Thifensulfuron-methyl

Annex B (Volume 3)

B.2 Physical and chemical properties

Version history

When	What
17-07-2014	Initial Renewal Assessment Report
February 2015	Updated following assessment of additional information requested by EFSA in support of renewal

Physical and Chemical Properties

B.2 Physical and chemical properties
Summary notes for Renewal Assessment Report

Throughout this document the original DAR, written by France, is referred to as the DAR and this evaluation, written by the UK, is referred to as the RAR (Renewal assessment report). Studies that were evaluated in the DAR have not been re-evaluated.

The study summaries presented in this report have, except where stated, been copied from the original DAR and Addenda; minor editorial and formatting changes have been made as appropriate. Where new information (e.g. historical control data, additional experimental details) or new interpretation of the data has been taken into account, changes have been highlighted in yellow.

New studies and new information not previously reviewed at the EU level, have been evaluated by the RMS. These are clearly marked in yellow.

The end of section summaries have been drafted by the RMS, and take account of information provided by both the new and previously submitted studies and the outcome of the original peer review.

B.2.1 Physical and chemical properties of the active substance (thifensulfuron-methyl)

DAR

Previous evaluation:	In DAR for original approval (1996) – these data are indicated where "DAR, 1996" appears in the reference column. Data requirements concluded from the ECCO peer review meeting were addressed in the addendum – these data are indicated where "Addendum, 2000" appears in the reference column. Data submitted for the purpose of renewal under Regulation 1141/2010 have been indicated where "RAR, 2014" appears in the reference column.

Table B.2.1 Summary of the physical and chemical properties of the active substance (studies were completed to an acceptable standard and results were considered to be valid unless specified otherwise)

section (Annex point)	**study**	**purity**	**method**	**results**	**comment**	**reference**
B.2.1.1 (IIA 2.1)	Melting point	~~Not stated~~		~~Measure up to 176-178°C~~	~~Non-GLP~~	~~Not stated (**DAR, 1996**)~~
		99.7%	EEC A.1. OECD 102 (capillary method) OPPTS 830.7200	Measure up to 171.1°C	GLP	Huntley and Edgar, 1999 Report DuPont 1500 (**Addendum, 2000**)

section (Annex point)	study	purity	method	results	comment	reference
B.2.1.2 (IIA 2.1)	Boiling point	984-LiN-38-3 99.2%	EEC method A 2	Not determinable – decomposes above 162^{o}C without boiling The Task Force is relying on the melting point data provided in the DAR Addendum (2000) which indicated a melting point of 171.1°C. The data provided by the Task Force for the decomposition indicates a decomposition temperature of 162^{o}C. As the decomposition temperature cannot be below the stated melting point, the Task Force Notifiers will be required to conduct further investigations of the melting point and decomposition temperatures – **Data gap.**	GLP	Comb, 2012 Report DGV0083 (**Task Force, RAR, 2014**)
B.2.1.3 (IIA 2.1)	Temperature of decomposition or sublimation	99.7%	EEC A.1 OECD 102 (capillary method), OPPTS 830.7200	Preliminary tests indicated that the test substance decomposed after melting	GLP	Huntley and Edgar, 1999 Report DuPont 1500 (**Addendum, 2000**)) additional details added in RAR which were not made

section (Annex point)	study	purity	method	results	comment	reference
						available previously.
		984-LiN-38-3 99.2%	EEC A2, OECD 103, Siwoloboff method	Decomposes above 162°C without boiling	GLP	Comb, 2012 Report DGV0083 (**Task Force, RAR, 2014**)
B.2.1.4 (IIA 2.2)	Relative density	~~93.8%~~	~~OECD 109 OPPTS 830.7300 CIPAC MT33 and MT169~~	~~1.49 g/ml (determined at 25°C)~~	~~Non-GLP~~	~~Not stated (**DAR, 1996**)~~
		DPX-M6316-186 99.7%	OECD 109 and U.S. EPA OPPTS 830.7300 (gas comparison pyknometer method)	D_4^{20} = 1.580 with a standard deviation (σ_{n-1}) of 0.004 g/cm^3	GLP	Greenwood, 2002 Report DuPont-6580 (**DuPont, RAR, 2014**)
		984-LiN-38-3 99.2%	EEC method A 3 OECD 109	D_4^{20} = 1.46	GLP	Comb, 2012 Report DGV0083 (**Task Force, RAR, 2014**)

section (Annex point)	study	purity	method	results	comment	reference
B.2.1.5 (IIA 2.3)	Vapour pressure	99.6%	OECD 104 EEC A.4. OPPTS 830.7950	5.6×10^{-11} mm Hg (20°C) 1.3×10^{-10} mm Hg (25°C)	Non-GLP Very slightly volatile	Barefoot, 1987 Report DuPont 6316/PC-23-CA (**DAR, 1996**)
		99.7%	OECD 104, U.S. EPA OPPTS 830.7950 and EEC method A 4 (gas saturation method)	2.18×10^{-6} Pa (50^{o}C) 8.01×10^{-7} Pa (40^{o}C) (The extrapolated vapour pressure at 20^{o}C is 5.19×10^{-9} Pa) Based on this, the active substance was determined to be very slightly volatile.	GLP	Ganesh, 2012 Report DuPont-31258 (**DuPont, RAR, 2014**)
		984-LiN-38-3 99.2%	EEC method A 4 OECD 104	4×10^{-8} Pa at 25^{o}C	GLP	Comb, 2012 Report DGV0083 (**Task Force, RAR, 2014**)

section (Annex point)	study	purity	method	results	comment	reference
B.2.1.6 (IIA 2.3)	Volatility, Henry's law constant	N/A	Calculated using solubility and vapour pressure at 20°C	2.8 x 10^{-13} atm.m^3/mol at pH 5 9.6 x 10^{-15} atm.m^3/mol at pH 7	Non-GLP Very slightly volatile The Task Force cite the original DAR data in support of their active substance package.	Hoffmann, 1988 (**DAR, 1996**)
				The Henry's law constant for Thifensulfuron-methyl was calculated as 3.25 × 10^{-08} Pa-m^3/mol (3.21 × 10^{-13} atm-m^3/mol) at pH 5 and 3.23 × 10^{-09} Pa-m^3/mol (3.20 × 10^{-14} atm-m^3/mol) at pH 7. A calculation could not be made for pH 9 solution, as at this pH Thifensulfuron-methyl is a salt and therefore not in the same physical state as for vapour pressure determination. This invalidated the calculation of the Henry's law constant.	GLP Thifensulfuron-methyl was determined to be very slightly volatile.	Tessier, 2012 Report DuPont-34492 (**DuPont, RAR, 2014**)
B.2.1.7 (IIA 2.4)	Appearance: physical state	~~Not stated~~	~~EPA Guideline (Subdivision D) Series 63-2-4~~	~~Crystalline solid~~	~~Non-GLP~~	~~Not stated (**DAR, 1996**)~~

section (Annex point)	study	purity	method	results	comment	reference
		Batch 199, stock #5389 98.17 %	U.S. EPA OPPTS 830.6303 -	Fine, free flowing white powder	GLP The Task Force cite the original DAR data in support of their active substance package.	Greenwood, 2002 Report DuPont-6581 (**DuPont, RAR, 2014**)
		Batch: 06050 9016 96.5%		Powder	GLP	Denny, 2006a Report R A6097 05 (**Task Force, RAR, 2014**)
		984-LiN-38-3 99.2%		Solid	GLP	Comb, 2012 Report DGV0083 (**Task Force, RAR, 2014**)
		Batch No		Powder	GLP	Pedersen, 2006

section (Annex point)	study	purity	method	results	comment	reference
		844-NO-95 96.5%				Report 006 TIM (**Task Force, RAR, 2014**)
B.2.1.8 (IIA 2.4)	Appearance: colour	~~Not stated~~	~~EPA Guideline (Subdivision D) Series 63-2-4~~	~~White~~	~~Non-GLP~~	~~Not stated (**DAR, 1996**)~~
		Batch 199, stock #5389 98.17 %	U.S. EPA OPPTS 830.6302	Off-white	GLP	Greenwood, 2002 Report DuPont-6581 (**DuPont, RAR, 2014**)
		Batch: 06050 9016 96.5%	-	Light yellow	GLP	Denny, 2006a Report R A6097 05 (**Task Force, RAR, 2014**)
		984-LiN-38-3 99.2%		White	GLP	Comb, 2012 Report DGV0083 (**Task Force, RAR, 2014**)

section (Annex point)	study	purity	method	results	comment	reference
		Batch No 844-NO-95 96.5%		Off-white	GLP	Pedersen, 2006 Report 006 TIM (**Task Force, RAR, 2014**)
B.2.1.9 (IIA 2.4)	Appearance: odour	~~Not stated~~	~~EPA Guideline (Subdivision D) Series 63-2-4~~	~~No odour~~	~~Non-GLP~~	~~Not stated (**DAR, 1996**)~~
		Batch 199, stock #5389 98.17 %	U.S. EPA OPPTS 830.6304	No odour	GLP	Greenwood, 2002 Report DuPont-6581 (**DuPont, RAR, 2014**)
		Batch: 06050 9016 96.5%	-	No characteristic odour	GLP	Denny, 2006a Report R A6097 05 (**Task Force, RAR, 2014**)
		984-		Odourless	GLP	Comb, 2012

section (Annex point)	study	purity	method	results	comment	reference
		LiN-38-3 99.2% Batch No 844-NO-95 96.5%		Odourless	GLP	Report DGV0083 (**Task Force, RAR, 2014**) Pedersen, 2006 Report 006 TIM (**Task Force, RAR, 2014**)
B.2.1.10 (IIA 2.5)	Spectra	Not stated		The ^{1}H-NMR spectrum was obtained with a Varian XL 200. Thifensulfuron-methyl was dissolved in deuterated chloroform (*d*-trichloromethane). Seven proton assignments were made. The mass spectrum was obtained using electron impact ionisation. An IR spectrum was obtained from 4000 to 400cm^{-1}. The UV/visible spectrum of the molecule was obtained using a 9.1	Non-GLP	Report DuPont 6316/PC 16, 1985-1986 (**DAR, 1996**)

section (Annex point)	study	purity	method	results	comment	reference
		99.7%	OECD 101	µg/ml solution of Thifensulfuron-methyl in acetonitrile. Wavelengths from 220-800 nm were scanned. Spectral record sheets were given without further interpretation data. UV/VIS spectra were recorded between 240 to 800 nm and maximum absorption was estimated to 243 and 270 nm. The UV/Vis Spectra was tested in 20.2 and 30.3 µg/mL concentrations in acidic, unadjusted (neutral) and alkaline solutions. The acidic, unadjusted and alkaline absorption maxima and the respective extinction coefficients are reported below UV/Vis, Molar extinction coefficients (ε, L mol^{-1} cm^{-1}) determined at maxima as: <u>Acidic conditions (pH <2):</u> 224 nm = 18302 ε (at20.2 µg/mL) 224 nm = 18323 ε (at30.3 µg/mL) 250 nm = 13619 ε (at20.2 µg/mL) 250 nm = 13421 ε (at30.3 µg/mL)	GLP	Huntley and Ambroz, 1999 Report DuPont 1498 (**Addendum, 2000**)

section (Annex point)	study	purity	method	results	comment	reference
				(Not a true maximum) 290 nm = 6784 ε (at30.3 µg/mL) 290 nm = 6658 ε (at40.4 µg/mL) <u>Neutral conditions (pH ~7):</u> 233 nm = 25619 ε (at10.1 µg/mL) 233 nm = 26630 ε (at20.2 µg/mL) (Not a true maximum) 290 nm = 6784 ε (at50.5 µg/mL) 290 nm = 6658 ε (at70.7 µg/mL) <u>Basic conditions (pH >10):</u> 234 nm = 25923 ε (at10.1 µg/mL) 234 nm = 27087 ε (at20.2 µg/mL) (Not a true maximum) 290 nm = 4424 ε (at50.5 µg/mL) 290 nm = 4446 ε (at70.4 µg/mL)	The Task Force cite the original DAR data in support of their active substance package.	
		DMX-M6316-186	NMR OECD 101 OPPTS	^{1}H-NMR (in d_6-acetone at 350 MHz) Chemical shift (multiplicity): δ 2.57 (s)	GLP	Schmuckler, 2000 Report

<table>
<tr><th>section (Annex point)</th><th>study</th><th>purity</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr><td></td><td></td><td>99.7%</td><td>830.7050</td><td>δ 3.88 (s)
δ 4.04 (s)
δ 7.70 (d)
δ 7.94 (d)
δ 9.67 (s)
δ 12.80 (s)</td><td></td><td>DuPont-3537 (DuPont, RAR, 2014)</td></tr>
<tr><td></td><td></td><td></td><td>Mass spectra
OECD 101
OPPTS
830.7050</td><td>Full scan MS spectra were produced by Desorption Chemical Ionisation (DCI) with a CH_4 probe. The obtained spectra were consistent with the chemical structure.
$[M + H]^+$ = m/z 388</td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td>IR (KBr disc method)
OECD 101
OPPTS
830.7050</td><td>Infra-red spectroscopy gave peaks characteristic of the test substance and consistent with the expected structure. The Infra-red frequencies for characteristic functional groups of thifensulfuron-methyl are presented below:
<table>
<tr><th>Group</th><th>Bond</th><th>Range</th><th>Mode</th></tr>
<tr><td>Urea</td><td>C=O

