. This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.	N	Globachem 2005 (DAR 2006 Revised DAR 2011)
	Visual / Organoleptic	92.5% w/w (GA4 – 60.4%) Lot no. 81-351-CD	White, odourless powder at room temperature. Four other batches were analysed, each having the same appearance.	Acceptable This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.	Y	Rojas 1996 (DAR 2006 Revised DAR 2011)

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.4. SPECTRA (UV/VIS, IR, NMR, MS), MOLAR EXTINCTION AT RELEVANT WAVELENGTHS, OPTICAL PURITY								
Ultraviolet/visible (UV/VIS) B.2.4/01	OECD 101	99% w/w Lot no. D104	Wavelength, max	Concentration of GA4/7	ϵ (L cm ⁻¹ mol ⁻¹)	Acceptable This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.	Y	Comb 1997 (DAR 2006 Revised DAR 2011)
			Neutral media: 205 nm	46.5 mg L ⁻¹	6090			
			Alkaline media: 218 nm	465 mg L ⁻¹	390			
			Acidic media: 206 nm	51.2 mg L ⁻¹	6190			
			Molar absorption coefficients at or above 298 nm are <10 L cm ⁻¹ mol ⁻¹ .					
	OECD 101	92.5% w/w (GA4 – 60.4%) Lot no. 81-351-CD	A methanol solution of GA4/7 absorbed wavelengths below <i>ca.</i> 250 nm. No maxima were observed above 210 nm. Four other batches were also tested, giving the same result.			Acceptable This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.	Y	Rojas 1996 (DAR 2006 Revised DAR 2011)
Optical purity	-	-	GA4 and GA7 are enantiomerically pure but due to the large number of stereogenic centres, analysis in plain polarised light would not confirm optical purity.			Acceptable	-	-
Infrared (IR)	IR (KBr)	99% w/w	Typical absorption peaks were at:			Acceptable	Y	Comb 1997

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.4/02		Lot no. D104	3510-3100 cm ⁻¹ 3100-2800 cm ⁻¹ 1753 cm ⁻¹ 1703 cm ⁻¹ 1659 cm ⁻¹ 1470-1000 cm ⁻¹ The IR spectrum between 4000 and 400 cm ⁻¹ was in agreement with the structure of GA4/7. An interpretation was provided in report.	This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.		(DAR 2006 Revised DAR 2011)
	IR	Pure GA4: 97.9% w/w Lot no. 85-932-BD Pure GA7: 99% w/w Lot no. 911-23-3 Technical: 90.1% w/w (GA4 - 70.6%, GA7 - 19.5) Lot no. 56-519-CD	Acceptable spectra were obtained using attenuated total reflectance FT-IR. An interpretation was provided in report.	Acceptable This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.	Y	Heiman 2005b (DAR 2006 Revised DAR 2011)
Nuclear magnetic resonance (NMR) B.2.4/03	¹ H NMR (400 MHz, CDCl ₃)	99% w/w Lot no. D104	The ¹ H NMR spectra were consistent with the structure of GA4/7.	Acceptable This study was evaluated in the original DAR. No new evaluation has been	Y	Comb 1997 (DAR 2006 Revised DAR 2011)

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
				performed. The conclusion has not been changed.		
	¹ H NMR 2.5.1.3/01 and ¹³ C NMR 2.5.1.3/02	Batches: 403, 404, 405, 406, 407	The ¹ H and ¹³ C NMR spectra were consistent with the structure of GA4/7.	acceptable (This study is <u>only</u> being used to address this endpoint. New 5 batch data have been provided. The study has been added to the confidential Doc K.) This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.	Y	Herling 2003 (DAR 2006 Revised DAR 2011)
	¹ H NMR (300 MHz) and ¹³ C NMR (75 MHz)	Pure GA4: 97.9% w/w Lot no. 85-932-BD Pure GA7: 95% w/w Lot no. 36267-29-1	Acceptable ¹ H and ¹³ C NMR spectra were obtained. An interpretation was provided in the report.	Acceptable This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.	Y	Heiman 2005c (DAR 2006 Revised DAR 2011)
	MS (ES, 30 eV)	99% w/w	The MS spectrum was found to be in agreement with the	Acceptable	Y	Comb 1997