NH-CO</td><td>1705-1635
cm^{-1}
~1600-</td><td>Stretch

Bend</td></tr>
</table></td><td></td><td></td></tr>
</table>

section (Annex point)	study	purity	method	results				comment	reference
					N-C-N	1515 cm^{-1} 1490-1465c m^{-1}	Asym met-ric stretch		
				SO_2	SO_2 SO_2 SO_2	1335-1325 cm^{-1} 1160-1150 cm^{-1} 610-545 cm^{-1}	Asym met-ric stretch Asym met-ric stretch Scissor i-ng		
				Ester	C=O C-O-C	1740-1705 cm^{-1} 1310-1250 cm^{-1}	Stretch Asym met-ric stretch		
				Triazin e	ring ring	1580-1520 cm^{-1} 1450-	Stretch Stretch		

section (Annex point)	study	purity	method	results	comment	reference
				<table><tr><td></td><td>ring</td><td>1350 cm^{-1} 820-810 cm^{-1}</td><td>Deform</td></tr><tr><td>Ether</td><td>C-O-C C-O-C</td><td>1270-1230 cm^{-1} 1120-1020 cm^{-1}</td><td>Asymmet-ric stretch Asymmet-ric stretch</td></tr><tr><td>Aromatic</td><td>C-H</td><td>3100-3010 cm^{-1}</td><td>Stretch</td></tr></table>		
		984-LiN-38-3 99.2%	UV-Vis OECD 101 OPPTS 830.7050 OECD 101 UV-Vis	UV/Vis, Molar extinction coefficients (ε, L mol^{-1} cm^{-1}) determined at maxima as: <u>Neutral conditions (pH 7):</u> 233 nm = 26100 ε (at 25°C) 290 nm = 5300 ε (at 25°C) UV/vis spectrum consistent with assigned structure pH 1.2 : λmax at 201 nm (ε = 27000	GLP	Comb, 2012 Report DGV0083 (**Task Force, RAR, 2014**)

section (Annex point)	study	purity	method	results	comment	reference
				L mol-1 cm-1), 223 nm (ε = 21400 L mol-1 cm-1), 245 nm (ε = 14200 L mol-1 cm-1), 281 nm (ε = 7580 L mol-1 cm-1) pH 4.2 : λmax at 230 nm (ε = 22700 L mol-1 cm-1), 246 nm (ε = 20000 L mol-1 cm-1), 281 nm (ε = 7640 L mol-1 cm-1) pH 13.2 : λmax at 235 nm (ε = 24200 L mol-1 cm-1), 246 nm (ε = 24200 L mol-1 cm-1), 275 nm (ε = 7610 L mol-1 cm-1) MS spectrum consistent with assigned structure		
B.2.1.11 (IIA 2.6)	Solubility in water	98.3%	CIPAC Method 157 MS	0.223 g/l at pH 5 and 25°C 2.24 g/l at pH 7 and 25°C 8.83 g/l at pH 9 and 25°C	GLP The method complies with EEC method A6 except that the solubility was determined at 25°C instead of 20°C. Technical material, purity 98.3%, was used instead of the purified active substance – this	Barefoot and Cooke, 1990 Report AMR-1662-90 (**DAR, 1996**)

section (Annex point)	study	purity	method	results	comment	reference
					was considered acceptable. The Task Force cite the original DAR data in support of their active substance package.	
		DMX-M6316-186 99.7%	EEC method A 6, OECD 105 and U.S. EPA OPPTS 830.7840	The solubility of Thifensulfuron-methyl pure active substance in un-buffered, distilled water at 20°C was 54.1 mg/L (n = 17, σ(n-1) 3.82 mg/L, coefficient of variation = 7.05%). The average pH for samples at equilibrium was 4.09.	GLP Thifensulfuron-methyl is moderately soluble.	Greenwood, 2002 Report DuPont-6579 (**DuPont, RAR, 2014**)
B.2.1.12 (IIA 2.7)	Solubility in organic solvents (technical active substance)	Not stated	Not stated	Solubility was determined at 25°C only. Acetone 11.9 mg/ml Acetonitrile 7.3 mg/ml Ethanol 0.9 mg/ml Ethyl Acetate 2.6 mg/ml Hexane < 0.1 mg/ml Methanol 2.6 mg/ml Methylene Chloride 27.5 mg/ml Xylenes 0.2 mg/ml	Non-GLP	Report DuPont 6316/PC-31 (**DAR, 1996**)

<table>
<tr><th>section (Annex point)</th><th>study</th><th>purity</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr><td></td><td></td><td>DPX-M6316-199

98.17 %</td><td>EEC method A 6,
OECD 105 and U.S. EPA OPPTS 830.7840 (shake flask method, with sample analysis performed by HPLC-UV)</td><td>Protocol - Solubility was estimated by successive additions of weighed portions of Thifensulfuron-methyl in organic solvents until the compound no more dissolved (vortexing).

Thifensulfuron-methyl showed increasing solubility in hexane (< 0.1 mg/ml), xylenes (0.2 mg/ml), ethanol (0.9 mg/ml), methanol (2.6 mg/ml), and ethyl acetate (2.6 mg/ml), acetonitrile (7.3 mg/ml), acetone (11.9 mg/ml) and methylene chloride (27.5 mg/ml) at 25°C.

Solubility was determined at 20°C only.

<table><tr><td>n-Heptane</td><td><0.100 mg/mL</td></tr><tr><td>n-Octanol</td><td>0.159 mg/mL</td></tr><tr><td>o-Xylene</td><td>0.212 mg/mL</td></tr><tr><td>Methanol</td><td>2.831 mg/mL</td></tr><tr><td>Ethyl acetate</td><td>3.299 mg/mL</td></tr><tr><td>Acetonitrile</td><td>7.749 mg/mL</td></tr><tr><td>Acetone</td><td>10.280 mg/mL</td></tr><tr><td>DCM</td><td>23.840 mg/mL</td></tr><tr><td>DMF</td><td>89.150 mg/mL</td></tr></table></td><td>GLP

The test substance was only sparingly soluble in n-heptane</td><td>Greenwood, 2002 Report DuPont-6582 (DuPont, RAR, 2014)</td></tr>
</table>

section (Annex point)	study	purity	method	results	comment	reference
		Lot No 06050 9016, Purity 96.54 %	EEC method A 6	The CV values obtained for the samples indicate that equilibrium had been reached for all samples with the exception of n-heptane. Solubility was determined at 25°C in both studies. n-Heptane: 0.6 mg/L Xylene: 254 mg/L 1,2-dichloroethane: 9.78 g/L Methanol: 12.2 g/L Acetone: 3.12 g/L Ethyl Acetate: 3.76 g/L n-Octanol: 229 mg/L	GLP	Denny, 2006a Report R A6097 08 (**Task Force, RAR, 2014**)
		Batch: 87080 92507 97.4%	CIPAC MT 181 EEC method A 6	Acetone: 10-14 g/L Acetonitrile: 10-14 g/L Dichloromethane: 29-33 g/L Ethyl acetate: 4.224g/L* n-Hexane: Not soluble* Methanol: 2.845 g/L* Xylene: 0.170 g/L* * Due to low solubility these values were determined by EEC method A.6	GLP	Dardemann, 2009 Report 130 TIM (**Task Force, RAR, 2014**)

section (Annex point)	study	purity	method	results	comment	reference
B.2.1.13 (IIA 2.8)	Partition co-efficient	Not stated	OST Guidelines CG1400	0.021 at pH 7 and 25°C (There was no concentration dependence.) Deviations from EEC method A 8: - the lot number and purity of the technical Thifensulfuron-methyl were not reported - the Kow was determined at pH 7 only, at 25°C (pKa = 4) - detailed results were not given	Non-GLP	Neal, 1984 Report AMR-183-84 (**DAR, 1996**)
		99.7%	EEC method A.8 (flask shake method)	Log Pow = 0.0253 at pH 5 Log Po/w = -1.65 at pH 7 Log Po/w = -2.10 at pH9	GLP The values indicate no potentiality for bioaccumulation	Huntley and Edgar, 1999 Report DuPont-1502 (**Addendum, 2000**)
		DMX-M6316-186 99.7%	OECD 107 OPPTS 830.7550	At pH 5, P_{ow} = 1.06 ± 0.11 (log P_{ow},= 0.0253) At pH 7, P_{ow} = 0.0222 ± 0.001 (log P_{ow}, = -1.65) At pH 9, P_{ow} = 0.0079 ± 0.001 (log p_{ow}, = -2.10)	GLP Given that the log K_{OW} is <3, the data suggests that fat solubility is unlikely.	Huntley and Edgar 2000 DuPont-1502 (**Addendum, 2000**)

section (Annex point)	study	purity	method	results	comment	reference
					The Task Force cite the original DAR data in support of their active substance package.	additional details added in RAR which were not made available previously.
B.2.1.14 (IIA 2.9)	Stability in water			See section 2.1.15		
B.2.1.15 (IIA 2.9)	Hydrolysis rate	Not stated	Not stated	(Samples were kept in darkness at 25°C) Half-life of Thifensulfuron-methyl was 4-6 days, k = 0.126-0.130 day^{-1} (DT90 = 18 days) at pH 5 and less than 20 % were degraded at pH 7 (DT50 was about 180 days, k = 0.0037-0.0039 day^{-1}) and pH 9 (DT 50 was about 90 days, k = 0.0075 day^{-1}, buffer at pH 9 was not stable and results were doubtful). An explanation was given by the	Non-GLP The hydrolysis of Thifensulfuron-methyl was relatively rapid at pH 5 and significantly slower at pH 7 and pH 9. Degradation at all three pH values occurred by cleavage of the sulfonyl urea bridge yielding 2-ester-3 -sulfonamide and triazine amine as major hydrolysis products	Koeppe and Rhodes, 1984 Report AMR-224-84 (**DAR, 1996**)

<table>
<tr><th>section (Annex point)</th><th>study</th><th>purity</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td>Notifier for the most important difference at pH 9. During the both studies, pH of the test solution was monitored. During the photochemical degradation study pH was stable while during the hydrolysis study, pH drops from 9 to 7.8 by day 8 and 7.2 by day 30. So results give more stability than expected and the true value must be lower. Results from hydrolysis study at pH 9 are doubtful.

The ECCO conclusion highlighted a need for the applicant to explain the different DT50 values for the AMR-224-84 and AMR-511-86 reports.

The submitted The document addressed the apparent difference in information found in the Thifensulfuron-methyl hydrolysis (AMR-224-84) and photolysis (AMR-511-86) studies. It was concluded, that the differences occurred as a result of a pH change over the course of the hydrolysis study</td><td></td><td>Peter and Frost, 2000 (Addendum, 2000)</td></tr>
<tr><td></td><td></td><td>[thioth ene-2-</td><td>OECD 111, EPA 161-1 and</td><td>At 20 ^{o}C<table><tr><td>pH</td><td>Rate</td><td>DT_{50}</td><td>DT_{90}</td></tr></table></td><td>GLP</td><td>Wardrope 2011</td></tr>
</table>

<table>
<tr><th>section (Annex point)</th><th>study</th><th>purity</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr><td></td><td></td><td>^{14}C]thifensulfuron-methyl

Specific activity: 10.7 µCi/mg

Radiochemical purity: ≥97.2 %

[triazine-2-^{14}C]thifensulfuron-methyl

Specific activit</td><td>OPPTS 835.2120 (equiv. To EEC method C.7)</td><td>
<table>
<tr><td></td><td>constant (days^{-1})</td><td>(days)</td><td>(days)</td></tr>
<tr><td>4</td><td>0.109 ±0.003</td><td>6.3</td><td>21</td></tr>
<tr><td>7</td><td>0.003 ±0.001</td><td>199</td><td>662</td></tr>
<tr><td>9</td><td>0.03 ±0.001</td><td>23.4</td><td>77.8</td></tr>
</table>
Hydrolysis products
<table>
<tr><td>pH</td><td>Label</td><td>Products</td><td>Max (%AR)</td><td>Day (max)</td></tr>
<tr><td rowspan="6">pH4/20° C</td><td>Thio</td><td>IN-A5546</td><td>52.40</td><td>30</td></tr>
<tr><td rowspan="3">Triaz</td><td>Polar MS 253.1</td><td>25.28</td><td>30</td></tr>
<tr><td>IN-A4098</td><td>29.57</td><td>30</td></tr>
<tr><td rowspan="2">Both</td><td>IN-L9226</td><td>11.66</td><td>8</td></tr>
<tr><td>INRDF00</td><td>31.85</td><td>30</td></tr>
<tr><td>pH7/20° C</td><td>Thio</td><td>IN-A5546</td><td>5.27</td><td>6</td></tr>
<tr><td>pH9/20° C</td><td>Both</td><td>IN-L9225</td><td>45.52</td><td>30</td></tr>
</table>
At 30 °C
<table>
<tr><td>pH</td><td>Rate constant (days^{-1})</td><td>DT_{50} (days)</td><td>DT_{90} (days)</td></tr>
<tr><td>4</td><td>0.367 ±0.011</td><td>1.9</td><td>6.3</td></tr>
</table>
</td><td></td><td>Report DuPont-30225 (DuPont, RAR, 2014)</td></tr>
</table>

<table>
<tr><th>section (Annex point)</th><th>study</th><th>purity</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr><td></td><td></td><td>y: 33.9 µCi/mg

Radiochemical purity: ≥98.9 %</td><td></td><td>
<table>
<tr><td>7</td><td>0.011 ±0.001</td><td>65</td><td>217</td></tr>
<tr><td>9</td><td>0.106 ±0.002</td><td>6.5</td><td>21.7</td></tr>
</table>

Hydrolysis products
<table>
<tr><th>pH</th><th>Label</th><th>Products</th><th>Max (%AR)</th><th>Day (max)</th></tr>
<tr><td rowspan="5">pH4/30° C</td><td>Thio</td><td>IN-A5546</td><td>72.93</td><td>21</td></tr>
<tr><td rowspan="2">Triaz</td><td>Polar MS 253.1</td><td>31.73</td><td>30</td></tr>
<tr><td>IN-A4098</td><td>40.57</td><td>30</td></tr>
<tr><td rowspan="2">Both</td><td>IN-L9226</td><td>11.86</td><td>2</td></tr>
<tr><td>IN-RDF00</td><td>24.22</td><td>21</td></tr>
<tr><td rowspan="5">pH7/30° C</td><td rowspan="3">Thio</td><td>IN-L9223</td><td>9.68</td><td>30</td></tr>
<tr><td>IN-A5546</td><td>14.14</td><td>30</td></tr>
<tr><td>Triaz</td><td>IN-A4098</td><td>15.01</td><td>30</td></tr>
<tr><td>Both</td><td>IN-L9225</td><td>5.19</td><td>30</td></tr>
<tr><td rowspan="4">pH9/30° C</td><td>Thio</td><td>IN-L9223</td><td>88.64</td><td>30</td></tr>
<tr><td rowspan="2">Triaz</td><td>Polar MW 253.1</td><td>23.56</td><td>30</td></tr>
<tr><td>IN-A4098</td><td>74.61</td><td>30</td></tr>
<tr><td>Both</td><td>IN-L9225</td><td>59.79</td><td>2</td></tr>
</table>

At 50 °C
</td><td></td><td></td></tr>
</table>

<table>
<tr><th>section (Annex point)</th><th>study</th><th>purity</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><th>pH</th><th>Rate constant (days^{-1})</th><th>DT_{50} (days)</th><th>DT_{90} (days)</th></tr>
<tr><td>4</td><td>3.145 ±0.163</td><td>0.2</td><td>0.7</td></tr>
<tr><td>7</td><td>0.173 ±0.005</td><td>4.0</td><td>13.3</td></tr>
<tr><td>9</td><td>1.133 ±0.021</td><td>0.6</td><td>2.0</td></tr>
</table>
Hydrolysis products
<table>
<tr><th>pH</th><th>Label</th><th>Products</th><th>Max (%AR)</th><th>Day (max)</th></tr>
<tr><td rowspan="6">pH4/50^{o}C</td><td rowspan="3">Thio</td><td>IN-A5546</td><td>93.73</td><td>21</td></tr>
<tr><td rowspan="3">Triaz</td><td>Polar MW-253.1</td><td>56.36</td><td>30</td></tr>
<tr><td>IN-A4098</td><td>54.41</td><td>2</td></tr>
<tr><td rowspan="2">Both</td><td>IN-L9226</td><td>8.11</td><td>4 hours</td></tr>
<tr><td>IN-RDF00</td><td>10.03</td><td>3</td></tr>
<tr><td rowspan="4">pH7/50^{o}C</td><td rowspan="2">Thio</td><td>IN-L9223</td><td>90.90</td><td>30</td></tr>
<tr><td>IN-A5546</td><td>16.50</td><td>6</td></tr>
<tr><td>Triaz</td><td>IN-A4098</td><td>90.50</td><td>30</td></tr>
<tr><td>Both</td><td>IN-L9225</td><td>6.71</td><td>6</td></tr>
<tr><td rowspan="2">pH9/50^{o}C</td><td>Thio</td><td>IN-L9223</td><td>88.64</td><td>30</td></tr>
<tr><td>Triazi</td><td>Polar MW</td><td>23.56</td><td>30</td></tr>
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section (Annex point)	study	purity	method	results	comment	reference
				<table><tr><td></td><td>ne</td><td>253.1</td><td></td><td></td></tr><tr><td></td><td></td><td>IN-A4098</td><td>74.61</td><td>30</td></tr><tr><td></td><td>Both</td><td>IN-L9225</td><td>59.79</td><td>2</td></tr></table> pH buffers 4, 7 and 9. Test at 25°C DT50: 2.4 and 7.1 days for pH 4, and 9 respectively. Test material was resistant to hydrolysis at pH = 7 (DT50 = 137 days). The following hydrolysis products were found to occur at > 10% applied radioactivity during 30 days incubation at 25°C: IN-L9225 (pH 9), IN-L9226 (pH 4), 2-ester-3-triuret (pH 4), IN-A5546 (pH 4), IN-L9223 (pH 9), thiophene urea (pH 4), IN-A4098 (pH 4 and 9) and Methyl triazine diol (pH 4). [Thiophene-2-^{14}C]-Thifensulfuron-methyl, specific radioactivity 5.17 MBq/g [Triazine-2-^{14}C]- Thifensulfuron-methyl, specific radioactivity 5.18 MBq/g Discussion of the hydrolysis products		
		[Thiophene-2-^{14}C]-Thifensulfuron-methyl, Lot No. 3784FDG037-4, purity 98.8% [Triazine-2-^{14}C]-Thifensulfuron-methyl, Lot No. 3783F	OECD 111		GLP	Simmonds and Buntain, I, 2012 Report 260 TIM (**Task Force, RAR, 2014**)

section (Annex point)	study	purity	method	results	comment	reference
		DG003-2, purity 99.4%		is made in part B8, section B.8.4.1 of this RAR		
B.2.1.16 (IIA 2.9)	Photochemical degradation	>98% radiochemical purity for [thiphene-2-^{14}C]DPX-M6316 and triazine-2-^{14}C]DPX-M6316 97% purity for [thiphene-2-^{13}C]DPX-M6316	EPA Guidelines 161-2	Linear DT50 in sunlight: DT_{50} = 98 hours at 25°C and pH 5 DT_{50} = 125 hours at 25°C and pH 7 DT_{50} = 97 hours at 25°C and pH 9 Linear DT50 in darkness: DT_{50} = 608 hours at 25°C and pH 5 DT_{50} = 4400 hours at 25°C and pH 7 DT_{50} = 381 hours at 25°C and pH 9 <u>Degradation products</u>: Triazine amine (14%) triazine urea (11%),methyl-3-(4-methoxy-6-methyl-1,3,5,-triazin-2-yl-amino)-2-thiophene carboxylate (7%) and a number of minor compounds (<4% each). Detection of $^{14}CO_2$ indicated extensive breakdown of the thiophene ring.	Non-GLP Mass balance was in the range 93-114 % and pH values were stable. In darkness, Thifensulfuron-methyl was significantly degraded at pH 5 and 9. In light, degradation was enhanced at every pH. When corrected for hydrolysis, the photolysis rate was independent of pH in the pH range 5-9 (117-129 hours)	Ryan, 1986 Report AMR-511-86 (**DAR, 1996**)

section (Annex point)	study	purity	method	results	comment	reference
		[thiothene-2-^{14}C]thifensulfuron-methyl Specific activity: 23.0 µCi/mg Radiochemical purity: ≥95% [triazine-2-^{14}C]thifensulfuron-methyl Specific activity: 33.9 µCi/mg	Japanese Guideline 12 Noshan No. 8147	Irradiated natural water pH 7 DT_{50} = 0.5 days at 25°C Rate constant = 1.3143 $days^{-1}$ Irradiated sterile water pH 7 DT_{50} = 0.5 days at 25°C Rate constant = 1.3943 $days^{-1}$ Dark control – sterile buffer at pH 7 DT_{50} = 126 days at 25°C Rate constant = 0.0055 $days^{-1}$	GLP Thifensulfuron-methyl is photolysed rapidly in natural water and pH 7.	Lentz, 2001 Report DuPont-6047 (**DuPont, RAR, 2014**)

section (Annex point)	study	purity	method	results	comment	reference
		Radiochemical purity: ≥95% ^{14}C-labelled thifensulfuron-methyl [Thiophene-2-^{14}C]-Thifensulfuron-methyl, Lot No. 3784FDG037-4, purity 98.8% [Triazine-2-^{14}C]-Thifensulfuron-methyl	OECD 316	pH buffer 7. Test at 25°C DT50 and DT90 values for the decline of thiophene and triazine labelled thifensulfuron-methyl in the irradiated experiments were 6.23 h and 2.96 h respectively (mean 4.6 hours). Significant degradation of thifensulfuron-methyl was observed with the formation of three major degradates (>10% AR): IN-A4098, IN-V7160 (triazine label) and thiophenyl triazinyl amine (both labels).	GLP	Oddy, 2012 Report 284 TIM (**Task Force, RAR, 2014**)
B.2.1.17 (IIA 2.9)	Quantum yield	[thiothene-2-^{14}C]thif	Japanese Guideline 12 Noshan No.	The quantum yield of thifensulfuron-methyl in a sterile pH7 buffer was calculated using chemical actinometry	GLP	Lentz, 2001 Report DuPont-6047

section (Annex point)	study	purity	method	results	comment	reference
		ensulfuron-methyl Specific activity: 23.0 µCi/mg Radiochemical purity: ≥95% [triazine-2-^{14}C]thifensulfuron-methyl Specific activity: 33.9 µCi/mg Radiochemical purity:	8147	to be 0.037.		(**DuPont, RAR, 2014**)

section (Annex point)	study	purity	method	results	comment	reference
		≥95% ^{14}C-labelled thifensulfuron-methyl [Thiophene-2-^{14}C]-Thifensulfuron-methyl, Lot No. 3784F DG037-4, purity 98.8% [Triazine-2-^{14}C]-Thifensulfuron-methyl	OECD 316	The quantum yield for thifensulfuron-methyl in aqueous solution at pH 7 was found to be 0.044.	GLP	Oddy, 2012 Report 284 TIM (**Task Force, RAR, 2014**)
B.2.1.18 (IIA 2.9)	Dissociation constant (pKa)	~~Not Stated~~	~~EPA 63-10~~	~~The dissociation constant for Thifensulfuron-methyl was determined from measurement of its aqueous solubility as a function of pH (pH 4.0, 5.0 and 6.0). Saturated solutions of~~	~~Non-GLP~~	~~Not stated (**DAR, 1996**)~~

section (Annex point)	study	purity	method	results	comment	reference
		99.7%	OECD 112	~~Thifensulfuron-methyl were prepared by passing buffered aqueous solutions through a column packed with glass beads coated with 10% DPX-M6316. The eluent was analysed by reversed-phase HPLC. The dissociation constant of Thifensulfuron-methyl was calculated by taking both the aqueous solubility and ionic strength into account.~~ ~~The pK_a of Thifensulfuron-methyl was 4.0.~~ pK_a = 4.0	GLP The Task Force cite the original DAR data in support of their active substance package.	Huntley and Sarff, 1999 Report DuPont 1501 (**Addendum, 2000**)

section (Annex point)	study	purity	method	results	comment	reference
B.2.1.19 (IIA 2.10)	Stability in air, photochemical oxidative degradation		Atkinson model calculation OECD Photochemical Oxidative Degradation in the Enviroment (1987a, 1988a) U.S. EPA Determination of Rates of Reaction in the Gas-Phase in the Troposphere §796.3900 (1992)	DT50 = 41.425 hours	GLP The Task Force cite the original DAR data in support of their active substance package.	Schmuckler, 1999 Report DuPont-3459 (**Addendum, 2000**)
B.2.1.20 (IIA 2.11)	Flammability and auto-flammability (technical active substance)	DPX-M6316 -100 Purity 98.3%	Flammability: EEC method A 10 and UN test method 14.5.5 (modified Bowes-Cameron Cage test)	Flammability: Not considered flammable Auto flammability: Thifensulfuron was auto flammable in the 100 mm^3 container only. The experimental data to determine auto flammability in 100-mm^3 and 25-mm^3 containers indicated that Thifensulfuron-methyl was not auto	GLP	Gravell, 1995 Report AMR 3100-94 (**DAR, 1996**)

section (Annex point)	study	purity	method	results	comment	reference
				flammable.		
		Batch: 06050 9016 96.5%	Flammability: EEC method A 10 Auto-flammability: ASTM E659	Not flammable Auto flammability: 470°C (at 99.99 kPa).	GLP It should be noted that method ASTM E659 is only applicable for the determination of the auto flammability for liquid formulations, as the active substance is a solid, data generated using this method cannot be considered supportive. However, the data presented in the original DAR may be relied upon in support of the Task Force submission.	Denny, 2006 Report R A6097 15 (**Task Force, RAR, 2014**)
B.2.1.21 (IIA 2.12)	Flash point (technical active substance)					
B.2.1.22 (IIA	Explosive properties	DPX-M6316	EEC method A 14	Not explosive.	GLP	Gravell, 1995 Report AMR