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference						
Mass spectra (MS) B.2.4/04		Lot no. D104	proposed structure of GA4/7. <table><tr><td>Identity</td><td>m/z</td></tr><tr><td>Molecular ion:</td><td>331</td></tr><tr><td>Fragments:</td><td>647, 445, 377 (association of sample with solvent)</td></tr></table>		Identity	m/z	Molecular ion:	331	Fragments:	647, 445, 377 (association of sample with solvent)	This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.		(DAR 2006 Revised DAR 2011)
	Identity	m/z											
	Molecular ion:	331											
Fragments:	647, 445, 377 (association of sample with solvent)												
MS	Batches: 403, 404, 405, 406, 407	The structure of gibberellins GA4/7 is confirmed by mass spectra.			Acceptable (N.B. This study is <i>only</i> being used to address this endpoint. New 5 batch data have been provided. The study has been added to the confidential Doc K.) This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.	Y	Herling 2003 (DAR 2006 Revised DAR 2011)						
MS (ES)	Pure GA4: 97.9% w/w Lot no. 85-932-BD. Pure GA7:	Acceptable spectra obtained. An interpretation is provided in report.			Acceptable This study was evaluated in the original DAR. No new evaluation	Y	Heiman 2005a (DAR 2006 Revised DAR 2011)						

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference
		99% w/w Lot no. 911-23-3			has been performed. The conclusion has not been changed.		
Spectra for impurities B.2.4/05	-	-	Notifier claims that the technical contains no toxicologically and ecotoxicologically relevant impurities		Acceptable explanation	-	-
B.2.5. SOLUBILITY IN WATER							
Solubility in water B.2.5/01	OECD 105, EEC A.6 (shake flask)	99% w/w Lot no. D104	Medium	Water solubility at 20 °C (mg/L)	Acceptable This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.	Y	Comb 1997 (DAR 2006 Revised DAR 2011)
			Pure water	127 ± 1.6			
			pH 4 buffer	141 ± 4.2			
			pH 7 buffer	40.0 ± 1.7			
			pH 9 buffer	>250			
	Literature data	Not listed	Medium	Water solubility at 20 °C (mg/L)	Acceptable This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion	N	Agritox Data Base (DAR 2006 Revised DAR 2011)
			Water	127			
			pH 4 buffer	141			
			pH 7 buffer	40.0			
			pH 9 buffer	>250			

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference						
					has not been changed.								
	Calculation (EPIWIN)	Not applicable	At 25 °C in water GA4: 40.199 mg/L GA7: 34.201 mg/L		Acceptable This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.	N	Ville 2005 (DAR 2006 Revised DAR 2011)						
	In-house method (shake flask)	92.5% w/w (GA4 – 60.4%) Lot no. 81-351-CD	343 mg/L in water at room temperature This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.		Acceptable This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.	Y	Rojas 1996 (DAR 2006 Revised DAR 2011)						
	OECD 105, EEC A.6 (shake flask)	90.6% w/w (GA7 – 60.4%, GA4 – 30.2%) Lot no. 21-973-CD	<table><tr><th>Medium</th><th>Water solubility at 20 °C (mg/L)</th></tr><tr><td>Pure water</td><td>310</td></tr><tr><td>pH 4 buffer</td><td>379</td></tr><tr><td>pH 7 buffer</td><td>>250</td></tr></table>	Medium	Water solubility at 20 °C (mg/L)	Pure water	310	pH 4 buffer	379	pH 7 buffer	>250	acceptable	Y
Medium	Water solubility at 20 °C (mg/L)												
Pure water	310												
pH 4 buffer	379												
pH 7 buffer	>250												