section (Annex point)	study	purity	method	results	comment	reference
2.13)	(technical active substance)	-100 Purity 98.3% Batch: 06050 9016 96.5%	 Thermal analyses (DSC, ATG)	The test for thermal sensitivity resulted in no explosions for either 6 or 2 mm orifice sizes. The test for mechanical sensitivity with respect to shock resulted in no explosions for 21 successive drop impact tests conducted at 49 Joules (3.5 kg at 1.4 m). The test for mechanical sensitivity with respect to friction resulted in no explosions for 6 trials conducted with a force of 360 Newtons. Thifensulfuron-methyl was not found sensitive to thermal, impact or friction stimuli. Not explosive. No exothermic decomposition energy above 500J/g was observed noticed in the DSC thermogram.	 GLP	3100-94 (**DAR, 1996**) Denny, 2006 Report R A6097 17 (**Task Force, RAR, 2014**)
B.2.1.23 (IIA 2.15)	Oxidising properties (technical active substance)		Case	Not Oxidising. *"All the nitrogen-containing rings have nitrogen in the -3 oxidation state, according to Roberts and Caserio, Bassic Principles of Organic Chemistry, 1st Ed, 1965; p671. This is a highly reduced state for of nitrogen; by comparison, nitrate ion is in the +5*		Gravell, 1995 Report AMR 3100-94 (**DAR, 1996**)

section (Annex point)	study	purity	method	results	comment	reference
				oxidation state. This means the nitrogen containing rings should have no oxidising tendencies. The urea moiety likewise has nitrogen in a -3 oxidation state and is non-oxidising. *The phenyl carboxylate ring is very stable and has no oxidising properties as evidenced by the millions of tons of polyester used every year to make bottles which contain delicate organic materials (i.e., foods). Likewise, polyphenylsulfone (which contains the phenylsulphonyl moiety) is a stable, non-oxidizing engineering thermoplastic.* *Thiophene contains sulphur in the -2 oxidation state, again the most highly-reduced form of sulphur (sulphate ion is+6). It will therefore be non-oxidizing."*		
		DPX-M6316-259 99.0%	EEC method A 17	Not oxidising	GLP	Radhakrishnan, 2011 DuPont-30783 (**DuPont, RAR, 2014**)

section (Annex point)	study	purity	method	results	comment	reference
		Batch: 06050 9016 96.5%	EEC method A 17 NF T20-035	Not oxidising	GLP	Denny, 2006 Report R A6097 19 (**Task Force, RAR, 2014**)
B.2.1.24 (IIA 2.14)	Surface tension	DPX-M6316 -221 98.08 %	EEC method A 5 and OECD 115	63.8 ±2.15 mN/m (at an average temperature of 19.5 ±0.0°C, conducted as a 1% solution in water)	GLP	Huntley, 2000 Report DuPont-3577 (**DuPont, RAR, 2014**)
		984-LiN-38-3 99.2%	EEC method A 5 OECD 115	72.0 mN/m (90% saturated solution, 20°C)	GLP	Comb, 2012 Report DGV0083 (**Task Force, RAR, 2014**)
		Batch: 06050 9016 96.5%	NF ISO 304	46.3 mN/m at 25°C (Saturated aqueous solution)	GLP	Denny, 2006 Report R A6097 18 (**Task Force, RAR, 2014**)

B.2.2 Physical, chemical and technical properties of the plant protection product

DAR

Two products, Harmony (a water dispersible granular formulation containing 75% Thifensulfuron-methyl) and Harmony M, (a water dispersible granular formulation containing 68.2% Thifensulfuron-methyl and 6.8% of Metsulfuron-methyl), were submitted by DuPont for consideration as representative products in the original DAR assessment (FR, 1996). The physical, chemical and technical properties data for these products have not been reproduced here - refer to the original DAR assessment for further information regarding these products.

Previous evaluation:	In DAR for original approval (1996)

HARMONY, a water dispersible granular formulation (75% Thifensulfuron-methyl)

The physico-chemical characteristics of HARMONY 75 DF are summarized in Table 2.2-1

Table 2.2-1 - Physico chemical characteristics of HARMONY 75 DF

Type of formulation	Water-dispersible granules (WG)
Color	Tan
Explosivity/auto-flammability	Not explosive nor flammable
pH (1% aqueous dilution)	4.35
Bulk density	0.65 g/ml
Wettability	1 second
Suspensibility	83%
Dispersibility	95%
Dust content	Essentially dust-free (0.01%)
Storage stability	Stable for a.s. content and physico-chemical properties when aged at 54°C for 2 weeks

Only explosivity, flammability, and auto-flammability tests were conducted under the GLP guidelines.

Study on oxidising properties of the formulated product is required.

Appearance
Appearance of HARMONY (DPX-M6316-132) was determined by visual determination (report FPC-93-05-63). Colour: tan, odour: non-descript.

Explosivity and oxidising properties
HARMONY (DPX-M6316-132) was not found to be sensitive to thermal, impact, or friction stimuli, by EEC method A.14 (report AMR-3108-94). No test on oxidising properties was conducted.

Flammability, auto-flammability

~~HARMONY (DPX-M6316-132) was found to be non-flammable, by EEC method A.10 (report AMR 3108-94)~~
~~In auto-flammability study (UN Bowes-Cameron-Cage test), the test substance gave a positive result for tests conducted in a 100 mm^3 at 140°C and a negative result for tests conducted in a 25 mm^3 at the same temperature.~~

~~pH of a 1% aqueous dilution~~
~~1% aqueous dilution of HARMONY (DPX-M6316-132) had pH = 4.35 (CIPAC MT 75 method, report FPC-93-05-63).~~

~~Bulk density~~
~~Bulk density of HARMONY (DPX-M6316-132) = 0.65 g/ml (method CIPAC MT 169, report FPC-93-05-63).~~

~~Accelerated stability~~
~~HARMONY (DPX-M6316-132) was placed in a glass cylinder under a pressure of 25g/cm^2 and the cylinder in turn was placed in a jar that was aged in a 54°C oven. An analysis of the active ingredient content and the required physical tests were conducted after completion of the accelerated ageing test (2 weeks at 54°C, method CIPAC MT46, report FPC-93-05-63).~~

- ~~Assay, 76.2% a.s.(75.9% before ageing)~~
- ~~pH: 4.44 (in distilled water)~~
- ~~Wet Sieve: 0.1% on a 75-µm sieve.~~
- ~~Suspensibility: 82%~~
- ~~Dispersibility: 95%~~

~~Shelf life storage at ambient temperature~~
~~The 2-year warehouse storage study is in progress.~~

~~Wettability~~
~~HARMONY (DPX-M6316-132) wettability: 1 second (method CIPAC MT 53.3.1, report FPC-93-05-63).~~

~~Persistent foaming~~
~~HARMONY (DPX-M6316-132): 13 ml of foam at 1 minute (method MT 47, FPC-93-05-63).~~

~~Suspensibility and suspension stability~~
~~Suspensibility of HARMONY (DPX-M6316-132): 83% (method CIPAC MT 168, report FPC-93-05-63).~~
~~Dispersibility of HARMONY (DPX-M6316-132): 95% (method CIPAC MT 174, report FPC-93-05-63).~~

~~Wet sieve test~~
~~HARMONY (DPX-M6316-132): 0.1 % was retained on a 75-µm sieve (method CIPAC MT 167, report FPC-93-05-63).~~

~~Particle size distribution~~
~~HARMONY (DPX-M6316-132) were sieved on a Gilson Sieve Shaker for a period of 5 minutes. The testing was conducted using sieves from 1410 µm (14 mesh) to 75 µm (200 mesh). Method CIPAC MT 170, report FPC-93-05-63. The smallest sieve where 90% of the material was retained was 150 µm (100 mesh). The largest sieve where 10% of the material was retained was 1410 µm (14 mesh).~~

~~Dust content of granular preparations~~
~~HARMONY (DPX-M6316-132): 0.01% dust collected (method CIPAC MT 171, report FPC-93-05-63).~~

Flowability

HARMONY (DPX-M6316-132): 100% of the test substance flowed through a 5-mm sieve spontaneously. (method CIPAC MT 172, report FPC-93-05-63).

Physical and chemical compatibility with other products

Internal or external experience and tests have shown that HARMONY was compatible with a broad range of cereal and corn plant protection products (other herbicides, fungicides, insecticides) and fertilisers or plant nutrients. In a limited number of cases a recommendation or caution can be made against mixing with certain product(s) in one given country whereas another country considers the mixture possible. Recommendations against tank mixing on cereals, corn and pastures include:

- products containing propiconazole, flutriafol, difenzoquat, diclofop methyl, flamprop-M-isopropyl, pyrazophos or chlorpyrifos (14 days should be allowed between HARMONY and pyrazophos or chlorpyrifos treatments and 7 days between HARMONY and flamprop-M-isopropyl, difenzoquat or diclofop methyl),
- the ammonium nitrate-urea solution (AHL) on pastures (Germany).

Summary

All data requirements have been met with the exception of explosivity and oxidising properties. However, a flammability test was conducted and repeated attempts to ignite the test substance with a propane torch (flame temperature >1800°C) were unsuccessful. The plant protection product is not flammable. The pH of a 1% concentration of the preparation in water was consistently measured around 4.4 pH units. The preparation was tested for dustiness and found to be "essentially non-dusty". The active ingredient content of this preparation was 75.9% (nominal active ingredient content of 75%). All physical and chemical properties specifications were met both prior to and after completion of accelerated storage at 54°C for a period of 2 weeks. The plant protection product can be conveniently measured using a calibrated volumetric measuring guide and easily disperses in water. It is compatible with commonly used cereal pesticides and can be sprayed through conventional application equipment without any screen or nozzle pluggage. Equipment cleaning is easily accomplished using standard wash out procedures. The plant protection product is a non-dusty, highly active dry flowable material and can easily be recovered when spilled in the granular form.

Previous evaluation:	In DAR for original approval (1996)

HARMONY M, a water dispersible granular formulation (68.2% Thifensulfuron-methyl and 6.8% of Metsulfuron-methyl)

The physico-chemical characteristics of HARMONY M are summarized in Table 2.2-2.

Table 2.2-2 - Physico chemical characteristics of HARMONY M

Type of formulation	Water-dispersible granules (WG)
Color	Tan
Explosivity/flammability	Not explosive nor flammable
pH (1% aqueous dilution)	4.3
Bulk density	0.68 g/ml

Wettability	1 second
Suspensibility	98% for Thifensulfuron-methyl 89% for Metsulfuron-methyl
Dispersibility	97%
Dust content	Essentially dust-free (0.01%)
Storage stability	Stable for a.s. contents and physico-chemical properties when aged at 54°C for 2 weeks

Study on oxidising properties of the formulated product is required

Appearance
Appearance of HARMONY M (DPX-E8698-16) was determined by visual determination (report FPC-93-06-63). Colour: tan, odour: non-descript.

Explosivity and oxidising properties
HARMONY M (DPX-E8698-16) was not found to be sensitive to thermal, impact, or friction stimuli, by EEC method A.14 (report AMR 3109-94)

Flammability, auto-flammability
HARMONY M (DPX-E8698-16) was found to be non-flammable, by EEC method A.10 (report AMR 3109-94).In auto-flammability study (UN Bowes-Cameron Cage test), the test substance gave a positive result for tests conducted in a 100 mm^3 at 140°C and a negative result for tests conducted in a 25 mm^3 at the same temperature.

pH of a 1% aqueous dilution
1% aqueous dilution of HARMONY M (DPX-E8698-16) had pH = 4.3 (CIPAC MT 75 method, report FPC-93-06-63)

Bulk density
Bulk density of HARMONY M (DPX-E8698-16) = 0.68 g/ml (method CIPAC MT 169, report FPC-93-06-63)

Accelerated stability
HARMONY M (DPX-E8698-16) was placed in a glass cylinder under a pressure of 25g/cm^2 and the cylinder in turn was placed in a jar that was aged in a 54°C oven. An analysis of the active ingredient content and the required physical tests were conducted after completion of the accelerated ageing test (2 weeks at 54°C, method CIPAC MT46, report FPC-93-06-63).

- Assay, 69.6 Thifensulfuron-methyl (68.6% before ageing)
- Assay, 7.9% Metsulfuron-methyl (8.0% before ageing)
- pH: 4.2 (in distilled water)
- Wet Sieve: 0.0% on a 75-µm sieve.

- Suspensibility: 99% for Thifensulfuron-methyl
- Suspensibility: 98% for Metsulfuron-methyl
- Dispersibility: 97%

Shelf life storage at ambient temperature
The 2-year warehouse storage study is in progress

~~Wettability~~
~~HARMONY M (DPX-E8698-16) wettability: 1 second (method CIPAC MT 53.3.1, report FPC-93-06-63)~~

~~Persistent foaming~~
~~HARMONY M (DPX-E8698-16): 11 ml of foam at 1 minute (method MT 47, FPC-93-06-63)~~

~~Suspensibility and suspension stability~~
~~Suspensibility of HARMONY M (DPX-E8698-16): 98% for Thifensulfuron-methyl and 89% for Metsulfuron-methyl (method CIPAC MT 168, report FPC-93-06-63)~~
~~Dispersibility of HARMONY M (DPX-E8698-16): 97% (method CIPAC MT 174, report FPC-93-06-63)~~

~~Wet sieve test~~
~~HARMONY M (DPX-E8698-16): 0.1 % was retained on a 75-µm sieve (method CIPAC MT 167, report FPC-93-06-63)~~

~~Particle size distribution~~
~~HARMONY M (DPX-E8698-16) were sieved on a Gilson Sieve Shaker for a period of 5 minutes. The testing was conducted using sieves from 1410 µm (14 mesh) to 75 µm (200 mesh). Method CIPAC MT 170, report FPC-93-06-63. The smallest sieve where 90% of the material was retained was 150 µm (100 mesh). The largest sieve where 10% of the material was retained was 1410 µm (14 mesh).~~

~~Dust content of granular preparations~~
~~HARMONY M (DPX-E8698-16): 0.01% dust collected (method CIPAC MT 171, report FPC-93-06-63)~~

~~Flowability~~
~~HARMONY M (DPX-E8698-16): 100% of the test substance flowed through a 5-mm sieve spontaneously (method CIPAC MT 172, report FPC-93-06-63).~~

~~Physical and chemical compatibility with other products~~
~~Internal or external experience and tests have shown that HARMONY M was compatible with a broad range of cereal and corn plant protection products (other herbicides, fungicides, insecticides) and fertilisers or plant nutrients. In a limited number of cases a recommendation or caution can be made against mixing with certain product(s) in one given country whereas another country considers the mixture possible. Recommendations against tank mixing on cereals include products containing Propiconazole, Flutriafol, Difenzoquat, Diclofop methyl, Flamprop M isopropyl, Pyrazophos or Chlorpyrifos (14 days should be allowed between HARMONY M and Pyrazophos or Chlorpyrifos treatments and 7 days between HARMONY M and Flamprop-M-isopropyl, Difenzoquat or Diclofop methyl).~~

~~Summary~~

~~All data requirements have been met with the exception of explosivity and oxidising properties. However, a flammability test was conducted and repeated attempts to ignite the test substance with a propane torch (flame temperature >1800°C) were unsuccessful. The plant protection product is not flammable. The pH of a 1% concentration of the preparation in water was consistently measured around 4.3 pH units. The preparation was tested for dustiness and found to be "essentially non-dusty". The active ingredient content of this preparation was 68.6% Thifensulfuron-methyl and 8% Metsulfuron-methyl (nominal active ingredient contents were 68.2% and 6.8% respectively). All physical and chemical properties specifications were met both prior to and after completion of accelerated storage at 54°C for a period of 2 weeks. The plant protection product can be conveniently measured using a calibrated volumetric measuring guide and easily disperses in water. It is compatible with commonly used cereal pesticides and can be sprayed through conventional application equipment without any screen or nozzle pluggage. Equipment cleaning is easily accomplished using standard wash out procedures. The plant protection product is a non-dusty, highly active dry flowable material and can easily be recovered when spilled in the granular form.~~

RAR - DuPont

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 1141/2010.

Product name: 'DPX-M6316 50g/L SG'/'Thifensulfuron-methyl 50 SG'
(Soluble granule formulation)

Table B.2.4 Summary of the physical and chemical properties of the plant protection product

section (Annex point)	study	method	results	comment	reference
B.2.2.1 (IIIA 2.1)	Appearance: physical state	Visual determination	Granules	GLP	Bloemer, 2003 Report DuPont-11986
		OPPTS 830.6303	Granules	GLP	Saravanan, 2013 (DuPont-36400)
B.2.2.2 (IIIA 2.1)	Appearance: colour	Visual determination	Light brown	GLP	Bloemer, 2003 Report DuPont-11986
		Visual determination	Brown	GLP	Saravanan, 2013 (DuPont-36400)
B.2.2.3 (IIIA 2.1)	Appearance: odour	Olfactory determination	Faint, slightly sour	GLP	Bloemer, 2003 Report DuPont-11986
		OPPTS 830.6304	Mild, basic odour.	GLP	Saravanan, 2013 (DuPont-36400)

<table>
<tr><th>section (Annex point)</th><th>study</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr><td>B.2.2.4 (IIIA 2.2)</td><td>Explosive properties</td><td>EEC method A 14</td><td>The product was not found to be sensitive to thermal, friction or impact stimuli.</td><td>GLP</td><td>Macdonald and Craig, 2003 Report DuPont-11738</td></tr>
<tr><td>B.2.2.5 (IIIA 2.2)</td><td>Oxidising properties</td><td>EEC method A 17</td><td>Test item trains
<table>
<tr><th>Test item / cellulose ratio</th><th>Time for flame to travel 200 mm</th><th>Reaction</th></tr>
<tr><td>10/90</td><td>Flame extinguished after 20s</td><td>Flame propagate 8 mm along apex of train</td></tr>
<tr><td>20/80</td><td rowspan="8">N/A</td><td rowspan="8">Failed to ignite</td></tr>
<tr><td>30/70</td></tr>
<tr><td>40/60</td></tr>
<tr><td>50/50</td></tr>
<tr><td>60/40</td></tr>
<tr><td>70/30</td></tr>
<tr><td>80/20</td></tr>
<tr><td>90/10</td></tr>
</table>
Reference item – barium nitrate) trains</td><td>GLP

Not oxidising</td><td>Macdonald and Craig, 2003 Report DuPont-11738</td></tr>
</table>

<table>
<tr><th>section (Annex point)</th><th>study</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr><td>B.2.2.5 (IIIA 2.2) Cont.</td><td></td><td></td><td>
<table>
<tr><td>Test item / cellulose ratio</td><td>Time for flame to travel 200 mm</td><td>Reaction</td></tr>
<tr><td>10/90</td><td>1 minute, 0 seconds</td><td>Burned with a green flame</td></tr>
<tr><td>20/80</td><td>1 minute, 21 seconds</td><td>Burned with a green flame</td></tr>
<tr><td>30/70</td><td>1 minute, 25 seconds</td><td>Burned with a green flame</td></tr>
<tr><td>40/60</td><td>1 minute, 15 seconds</td><td>Burned with a vigorous green flame</td></tr>
<tr><td>50/50</td><td>1 minute, 20 seconds</td><td>Burned with a vigorous green flame</td></tr>
<tr><td>60/40</td><td>1 minute, 15 seconds</td><td>Burned with a vigorous green flame</td></tr>
</table>
</td><td></td><td></td></tr>
</table>

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section (Annex point)	study	method	results	comment	Reference
B.2.2.5 (IIIA 2.2) Cont.			<table><tr><td>70/30</td><td>1 minute, 15 seconds</td><td>Burned with a vigorous green flame</td></tr><tr><td>80/20</td><td>2 minute, 06 seconds</td><td>Burned with a vigorous green flame</td></tr><tr><td>90/10</td><td>N/A</td><td>No ignition, mixture appeared to melt</td></tr></table>		
B.2.2.6 (IIIA 2.3)	Flammability	EEC method A 10	Not highly flammable	GLP	Macdonald and Craig, 2003 Report DuPont-11738
B.2.2.7 (IIIA 2.3)	Auto-flammability	EEC method A 16	No self ignition below 400°C	GLP	Macdonald and Craig, 2003 Report DuPont-11738
B.2.2.8 (IIIA 2.3)	Flash point		Not required, the formulation is not a liquid.		

section (Annex point)	study	method	results	comment	Reference
B.2.2.9 (IIIA 2.4)	Acidity/alkalinity		Not applicable as the pH of a 1% dilution with deionised water is not lower than pH 4 or greater than pH 10.		
B.2.2.10 (IIIA 2.4)	pH	CIPAC MT 75.2 CIPAC MT 75.2	pH = 9.2 (1% aqueous dilution at 22°C) pH = 8.7 (1% aqueous dilution)	GLP GLP It should be noted that the tests were conducted in conjunction with 0.1%w/v Trend 90 spray tank adjuvant.	Bloemer, 2003 Report DuPont-11986 Saravanan, 2013 (DuPont-36400)
B.2.2.11 (IIIA 2.5)	Surface tension		Not required, the formulation is not a liquid.		
B.2.2.12 (IIIA 2.5)	Viscosity		Not required, the formulation is not a liquid.		
B.2.2.13 (IIIA 2.6)	Relative density		Not required, the formulation is not a liquid.		
B.2.2.14 (IIIA 2.6)	Bulk (tap) density	CIPAC Methods MT 169	0.615 g/mL (loose bulk density) 0.696 g/mL (tapped bulk density)	Non-GLP	Bloemer, 2003 Report DuPont-11986

section (Annex point)	study	method	results	comment	Reference
B.2.2.14 (IIIA 2.7)	Storage stability	CIPAC Method MT 46.3 In-house method (M6316.220.01.ES) CIPAC MT 75 CIPAC MT 53.3 CIPAC MT 182 CIPAC MT 179 CIPAC MT 171 CIPAC MT 170	*Accelerated storage for 14 days at 54°C.* Solutions prepared for the measurement of the pH and degree of dissolution of the "accelerated aged" product were more cloudy and darker than those of the "as made" product solutions. After accelerated storage (in a HDPE container), the product changed in colour from light brown to light rust. There were no significant changes in the physical properties or chemical stability.	GLP with respect to pH, dry sieve analysis and dust. It is noted that the product appearance has changed following storage. Additionally, the pH of the formulation changed from 9.2 to 7.2. The pH change is minimal and does not pose an issue with respect to classification. As all of the other properties have remained close to their initial vales prior to storage, the study can be considered to be acceptable.	Bloemer, 2003 Report DuPont-11986

section (Annex point)	study	method	results	comment	Reference
B.2.2.14 (IIIA 2.7) Cont.			**Active substance content** *Initial*: 49.5%; *After storage for 14 days at 54°C*: 48.9% **pH (1% dispersion at 25°C)** *Initial*: 9.2; *After storage for 14 days at 54°C*: 7.2	A loss of 1.21% was noted following storage, which is within the maximum acceptable loss of <5%	
			Wettability (complete wetting) *Initial*: 12 seconds; *After storage for 14 days at 54°C*: 8 seconds **Wet sieve (retained on a 75 µm sieve)** *Initial*: 0.1%; *After storage for 14 days at 54°C*: 0.1%		Report DuPont-11986

section (Annex point)	study	method	results	comment	Reference
B.2.2.14 (IIIA			**Dust content** *Initial*; *After storage*		

2.7) Cont.			*for 14 days at 54°C* 1.5 mg | 1.6 mg **Dry Sieve** *Initial* | *After storage for 14 days at 54°C* rx >90% on 1000 µm rx <10% on 1.4 mm | rx >90% on 1000 µm rx <10% on 1.4 mm		
		CIPAC MT 46.3 (accelerated storage) Visual assessment	<u>Accelerated storage for 14 days at 54°C in water soluble packaging</u> Thifensulfuron methyl 50SG was stored in a water soluble bag at a temperature of 54°C for a period of 2 weeks. Visual assessment showed no perforations, darkening, leakage or rust in the seam of the packaging. At the conclusion of the storage period the packaging remained intact and unaffected by the storage. The following tests were conducted and results reported after completion of accelerated storage: Appearance: brownish, water soluble granules with a mild, basic odour.	GLP The provided data show that the formulation is stable when stored in water soluble packaging under accelerated storage conditions. It should be noted that the tests were conducted in conjunction with 0.1%w/v Trend 90 spray tank adjuvant.	Saravanan, 2013 (DuPont-36400)

		OPPTS 830.6304 OPPTS 830.6303 CIPAC MT 75.3 CIPAC MT 47.2 CIPAC MT 179 CIPAC MT 176 In-house method (MU316.220.02.ST)	pH: 8.7 Persistent foam: 41 ± 1 mL after 10 ± 1 seconds 35 ± 2 mL after 1 minute ± 10 seconds 31 ± 1 mL after 3 minutes ± 10 seconds 30 ± 0 mL after 12 minutes ± 10 seconds Degree of dissolution and solution stability: 0.032 ± 0.005% after 5 minutes 0.033 ± 0.003% after 18 hours Dissolution of water soluble bags: 9.4 ± 0.1 seconds Initial concentration of Thifensulfuron methyl 50SG as made = 50.1 ± 0.1%. The concentration of active substance following storage for 14 days at temperature 54°C = 49.6 ± 0.4%.		