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
			pH 9 buffer	>250				
B.2.6. SOLUBILITY IN ORGANIC SOLVENTS								
Solubility in organic solvents B.2.6/01	OECD 105 / EEC A.6 (shake flask)	99% w/w Lot no. D104	Solvent	Solubility at 20 ± 0.5 °C		acceptable	Y	Comb 1997 This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.
			n-heptane	<0.5 mg/L				
			Xylene	78.9 ± 1.4 mg/L				
			1,2-dichloroethane	3380 ± 220 mg/L				
			Methanol	>250 g/L				
			Acetone	>250 g/L				
			Ethyl acetate	56 ± 2.4 g/L				
			The material is very slightly or slightly soluble in n-heptane; moderately soluble in xylene and readily soluble in acetone, 1,2-dichloroethane, methanol and ethyl acetate.					
	Literature data	Not listed	Solvent	Solubility		acceptable	N	Agritox Data Base This study was evaluated in the original DAR. No new evaluation has been performed.
			Heptane	<0.5 mg/L				
			Xylene	78.9 mg/L				
			Dichloroethane	3.38 g/L				
			Methanol	>250 g/L				
			Acetone	160 mg/L				
			Ethyl acetate	56 g/L				
			The material is very slightly or slightly soluble in n-heptane;					

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
			moderately soluble in xylene and readily soluble in acetone, 1,2-dichloroethane, methanol and ethyl acetate.					The conclusion has not been changed.
	CIPAC MT 181 / EEC A.6 (shake flask)	92.5% w/w (GA4 – 60.4%) Lot no. 81-351-CD	Solvent	Solubility at 20 °C (g/L)		acceptable	Y	Rojas 1996 This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.
			Pyridine	41				
			Propan-2-ol	243				
			Tetra-hydro-furfuryl alcohol	272				
			Methanol	378				
			Acetone	186				
			Ethyl acetate	68.9				
			The material is readily soluble in the solvents tested.					
	OECD 105 (shake flask)	90.6% w/w (GA7 – 30.2%, GA4 – 60.4%) Lot no. 81-351-CD	Solvent	Solubility at 20 °C (g/L)		acceptable	Y	Comb 2008b
			Xylene	0.096				
			1,2-Dichloroethane	2.0				
			n-Heptane	<0.0003				
			n-Octanol	70				
B.2.7. PARTITION COEFFICIENT N-OCTANOL/WATER								
Partition coefficient n-octanol/water B.2.7/01	OECD 107 / EEC A.8 (Hansch method)	99% w/w Lot no. D104	pH	log P _{ow} (determined by HPLC at 20 °C)		acceptable	Y	Comb 1997 This study was evaluated in
			4	2.47				

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference
			7	0.146			the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.
			10	-1.23			
	Calculation (EPIWIN)	Not applicable	GA4 log P _{ow} = 1.76 GA7 log P _{ow} = 1.55		acceptable	N	Ville 2005 This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.
	OECD 107, EEC A.8 (shake flask)	90.8% w/w (GA7 – 24.97%, GA4 – 65.83%)	GA4 log P _{ow} = 2.34 GA7 log P _{ow} = 2.25 (at 20 °C, without pH control)		acceptable	Y	Purghart 2000b This study was evaluated in the original

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
		Lot no. 33-263-CD-00						DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.
	OECD 107, EEC A.8 (shake flask)	90.6% w/w (GA7 – 30.2%, GA4 -60.4%) Lot no. 33-263-CD-00	pH	log P _{ow} (determined by HPLC at 20 °C)		acceptable	Y	Comb 2008c
			4	2.5				
			7	-0.05				
			10	-1.2				
B.2.8. DISSOCIATION IN WATER								
Dissociation constant B.2.8/01	OECD 112 (potentiometric titration)	99% w/w Lot no. D104	pK _a = 4.3 at 23 °C The dissociated species is the carboxylate anion.			acceptable	Y	Comb 1997 This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
						has been performed. The conclusion has not been changed.
	Literature data	Not listed	pK _a = 4.5 The dissociated species is the carboxylate anion. This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.	acceptable	N	Agritox Data Base This study was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.
	Calculation (ACD labs software)	N/A	GA4 pK _a = 4.30; GA7 pK _a = 4.27 The dissociated species is the carboxylate anion.	acceptable	N	Curl 2005b This study was evaluated in the original DAR. No new evaluation has been performed. The