		In-house method (M6316.220.01.ES) CIPAC Methods MT 39, MT 48, MT 51 or MT 54	<u>Ambient temperature storage at 25°C</u> No signs of corrosion or deterioration of the packaging (200 ml HDPE bottle – the proposed packaging material) were observed. The appearance, odour, pH, dust content, wettability, wet sieve test, particle size distribution, friability and attrition characteristics and persistent foam of the test material remained stable throughout the storage period.	Similar changes were noted to the product appearance as was noted previously for the accelerated storage stability study. Again a similar decrease to the pH was noted and all of the other properties generally remain constant following storage. The one exception to this is for the wettability, which decreases from 12 to 4 seconds following storage. The active content remains stable and it can therefore be concluded that the study acceptably demonstrates that the product is stable over the 2 year ambient storage period.	Report DuPont-11987

<table>
<tr><th>section (Annex point)</th><th>study</th><th>method</th><th>results</th><th>comment</th><th>Reference</th></tr>
<tr><td>B.2.2.14 (IIIA 2.7) Cont.</td><td></td><td></td><td>As noted for the accelerated storage stability study the product was more cloudy and darker than that of the “as made” product solution. After ambient storage, the product changed in colour from light brown to light rust. There were no significant changes in the physical properties or chemical stability.</td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td colspan="2">Active substance content</td></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td>49.5%</td><td>49.46%</td></tr>
<tr><td colspan="2">pH (1% dispersion at 25°C)</td></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td>9.2</td><td>7.5</td></tr>
<tr><td colspan="2">Wettability (complete wetting)</td></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td>12 seconds</td><td>4 seconds</td></tr>
<tr><td colspan="2">Persistent foaming (at ambient) (0.06% w/v dilution)</td></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td>After 1 min.: 0 mL</td><td>After 1 min.: 0 mL</td></tr>
</table>
</td><td></td><td></td></tr>
</table>

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<table>
<tr><th>section (Annex point)</th><th>study</th><th>method</th><th>results</th><th>comment</th><th>Reference</th></tr>
<tr><td>B.2.2.14 (IIIA 2.7) Cont.</td><td></td><td></td><td>
<table>
<tr><td colspan="2">Wet sieve
(retained on a 75 µm sieve)</td></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td>0.1%</td><td>0.1%</td></tr>
<tr><td colspan="2">Nominal size range</td></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td>rx >90% on 1000 µm
rx <10% on 1.4 mm</td><td>rx >90% on 1000 µm
rx <10% on 1.4 mm</td></tr>
<tr><td colspan="2">Dust content</td></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td>1.5 mg</td><td>1.7 mg</td></tr>
<tr><td colspan="2">Friability and attrition</td></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td>99.6%</td><td>99.9%</td></tr>
<tr><td colspan="2">Degree of Dissolution and Solution Stability</td></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td>After 5 minutes, 0.033% residue was collected on a 75 µm sieve</td><td>After 5 minutes, 0.27% residue was collected on a 75 µm sieve. After 18 hours, 0.13% remained.</td></tr>
</table>
</td><td></td><td></td></tr>
</table>

section (Annex point)	study	method	results	comment	Reference
B.2.2.15 (IIIA 2.7)	Shelf life		The product is considered to be stable for at least 2 years in the commercial packaging based on available testing data.	A loss of 0.08% was noted following storage, which is within the maximum acceptable loss of <5%. Based on this result and the data provided under IIIA 2.7, the formulation can be considered to be stable for at least 2 years.	
B.2.2.16 (IIIA 2.8)	Wettability	CIPAC Method MT 53.3	12 seconds (Approximately 20% of the product remains floating beneath the surface for a few minutes but does wet in.)	Non-GLP The Notifier has confirmed that the formulation lies below the water surface within 12 seconds which is within the requirements stated in the test method MT 53.3. The method describes that a fine film on the surface is permitted: Note 15 of the method – *"Neglect a film of fine particles remaining on the surface"*. As all of the material lies below the surface of the water after 12 seconds, the result is considered to be acceptable. Member States should note that when granting product authorisations an appropriate label amendment may be required, as a consequence of this result (i.e. by recommending that agitation should be maintained throughout the spraying operation).	Bloemer, 2003 Report DuPont-11986

section (Annex point)	study	method	results	comment	Reference
B.2.2.17 (IIIA 2.8)	Persistent foaming	CIPAC Method MT 47.2	0 ml of foam at 1 minute (0.6 g/L)	Non-GLP	Bloemer, 2003 Report DuPont-11986
			15 ml of foam at 1 minute (1 g/L)	GLP The maximum use rate proposed in the product GAP is 0.38 g/L. Both of these studies use concentrations in excess of this value. This is acceptable as it presents a worst case concentration with values for foam produced found to be below the trigger limit of 60 mL.	Robson, 2012 Report DuPont-11986 Supplement No.1
		CIPAC Method MT 47.2	Thifensulfuron methyl 50SG (at its highest recommended use rate) was added to CIPAC standard hard water "D" containing a representative sample of water soluble film and 0.1% w/v of DPX-KG691 spray tank adjuvant and agitated as directed by the method and the volume of foam recorded after the cylinder was left standing, undisturbed for a total of 12	GLP Studies were conducted using 0.12% w/v, which is appropriate to the label rate. The value at one minute was 37 mL, which is within the trigger limit of 60 mL.	Saravanan, 2013 (DuPont-36400)

			minutes. Persistent foam: 41 ± 1 mL after 10 ± 1 seconds 37 ± 1 mL after 1 minute ± 10 seconds 32 ± 0 mL after 3 minutes ± 10 seconds 30 ± 0 mL after 12 minutes ± 10 seconds		
B.2.2.18 (IIIA 2.8)	Suspensibility		Not applicable to water soluble formulations.		
B.2.2.19 (IIIA 2.8)	Suspension stability		Not applicable to water soluble formulations.		

section (Annex point)	study	method	results	comment	Reference
B.2.2.20 (IIIA 2.8)	Dilution stability	CIPAC Method MT 179 CIPAC Method MT 179	After 5 minutes, 0.033% residue was collected on a 75 µm sieve. After 18 hours, no evidence of residue remained. A 3.0 gram sample of Thifensulfuron methyl 50SG was added to a 250-mL graduated cylinder containing 250-mL of Standard Water D at a temperature of 25°C. After standing for 30 seconds, the cylinder was inverted 15 times and allowed to stand for 5 minutes. The contents of the cylinder were then poured through a 75 µm sieve and the filtrate was collected. After 18 hours, the filtrate was examined for sediment. After 5 minutes, 0.032 ± 0.005% residue was collected on the 75 µm sieve. After 18 hours 0.030 ± 0.006% residue remained.	Non-GLP GLP It should be noted that the tests were conducted in conjunction with 0.1%w/v Trend 90 spray tank adjuvant.	Bloemer, 2003 Report DuPont-11986 Saravanan, 2013 (DuPont-36400)
B.2.2.21 (IIIA 2.8)	Dry sieve test		Not required.		
B.2.2.22 (IIIA 2.8)	Wet sieve test	CIPAC Method MT 182	0.1% was retained on a 75 um sieve.	Non-GLP	Bloemer, 2003 Report DuPont-11986

<table>
<tr><th>section (Annex point)</th><th>study</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr><td>B.2.2.23 (IIIA 2.8)</td><td>Particle size distribution</td><td>CIPAC MT 170</td><td>The smallest sieve where 90% of the material was retained was 1000 µm

The largest sieve where 10% of the material was retained was 1.4 mm
_____

The Notifer has provided the data in the Table below to expand on the results above. These data were used to draw the above conclusions which were presented in DuPont-11986 (however the data presented in the Table was not originally included in the report).
<table>
<tr><th>Sieve size</th><th>Weight, g</th><th>Residue, rx, %</th><th>Sum of residue, %</th></tr>
<tr><td>250 µm</td><td>0,02</td><td>0,03</td><td>99,77</td></tr>
<tr><td>500 µm</td><td>4,94</td><td>7,1</td><td>99,74</td></tr>
<tr><td>1000 µm</td><td>63,5</td><td>91,24</td><td>92,64</td></tr>
<tr><td>1400µm</td><td>0,98</td><td>1,4</td><td>1,4</td></tr>
<tr><td>2000 µm</td><td>0</td><td>0</td><td>0</td></tr>
</table></td><td>GLP

It is noted that the additional data did not include analyses conducted using 75 or 50 µm sieves. However, it is noted that the cumulative residue total up to the 250 µm sieve accounts for 99.77 % for the residue. This leaves 0.23% of the residue unaccounted for, which is less than the 1 % trigger limit. On this basis these data can be considered to be sufficient</td><td>Bloemer, 2003 Report DuPont-11986</td></tr>
<tr><td>B.2.2.24 (IIIA 2.8)</td><td>Content of dust/fines</td><td>CIPAC Method MT 171</td><td>1.5 mg (0.005%) dust collected</td><td>GLP

“nearly dust-free”</td><td>Bloemer, 2003 Report DuPont-11986</td></tr>
</table>

section (Annex point)	study	method	results	comment	Reference
B.2.2.25 (IIIA 2.8)	Attrition and friability	CIPAC Method MT 178	99.6%	Non-GLP	Bloemer, 2003 Report DuPont-11986
B.2.2.26 (IIIA 2.8)	Emulsifiabilty, re-emulsifiabilty and emulsion stability		Not applicable to water soluble formulations.		
B.2.2.27 (IIIA 2.8)	Stability of dilute emulsion		Not applicable to water soluble formulations.		
B.2.2.28 (IIIA 2.8)	Flowability	CIPAC Method MT 172	Product flows spontaneously through a 5-mm sieve.	Non-GLP	Bloemer, 2003 Report DuPont-11986
B.2.2.29 (IIIA 2.8)	Pourability (rinsibility)		Not applicable, the product is a granular preparation.		
B.2.2.30 (IIIA 2.8)	Dustability		Not applicable, the product is a granular preparation.		
B.2.2.31 (IIIA 2.8)	Adherence and distribution to seeds		The product is not a seed treatment.		
B.2.2.32 (IIIA 2.15)	Other special studies Dissolution of water soluble bag	CIPAC MT 176	An aqueous suspension of the formulation was prepared. A 50 - 100 mm piece of the bag was	GLP It should be noted that the tests were	Saravanan, 2013 (DuPont-

			immersed in the suspension for 10 minutes and then stirred as directed by the method. The suspension was then passed through a filter and the flow time recorded. All of the aqueous test substance flowed freely through the filter in 9.4 ± 0.1 seconds with no residue of water soluble film remaining on the screen.	conducted in conjunction with 0.1%w/v Trend 90 spray tank adjuvant.	36400)

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 1141/2010.

Task Force - Rotam

Product name: 'Thifensulfuron-methyl + Metsulfuron-methyl, 682 + 68 g/kg WG' Product code FH-009

Table B.2.5 Summary of the physical and chemical properties of the plant protection product

section (Annex point)	study	method	results	comment	reference
B.2.2.1 (IIIA 2.1)	Appearance: physical state	In house visual assessment Thifensulfuron-methyl + Metsulfuron-methyl, 682 + 68 g/kg, WG Batch no.: 060814001, content 67.98% + 6.85% (w/w)	Granules	GLP	Denny, O., 2006a, (R A6148 23),

section (Annex point)	study	method	results	comment	reference
B.2.2.2 (IIIA 2.1)	Appearance: colour	In house visual assessment Thifensulfuron-methyl + Metsulfuron-methyl, 682 + 68 g/kg, WG Batch no.: 060814001, content 67.98% + 6.85% (w/w)	Off-white	GLP	Denny, O., 2006a, (R A6148 23),
B.2.2.3 (IIIA 2.1)	Appearance: odour	In house visual assessment Thifensulfuron-methyl + Metsulfuron-methyl, 682 + 68 g/kg, WG Batch no.: 060814001, content 67.98% + 6.85% (w/w)	No characteristic odour	GLP	Denny, O., 2006a, (R A6148 23),

section (Annex point)	study	method	results	comment	reference
B.2.2.4 (IIIA 2.2)	Explosive properties	Estimation based on DSC and TGA techniques.	The molecular structure of the test item does not exhibit a particular sub-unit likely to produce a violent degradation of the substance. Thermal analyses (DSC, TGA) showed only moderate and/or slow degradation processes (no exothermic decomposition energy higher than 500J/g). Not explosive.	GLP	Denny, O., 2006c, (R A6148 05)
B.2.2.5 (IIIA 2.2)	Oxidising properties	Standard method NF-T 20- 035 as stated in EEC A.17	Not oxidising	GLP	Denny, O., 2006d, (R A6148 06)
B.2.2.6 (IIIA 2.3)	Flammability	EEC method A 10	Not highly flammable	GLP	Denny, O., 2006e, (R A6148 07)

section (Annex point)	study	method	results	comment	reference
B.2.2.7 (IIIA 2.3)	Auto-flammability	~~EEC method A 15~~	~~No self ignition below 500°C~~	~~GLP~~ ~~It should be noted that EEC method A 15 is only applicable for the determination of the auto flammability for liquid formulations, as the active substance is a solid (WG), data generated using this method cannot be considered supportive (**data gap**).~~	~~Denny, O., 2006f, (R A6148 08)~~
		EEC method A 16	The test substance is not auto-flammable (tested to 400°C)	GLP	Srinivasan, A., 2013, (0993)
B.2.2.8 (IIIA 2.3)	Flash point		Not relevant as the formulation is a solid and does not contain flammable liquids		
B.2.2.9 (IIIA 2.4)	Acidity/alkalinity	CIPAC Method MT 31.2.2	1.53% w/w as sulphuric acid	GLP	Denny, O., 2006g, (R A6148 09), Denny, O., 2006a, (R A6148 23)

section (Annex point)	study	method	results	comment	reference
B.2.2.10 (IIIA 2.4)	pH	CIPAC MT 75.3	pH of a 1% dispersion = 5.64 at 20°C	GLP	Denny, O., 2006h, (R A6148 10),
B.2.2.11 (IIIA 2.5)	Surface tension		Not relevant as the formulation is a solid		
B.2.2.12 (IIIA 2.5)	Viscosity		Not relevant as the formulation is a solid		
B.2.2.13 (IIIA 2.6)	Relative density		Not relevant as the formulation is a solid		
B.2.2.14 (IIIA 2.6)	Bulk (tap) density	CIPAC MT 169 (equivalent to MT 186)	Bulk (tap) density = 0.677 g/mL	GLP	Denny, O., 2006i, (R A6148 11)
B.2.2.14 (IIIA 2.7)	Storage stability	CIPAC Method MT 46 CIPAC	*Accelerated storage for 14 days at 54°C.* The appearance, odour, pH, dust content, wet sieve test, degree of dispersion, suspensibility and persistent foam of the test material remained stable throughout the storage period. **Active substance content**	GLP	Denny, O., 2006, (R A6148 23)

<table>
<tr><th>section (Annex point)</th><th>study</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr><td></td><td></td><td>452/WG/M/3</td><td>
<table>
<tr><td colspan="2">(Thifensulfuron-methyl)</td></tr>
<tr><td>Initial</td><td>After storage for 14 days at 54°C</td></tr>
<tr><td colspan="2">(Thifensulfuron-methyl)</td></tr>
<tr><td>682.8 g/kg</td><td>684.8 g/kg</td></tr>
<tr><td colspan="2">(Metsulfuron-methyl)</td></tr>
<tr><td>66.5 g/kg</td><td>66.4g/kg</td></tr>
<tr><td colspan="2">Free acidity / alkalinity</td></tr>
<tr><td>Initial</td><td>After storage for 14 days at 54°C</td></tr>
<tr><td>1.53% w/w as sulphuric acid</td><td>1.48% w/w as sulphuric acid</td></tr>
<tr><td colspan="2">pH (1% dispersion at 25°C)</td></tr>
<tr><td>Initial</td><td>After storage for 14 days at 54°C</td></tr>
<tr><td>5.64</td><td>5.62</td></tr>
<tr><td colspan="2">Persistent foaming</td></tr>
<tr><td>Initial</td><td>After storage for 14 days at 54°C</td></tr>
<tr><td>After 1 min.: 6.0 mL</td><td>After 1 min.: 5.0 mL</td></tr>
<tr><td colspan="2">~~Suspensibility~~</td></tr>
<tr><td>~~Initial~~</td><td>~~After storage for 14 days at~~</td></tr>
</table>
</td><td></td><td></td></tr>
</table>

<table>
<tr><th>section (Annex point)</th><th>study</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr>
<td></td>
<td></td>
<td>CIPAC Methods MT 39, MT 48, MT 51 or MT 54

CIPAC Method MT 184</td>
<td>
<table>
<tr><td></td><td><s>54°C</s></td></tr>
<tr><td><s>(max) 94%
(min) 91%</s></td><td><s>(max) 87%
(min) 91%</s></td></tr>
<tr><td colspan="2">Spontaneity of dispersion</td></tr>
<tr><td>Initial</td><td>After storage for 14 days at 54°C</td></tr>
<tr><td>89%</td><td>82%</td></tr>
<tr><td colspan="2">Wet sieve
(retained on a 75 µm sieve)</td></tr>
<tr><td>Initial</td><td>After storage for 14 days at 54°C</td></tr>
<tr><td>0.03%</td><td>0.06%</td></tr>
<tr><td colspan="2">Dust content</td></tr>
<tr><td>Initial</td><td>After storage for 14 days at 54°C</td></tr>
<tr><td>0.54 mg</td><td>0.59 mg</td></tr>
</table>
Results for thifensulfuron-methyl after 14 days storage at 54°C

(Tested using CIPAC water D at 30°C)

<u>Max. Concentration (0.9 g/L)</u>
100.5%
</td>
<td>GLP

Values reported are within the acceptable range 60-105%.</td>
<td>Srinivasan, A., 2013, (0993)</td>
</tr>
</table>

<table>
<tr><th>section (Annex point)</th><th>study</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr><td></td><td></td><td>CIPAC 452/WG/M/3</td><td>Min. Concentration (0.15 g/L) 101.7%

Ambient temperature storage at 25°C

The appearance, odour, corrosion characteristics, pH, dust content, wet sieve test, degree of dispersion, suspensibility and persistent foam of the test material (HDPE) remained stable throughout the storage period.

<table>
<tr><th colspan="2">Active substance content</th></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td colspan="2">(Thifensulfuron-methyl)</td></tr>
<tr><td>682.8 g/kg</td><td>673.3 g/kg</td></tr>
<tr><td colspan="2">(Metsulfuron-methyl)</td></tr>
<tr><td>66.5 g/kg</td><td>66.9 g/kg</td></tr>
<tr><th colspan="2">Free acidity / alkalinity</th></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td>1.53% w/w as sulphuric acid</td><td>1.38% w/w as sulphuric acid</td></tr>
<tr><th colspan="2">pH (1% dispersion at 25°C)</th></tr>
<tr><td>Initial</td><td>After 24 months</td></tr>
</table></td><td>GLP</td><td>Denny, O., 2009, (R A6148 SL)</td></tr>
</table>

section (Annex point)	study	method	results	comment	reference

	at 25°C
5.64	5.70
Wettability (complete wetting)	
Initial	*After 36 months at 25°C*
9.28 seconds	5 seconds
Persistent foaming (at ambient) (0.03% w/v dilution)	
Initial	*After 24 months at 25°C*
After 1 min.: 6 mL	After 1 min.: 5 mL
Suspensibility	
Initial	*After 24 months at 25°C*
(max) 94% (min) 91%	(max) 93% (min) 93%
Spontaneity of dispersion	
Initial	*After 24 months at 25°C*
83%	93%
Wet sieve (retained on a 75 µm sieve)	
Initial	*After 24 months at 25°C*
0.03%	0.03%
Nominal size range	
Initial	*After 24 months*

section (Annex point)	study	method	results	comment	reference
			<table><tr><td></td><td>*at 25°C*</td></tr><tr><td>Pan receiver: 0.04% 75 µm sieve: 0.01%</td><td>Not reported</td></tr><tr><td colspan="2">**Dust content**</td></tr><tr><td>*Initial*</td><td>*After 24 months at 25°C*</td></tr><tr><td>0.54 mg</td><td>0.53 mg</td></tr><tr><td colspan="2">**Friability and attrition**</td></tr><tr><td>*Initial*</td><td>*After 36 months at 25°C*</td></tr><tr><td>99.9%</td><td>99.7%</td></tr></table> No signs of corrosion or deterioration of the packaging were observed. The appearance, odour, pH, dust content, wettability, wet sieve test, particle size distribution, degree of dispersion, suspensibility, friability and attrition characteristics and persistent foam of the test material remained stable throughout the storage period.		

section (Annex point)	study	method	results	comment	reference
B.2.2.15 (IIIA 2.7)	Shelf life		The product is considered to be stable for at least 2 years in the commercial packaging (HDPE) based on available testing data.	A loss of 0.3% was noted following storage, which is within the maximum acceptable loss of <5%. Based on this result and the data provided under IIIA 2.7, the formulation can be considered to be stable for at least 2 years.	
B.2.2.16 (IIIA 2.8)	Wettability	CIPAC Method MT 53.3	Wettability without swirling: 9.28 sec Wettability with swirling: 2.39 sec	GLP	Denny, O., 2006k, (R A6148 12)
B.2.2.17 (IIIA 2.8)	Persistent foaming	CIPAC Method MT 47.1	Dilution at 0.03% w/v in standard water C After 0 sec.: 8.0 mL After 1 min.: 6.0 mL	GLP The concentration used in the study does not cover the maximum in use rate concentration (0.05%w/v). However, the concentrations are close and it is not anticipated that if the study were repeated at the increased rate, that the foam produced would exceed the limit (60ml).	Denny, O., 2006a, (R A6148 23), Denny, O., 2006l, (R A6148 13)

section (Annex point)	study	method	results	comment	reference
B.2.2.18 (IIIA 2.8)	Suspensibility	~~CIPAC Method MT 168~~	~~Max. Concentration (0.3 g/L) 91%~~ ~~Min. Concentration (0.2 g/L) 94%~~	~~GLP~~ ~~It is noted that the proposed minimum and maximum application concentrations are 0.10 g/L and 0.51 g/L. The data submitted by the Notifier were generated using a maximum of 0.3 g/L which does not include the minimum proposed concentration. This data will be required.~~	~~Denny, O., 2006a, (R A6148 23),~~ ~~Denny, O., 2006m, (R A6148 14)~~
		CIPAC Method MT 184	Results for thifensulfuron-methyl (Tested using CIPAC water D at 30°C) Max. Concentration (0.9 g/L) 100.5% Min. Concentration (0.15 g/L) 101.7%	GLP Values reported are within the acceptable range 60-105%. Tested concentrations cover those recommended on the product label (0.3-0.6 g/L)	Srinivasan, A., 2013, (0993)

section (Annex point)	study	method	results	comment	reference
B.2.2.19 (IIIA 2.8)	Suspension stability	CIPAC MT 174 (TSM determined by CIPAC 452/WG/M/3)	89%	GLP	Denny, O., 2006a, (R A6148 23), Denny, O., 2006n, (R A6148 16)
B.2.2.20 (IIIA 2.8)	Dilution stability		Not relevant as the formulation is not a water soluble preparation		
B.2.2.21 (IIIA 2.8)	Dry sieve test	CIPAC Method MT 59.1	Dry sieve test used for data in IIIA 2.8.		
B.2.2.22 (IIIA 2.8)	Wet sieve test	CIPAC Method MT 167	0.03%	GLP	Denny, O., 2006a, (R A6148 23),
B.2.2.23 (IIIA 2.8)	Particle size distribution	CIPAC MT 170	Final pan: 0.04% (99.91% sum) 75 µm sieve: 0.01% (99.87% sum) 125 µm sieve: 0.03% (99.86% sum) 250 µm sieve: 0.5% (99.83% sum) 500 µm sieve: 99.1% (99.38% sum) 2000 µm sieve: 0.3% (0.03% sum)	GLP	Denny, O., 2006p, (R A6148 19)

section (Annex point)	study	method	results	comment	reference
B.2.2.24 (IIIA 2.8)	Content of dust/fines	CIPAC Method MT 171	Dust content: 0.54 mg	GLP "Nearly dust free"	Denny, O., 2006a, (R A6148 23),
B.2.2.25 (IIIA 2.8)	Attrition and friability	CIPAC Method MT 178	Attrition resistance: 99.9%	GLP	Denny, O., 2006r, (R A6148 21)
B.2.2.26 (IIIA 2.8)	Emulsifiabilty, re-emulsifiabilty and emulsion stability		Not relevant as the formulation is a granular solid		
B.2.2.27 (IIIA 2.8)	Stability of dilute emulsion		Not relevant as the formulation is a granular solid		
B.2.2.28 (IIIA 2.8)	Flowability	CIPAC Method MT 172	99.4% of test item passed through the 2000 µm sieve.	GLP	Denny, O., 2006s, (R A6148 22)
B.2.2.29 (IIIA 2.8)	Pourability (rinsibility)		Pourability is not relevant as the formulation is a granular solid		
B.2.2.30 (IIIA 2.8)	Dustability		Not relevant as the formulation is a granular solid		
B.2.2.31 (IIIA 2.8)	Adherence and distribution to seeds		Not relevant as the formulation is not used as a seed treatment		

Previous evaluation:	None: Submitted for the purpose of renewal under Regulation 1141/2010.

Task Force – Cheminova A/S

Product name: 'Thifensulfuron-methyl + Metsulfuron-methyl, 680 + 70 g/kg WG' Product code CHA 8730