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
						conclusion has not been changed.
B.2.9. FLAMABILITY AND SHELF-HEATING						
Flammability B.2.9/01	EEC A.10	99% w/w Lot no. D104	The test material melted but did not sustain flame. Therefore the test substance is not classified as highly flammable under the test conditions.	acceptable	Y	Comb 1997 This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.
	EEC A.10	90.8% w/w (GA4 – 72.5%) Lot no. 33-263-CD-00	The test material melted but failed to ignite. Therefore the test substance is not classified as highly flammable under the test conditions.	acceptable	Y	Young 2000 This study was evaluated in the original DAR and has been considered by EFSA. No

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
						new evaluation has been performed. The conclusion has not been changed.
Self heating B.2.9/02	EEC A.16	99% w/w Lot no. D104	GA4/7 does not self-ignite before melting (the melting point was measured to be 206 – 231 °C). The test substance is not classified as highly flammable or auto-flammable under the test conditions.	acceptable	Y	Comb 1997 This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.
	-	-	Applicant statement: Self-heating: Gibberellin is a naturally occurring plant hormone that features no chemically unstable functional groups that could lead to an exothermic reaction with the oxygen in the air. Consequently it can be concluded that GA4/7 should not be classified as self-heating under Regulation (EC) No 1272/2008.	Acceptable explanation	-	-

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.10. FLASH POINT						
Flash point B.2.10/01	-	-	Not applicable as the melting point of GA4/7 was measured to be above 40 °C.	acceptable	-	-
B.2.11. EXPLOSIVE PROPERTIES						
Explosive properties B.2.11/01	EEC A.14	99% w/w Lot no. D104	The material is not thermally sensitive, shock sensitive or sensitive to friction. Therefore the test substance is not considered as explosive under the test conditions.	acceptable	Y	Comb 1997 This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.
	EEC A.14	90.8% w/w (GA4 – 72.5%) Lot no. 33-263-CD-00	The test material is not mechanically or thermally sensitive. Therefore the test substance is not considered as explosive under the test conditions.	acceptable	Y	Young 2000 This study was evaluated in the original DAR and has been

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
						considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.
	Expert statement	N/A	GA4 and GA7 have no explosive properties i.e. the molecule has a low oxygen balance and contains no “plosive” groups.	acceptable	N	Lee 2005 This statement was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.
B.2.12. SURFACE TENSION						
Surface tension B.2.12/01	OECD 115 / EEC A.5 (Ring method)	99% w/w Lot no. D104	64 mN m ⁻¹ at 114 mg L ⁻¹ (20 °C) The test substance is not surface active.	acceptable	Y	Comb 1997 This study was evaluated in

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
						the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.
B.2.13. OXIDISING PROPERTIES						
Oxidizing properties B.2.13/01	EEC A.17	99% w/w Lot no. D104	No oxidising properties under the test conditions.	acceptable	Y	Comb 1997 This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	EEC A.17	90.8% w/w (GA4 – 72.5%) Lot no. 33-263-CD-00	The test substance is not classified as an oxidiser.	acceptable	Y	Young 2000 This study was evaluated in the original DAR and has been considered by EFSA. No new evaluation has been performed. The conclusion has not been changed.
	Expert statement	N/A	GA4 and GA7 do not exhibit any of the primary oxidant groupings listed in Brethericks.	acceptable	N/A	Lee 2005 This statement was evaluated in the original DAR. No new evaluation has been performed. The conclusion has not been changed.

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.14. OTHER STUDIES						
	-	-	<p>Applicant statement:</p> <p>Self-reacting: Gibberellins is a naturally occurring plant hormone that is not classified as explosive, oxidising or an organic peroxide under EU CLP. No chemical moieties associated with the property of self-heating are featured on gibberellins. It can therefore be concluded that the substance should not be classified under this EU CLP endpoint.</p> <p>Corrosive to metals: For a mixture to be classified under this CLP endpoint, it must corrode steel or aluminium at a rate of 6.5 mm per year or greater at 55 °C. A material would have to be significantly corrosive to corrode metal at this rate, which would not be expected to apply to this substance.</p> <p>This property is associated with substances or mixtures with a low melting point, extreme pHs and aqueous solutions, and chemical characteristics associated with this property include acidic or basic functional groups and halogens - there are none present in gibberellins. Additionally, currently there is no accepted test method to measure this property of solids. It can therefore be concluded that this substance is not corrosive to metals.</p>	Acceptable explanation and statement	-	-

B.2.15. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 2.1/ 01, K CA 2.2/ 01, K CA 2.3/ 01, KCA 2.4/ 01, KCA 2.5/ 01, KCA 2.6/ 01, KCA 2.7/ 01, KCA 2.8/ 01, KCA 2.9/ 01, KCA 2.11/ 01, KCA 2.12, KCA 2.13/ 01	Comb, A. L.	1997	GA4/7 (99% technical): Determination of the Physico- Chemical Properties Report No. 96/FNA052/12 21 Huntingdon Life Sciences Ltd, Cambridgeshir e, UK, PE28 4HS. GLP Unpublished	N	N	-	Fine Agroch emical s Ltd.	In DAR: B.2.1.1 FA, B.2.1.3 FA, B.2.1.5 FA, B.2.1.6 FA, B.2.1.7 FA, B.2.1.8 FA, B.2.1.9 FA, B.2.1.10 FA, B.2.1.10 FAb, B.2.1.10 FAc, B.2.1.10 FAd, B.2.1.12 FA, B.2.1.13 FA, B.2.1.14 FA, B.2.1.18 FA, B.2.1.20 FA, B.2.1.21 FA, B.2.1.23 FA, B.2.1.24 FA, B.2.1.25 FA
KCA 2.1/ 02, KCA 2.2/ 03, KCA 2.5/ 03, KCA 2.7/ 02	Ville, C., Beltran, E., Adrian, P.	2005	QSAR (Quantitative Structure- Activity Relationship), Gibberellins GA4/7 Report No. None CEHTRA, Le Space C, 208- 212, route de Grenoble, 06200 Nice, France Non-GLP Unpublished	N	N	-	Globac hem	In DAR: B.2.1.1 GC, B.2.1.2 GC, B.2.1.5 GCb, B.2.1.5 GCc, B.2.1.12 GCb, B.2.1.14 GCb
KCA 2.1/ 03,	Rojas, F. G.	1996	Physical and Chemical	N	N	-	Valent BioSci	In DAR: B.2.1.1 VA,

KCA 2.3/ 04, KCA 2.4/ 06, KCA 2.5/ 04, KCA 2.6/ 03			Properties Characterisation of Gibberellin A4/A7 Code 2519, Technical Grade Active Ingredient Report No. 85- 2493-62 Abbott Laboratories, USA GLP Unpublished				ences	B.2.1.3 VA, B.2.1.7 VA, B.2.1.8 VA, B.2.1.9 VA, B.2.1.10 VA, B.2.1.12 VA, B.2.1.13 VA
KCA 2.2/ 02, KCA 2.5/ 02, KCA 2.6/ 02, KCA 2.8/ 02	-	2004	AgriTox Data Base – Gibberelline A4 A7	N	N	-	-	In DAR: B.2.1.5 GC, B.2.1.6 GC, B.2.1.12 GC, B.2.1.13 GC, B.2.1.18 GC
KCA 2.2/ 04	Purghart, V.	2000a	Gibberellin A4 / Gibberellin A7: Determination of the Vapour Pressure Report No. 1042.003.816 Springborn Laboratories (Europe) AG GLP Unpublished	N	N	-	Valent BioSciences	In DAR: B.2.1.5 VA
KCA 2.2/ 05	Curl, M. G	2005a	The Calculation of Henry's Law Constant for Gibberellin GA4A7 Report No. TSGE 22-1- 02.HLC TSGE Consulting, Concordia House, St. James Business Park, Grimbald Crag Court, Knaresborough , North Yorkshire, HG5 8QB	N	N	-	Valent BioSciences	In DAR: B.2.1.6 VA

			Non-GLP Unpublished					
KCA 2.3/ 02	-	2005	Material Safety Data Sheet, Gibberellin A4/A7 Globachem nv, Leeuwerweg 138, B-3803 Sint-Truiden, Belgium.	N	N	-	Globac hem	In DAR: B.2.1.7 GC, B.2.1.8 GC, B.2.1.9 GC
KCA 2.4/ 02	Herling, H.	2003	Gibberellin GA4/7-5 Batch Analysis Report No. SSL04403 Spectral Service, Köln, Germany. GLP Unpublished N.B. This study is <i>only</i> being used to address KCA 2.4/ 02. New 5 batch data have been provided. The study has been added to the confidential Doc K.	N	N	-	Globac hem	In DAR: B.2.1.10 GCb, B.2.1.10 GCd
KCA 2.4/ 03	Heiman, D. F.	2005a	Valent BioSciences Chemistry Report Mass Spectra of Gibberellins GA4A7. Report No. VCB-LG-C- 05-06-0008 Valent BioSciences Corporation Research Center, Long Grove, IL, USA. Not GLP Unpublished	N	N	-	Valent BioSci ences	In DAR: B.2.1.10 VAd
KCA 2.4/ 04	Heiman, D. F.	2005b	Valent Biosciences Chemistry Report Attenuated	N	N	-	Valent BioSci ences	In DAR: B.2.1.10 VAc

			Total Reflectance Fourier Transform Infrared Spectra of Gibberellins GA4A7. Report No. VCB-LG-C-05-06-0007 Valent BioSciences Corporation Research Centre, Long Grove, Illinois, USA. Not GLP Unpublished					
KCA 2.4/05	Heiman, D. F.	2005c	Valent Biosciences Chemistry Report Nuclear Magnetic Resonance Spectra of Gibberellins GA4A7. Report No. VCB-LG-C-05-06-0009 Valent BioSciences Corporation Research Centre, Long Grove, Illinois, USA. Not GLP Unpublished	N	N	-	Valent BioSciences	In DAR: B.2.1.10 VAb
KCA 2.5/05	Comb, A.L.	2008a	GA4/7 Water Solubility Report No. ZAB0086 Huntingdon Life Sciences Ltd, Cambridgeshire, UK, PE28 4HS. GLP Unpublished	N	Y	New study for the purposes of renewal	Valent Biosciences	-
KCA 2.6/04	Comb, A.L.	2008b	GA4/7 Solvent Solubility Report No.	N	Y	New study for the purposes of renewal	Valent Biosciences	-

			ZAB0090 Huntingdon Life Sciences Ltd, Cambridgeshir e, UK, PE28 4HS. GLP Unpublished					
KCA 2.7/ 03	Purghart, V.	2000b	Gibberellin A4/A7: Determination of the Partition Coefficient (n- octanol/water) Report No. 1042.003.705 Springborn Laboratories (Europe) AG. GLP Unpublished	N	N	-	Valent BioSci ences	In DAR: B.2.1.14 VA
KCA 2.7/ 04	Comb, A.L.	2008c	GA4/7 Partition Coefficient Report No. ZAB0087 Huntingdon Life Sciences Ltd, Cambridgeshir e, UK, PE28 4HS. GLP Unpublished	N	Y	New study for the purposes of renewal	Valent Bioscie nces	-
KCA 2.8/ 03	Curl, M. G.	2005b	Computer Estimation of Dissociation Constant of Gibberellin GA4A7 Report No. TSGE 22-1- 02.PKA TSGE Consulting, Concordia House, St. James Business Park, Grimbald Crag Court, Knaresborough , North Yorkshire, HG5 8QB.	N	N	-	Valent BioSci ences	In DAR: B.2.1.18 VA

			Non-GLP Unpublished					
KCA 2.9/ 02 KCA 2.11/ 03 KCA 2.13/ 03	Young, S.	2000	Gibberellin A4/A7 Physicochemic al Properties Report No. VLT 013/004024 Huntingdon Life Sciences. GLP Unpublished	N	N	-	Valent BioSci ences	In DAR: B.2.1.20 VA B.2.1.23 VA B.2.1.25 VA
KCA 2.11/ 0 2 KCA 2.13/ 02	Lee, S.	2005	Determination of Storage Stability and Shelf Life Specification Data for Gibberellins GA4 and GA7 (a Soluble Concentrate Formulation) Stored for Specified Time Intervals and at Specified Temperatures in Compliance with Good Laboratory Practice Report No. OA00902. Oxford Analytical Ltd., Oxon, UK, report GLP Unpublished	N	Y	-	Globac hem	In DAR: B.2.1.23 GC B.2.1.25 GC