Table B.2.6 Summary of the physical and chemical properties of the plant protection product

section (Annex point)	study	method	results	comment	reference
B.2.2.1 (IIIA 2.1)	Appearance: physical state	In-house visual assessment Thifensulfuron-methyl + Metsulfuron-methyl, 680 + 70 g/kg WG (CHA 8730). Batch no.: 947-DJø-06, content 67.6% + 6.83% (w/w)	Hard, solid, free flowing granules	GLP	White, D.F., & Mullee, D.M., 2006a (20 TIM)
B.2.2.2	Appearance: colour	In-house	Beige (opaque)	GLP	White, D.F.,

section (Annex point)	study	method	results	comment	reference
(IIIA 2.1)		visual assessment Thifensulfuron-methyl + Metsulfuron-methyl, 680 + 70 g/kg WG (CHA 8730). Batch no.: 947-DJø-06, content 67.6% + 6.83% (w/w)			& Mullee, D.M., 2006a (20 TIM)
B.2.2.3 (IIIA 2.1)	Appearance: odour	In-house olfactory assessment Thifensulfuron-methyl + Metsulfuron-methyl, 680 + 70 g/kg WG (CHA 8730). Batch no.: 947-DJø-06, content 67.6% + 6.83% (w/w)	Moderate creosote like odour	GLP	White, D.F., & Mullee, D.M., 2006a (20 TIM)

section (Annex point)	study	method	results	comment	reference
B.2.2.4 (IIIA 2.2)	Explosive properties	EEC A.14 Expert statement based on UN Appendix 6	Not explosive	GLP	Høgh, 2007a (68 TIM)
B.2.2.5 (IIIA 2.2)	Oxidising properties	EEC A.17 Expert statement based on UN Appendix 6	Not oxidising	GLP	Høgh, 2007b (69 TIM)
B.2.2.6 (IIIA 2.3)	Flammability	EEC method A 10	Not highly flammable	GLP	Comb, 2006 (8 TIM)
B.2.2.7 (IIIA 2.3)	Auto-flammability	EEC method A 16	No self ignition below 400°C	GLP	Comb, 2006 (8 TIM)
B.2.2.8 (IIIA 2.3)	Flash point		Not relevant as the formulation is a solid and does not contain flammable liquids		
B.2.2.9 (IIIA 2.4)	Acidity/alkalinity	CIPAC MT 31.2.3 CIPAC MT 31.2.3	9.83% w/w (as sulphuric acid)	GLP	White, D.F., & Mullee, D.M., 2006a (20 TIM)

section (Annex point)	study	method	results	comment	reference
B.2.2.10 (IIIA 2.4)	pH	CIPAC MT 75.3	pH of a 1% dispersion = 3.96 at 25°C	GLP	White, D.F., & Mullee, D.M., 2006a (20 TIM)
B.2.2.11 (IIIA 2.5)	Surface tension		Not relevant as the formulation is a solid		
B.2.2.12 (IIIA 2.5)	Viscosity		Not relevant as the formulation is a solid		
B.2.2.13 (IIIA 2.6)	Relative density		Not relevant as the formulation is a solid		
B.2.2.14 (IIIA 2.6)	Bulk (tap) density	CIPAC MT 169 (equivalent to MT 186)	Bulk (tap) density = 0.678 g/mL	GLP	White, D. F., Mullee, D. M., 2006b (7 TIM)
B.2.2.14 (IIIA 2.7)	Storage stability	CIPAC Method MT 46	*Accelerated storage for 14 days at 54°C.* No signs of corrosion or deterioration of the HDPE packaging were observed. The appearance and odour remained stable throughout the storage period.	GLP	White and Mullee, 2006a (20 TIM)

section (Annex point)	study	method	results	comment	reference
		CIPAC 452/WG/M/3	**Active substance content** *Initial* | *After storage for 14 days at 54°C* (Thifensulfuron-methyl) 66.9% w/w | 67.6% w/w (Metsulfuron-methyl) 6.18% w/w | 6.01% w/w **Free acidity / alkalinity** *Initial* | *After storage for 14 days at 54°C* 9.83% w/w as sulphuric acid | 9.56% w/w as sulphuric acid **pH (1% dispersion at 25°C)** *Initial* | *After storage for 14 days at 54°C* 3.96 | 3.78 **Wettability (complete wetting)** *Initial* | *After storage for 14 days at 54°C* 2 seconds | 1 seconds **Persistent foaming (at ambient)** *Initial* | *After storage for 14 days at 54°C*		

section (Annex point)	study	method	results	comment	reference
		CIPAC	After 1 min.: 8.2 mL / After 1 min.: 6.9 mL **Suspensibility** *Initial* / *After storage for 14 days at 54°C* (max 2.0 g/L) 97% (min0.3 g/L) 98% / (max) 97% (min) 98% **Spontaneity of dispersion** *Initial* / *After storage for 14 days at 54°C* 99% / 98% **Wet sieve (retained on a 75 µm sieve)** *Initial* / *After storage for 14 days at 54°C* <0.01% / <0.01% **Nominal size range** *Initial* / *After storage for 14 days at 54°C* Pan receiver: 0.236% 75 µm sieve: / Pan receiver: 0.266% 75 µm sieve:		

<table>
<tr><th>section (Annex point)</th><th>study</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr>
<td></td>
<td></td>
<td>Methods MT 39, MT 48, MT 51 or MT 54

CIPAC 452/WG/M/3</td>
<td>
<table>
<tr><td>0.086%</td><td>0.128%</td></tr>
<tr><td colspan="2">Dust content</td></tr>
<tr><td>Initial</td><td>After storage for 14 days at 54°C</td></tr>
<tr><td>10.1 mg</td><td>6.3 mg</td></tr>
<tr><td colspan="2">Friability and attrition</td></tr>
<tr><td>Initial</td><td>After storage for 14 days at 54°C</td></tr>
<tr><td>97.3%</td><td>97.8%</td></tr>
</table>

<u>24 months storage at 25°C</u>

<table>
<tr><td colspan="2">Active substance content</td></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td colspan="2">(Thifensulfuron-methyl)</td></tr>
<tr><td>66.9% w/w</td><td>66.7% w/w</td></tr>
<tr><td colspan="2">(Metsulfuron-methyl)</td></tr>
<tr><td>6.18% w/w</td><td>6.76% w/w</td></tr>
<tr><td colspan="2">Free acidity / alkalinity</td></tr>
<tr><td><u>Initial</u></td><td>After 24 months at 25°C</td></tr>
<tr><td>9.83% w/w as sulphuric acid</td><td>9.74% w/w as sulphuric acid</td></tr>
<tr><td colspan="2">pH (1% dispersion at 25°C)</td></tr>
</table>
</td>
<td>Initially categorised as “essentially non dusty” and then as “nearly dust-free” following storage.

The increase in the metsulfuron-methyl content is discussed further in section B.2.3.2</td>
<td>White, D. F., Wooley, S. M., 2008 (104 TIM)</td>
</tr>
</table>

section (Annex point)	study	method	results	comment	reference
			Initial | *After 24 months at 25°C* 3.96 | 3.95 **Wettability (complete wetting)** *Initial* | *After 24 months at 25°C* 2 seconds | <1 second **Persistent foaming (at ambient)** *Initial* | *After 24 months at 25°C* After 1 min.: 8.2 mL (0.375 g/L) | After 1 min.: 7.0 mL **Suspensibility** *Initial* | *After 24 months at 25°C* (max) 97% (min) 98% | (max) 98% (min) 98% **Spontaneity of dispersion** *Initial* | *After 24 months at 25°C* 99% | 97% **Wet sieve (retained on a 75 µm sieve)** *Initial* | *After 24 months at 25°C* <0.01% | <0.01% **Nominal size range**		

<table>
<tr><th>section (Annex point)</th><th>study</th><th>method</th><th>results</th><th>comment</th><th>reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td>Pan receiver: 0.236%
75 µm sieve: 0.086%</td><td>Pan receiver: 0.161%
75 µm sieve: 0.096%</td></tr>
<tr><td colspan="2">Dust content</td></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td>10.1 mg</td><td>9.3 mg</td></tr>
<tr><td colspan="2">Friability and attrition</td></tr>
<tr><td>Initial</td><td>After 24 months at 25°C</td></tr>
<tr><td>97.3%</td><td>97.3%</td></tr>
</table>

No signs of corrosion or deterioration of the HDPE packaging were observed.

The appearance, odour, pH, dust content, wettability, wet sieve test, particle size distribution, degree of dispersion, suspensibility, friability and attrition characteristics and persistent foam of the test material remained stable throughout the storage period.</td><td></td><td></td></tr>
</table>

section (Annex point)	study	method	results	comment	reference
B.2.2.15 (IIIA 2.7)	Shelf life		The product is considered to be stable for at least 2 years in the commercial packaging based on available testing data.		
B.2.2.16 (IIIA 2.8)	Wettability	CIPAC MT 53.3.1	Time taken for complete wetting of the sample: 2 seconds		White, D. F., Mullee, D. M., 2006a (20 TIM)
B.2.2.17 (IIIA 2.8)	Persistent foaming	CIPAC MT 47.2	Tests conducted at 0.375 g formulation / L After 10 sec.: 10.5 mL After 1 min.: 8.2 mL After 3 min.: 6.6 mL After 12 min.: 6.2 mL	GLP The concentration used in the study does not cover the maximum in use rate concentration (0.51 g/mL). However, the concentrations are close and it is not anticipated that if the study were repeated at the increased rate, that the foam produced would exceed the limit (60ml).	Kusk, T., 2007 (67 TIM)

section (Annex point)	study	method	results	comment	reference
B.2.2.18 (IIIA 2.8)	Suspensibility	CIPAC Method MT 184 CIPAC 452/WG/M/3	Max. Concentration (2.0 g/L) 97% Min.concentration (0.3 g/L) 98%	GLP It is noted that the proposed minimum and maximum application concentrations are 0.10 g/L and 0.51 g/L. The data submitted by the Notifier was generated using a minimum of 0.3 g/L which does not include the minimum proposed concentration. However, the initial data generated for the accelerated storage stability study was conducted using a minimum concentration of 0.037 g/L and yielded a suspensibility result of 102%. Based on this data the active suspensibility for the formulation can be considered to be acceptable.	Kusk, T., 2007 (67 TIM)
B.2.2.19 (IIIA 2.8)	Suspension stability	CIPAC MT 174	99%	GLP	Kusk, T., 2007 (67 TIM)
B.2.2.20 (IIIA 2.8)	Dilution stability		Not relevant as the formulation is not a water soluble preparation		
B.2.2.21 (IIIA 2.8)	Dry sieve test		Not relevant as the formulation is applied in water		

section (Annex point)	study	method	results	comment	reference
B.2.2.22 (IIIA 2.8)	Wet sieve test	CIPAC MT 167	<0.01%	GLP	White, D. F., Mullee, D. M., 2006a (20 TIM)
B.2.2.23 (IIIA 2.8)	Particle size distribution	MT 170	Pan receiver: 0.236% 75 µm sieve: 0.086% 125 µm sieve: 0.075% 250 µm sieve: 0.043% 500 µm sieve: 33.1% 1000 µm sieve: 66.5% 2000 µm sieve: 0.011% 3350 µm sieve: 0%	GLP	White, D. F., Mullee, D. M., 2006a (20 TIM)
B.2.2.24 (IIIA 2.8)	Content of dust/fines	CIPAC Method MT 171	Data from initial mass taken of approximately 30g Dust content: 10.1 mg The formulation can be described as nearly dust-free	GLP	White, D. F., Mullee, D. M., 2006a (20 TIM)
B.2.2.25 (IIIA 2.8)	Attrition and friability	CIPAC Method MT 178.2	Attrition resistance 97.3%	GLP	White, D. F., Mullee, D. M., 2006a (20 TIM)

section (Annex point)	study	method	results	comment	reference
B.2.2.26 (IIIA 2.8)	Emulsifiabilty, re-emulsifiabilty and emulsion stability		Not relevant as the formulation is a granular solid		
B.2.2.27 (IIIA 2.8)	Stability of dilute emulsion		Not relevant as the formulation is a granular solid		
B.2.2.28 (IIIA 2.8)	Flowability	CIPAC Method MT 172	The preparation passed through a 4.75 mm aperture sieve spontaneously after storage at elevated conditions of temperature and pressure.	GLP	White, D. F., Mullee, D. M., 2006b (7 TIM)
B.2.2.29 (IIIA 2.8)	Pourability (rinsibility)		Pourability is not relevant as the formulation is a granular solid		
B.2.2.30 (IIIA 2.8)	Dustability		Not relevant as the formulation is a granular solid		
B.2.2.31 (IIIA 2.8)	Adherence and distribution to seeds		Not relevant as the formulation is not used as a seed treatment		

B.2.2.32 Summary of physical and chemical compatibility with other products (IIIA 2.9)

DuPont
The Notifier has made the following statement:

"Thifensulfuron-methyl 50SG may be recommended in a tank mix with certain registered plant protection products in certain countries and/or for certain uses. Thifensulfuron-methyl 50SG was tested with various potential tank mix partners for additional weed and pest control."

Task Force
No tank mixes are recommended for the Rotam or Cheminova A/S formulations.

B.2.3 Summary of physical and chemical properties

B.2.3.1 Active substance

DuPont

Thifensulfuron-methyl is a selective herbicide with a minimum purity of 97.9%, which can be formulated as a water-soluble granule. It has no adverse physical and chemical properties. It is off-white, odourless, lumpy powder that melts at 171°C and decomposes above 176°C. Its vapour pressure is low (5.19×10^{-9} Pa at 20°C) and therefore it is essentially non-volatile. The water solubility of Thifensulfuron-methyl is pH dependent; solubility increases with increasing pH. Solubility of Thifensulfuron-methyl in organic solvents increases with increasing solvent polarity. The octanol/water partition coefficient is pH-dependent, ranging from 1.06 at pH 5 to 0.008 at pH 9. The K_{ow} values indicate that Thifensulfuron-methyl will not accumulate in the environment. Hydrolysis is pH-dependent and is faster in acidic and alkaline media than in neutral media (DT_{50} are 6, 199, and 23 days at pH 4, 7 and 9, respectively). Direct photolysis of Thifensulfuron-methyl is a significant route of degradation. The photolysis DT_{50} in natural water and pH 7 buffer is 0.5 days. Thifensulfuron-methyl does not exhibit oxidizing, explosive, or flammability properties.

Task Force (Rotam and Cheminova A/S)

Thifensulfuron-methyl is a white solid with a relative density of 1.46 and a melting point of 171°C (purity 99.7%). It has a high water solubility (>2 g/L at pH 7 and 25°C) and a low vapour pressure (4.8×10^{-8} Pa at 25°C) and has no characteristic odour. Thifensulfuron-methyl is non volatile (Henry's law constant 1.3×10^{-12} Pa m^3 mol^{-1} and is non lipophilic as characterised by its octanol-water partition coefficient (Log Pow = -1.65 at pH 7). Thifensulfuron-methyl is hydrolytically stable under neutral conditions but hydrolyses under alkaline and acidic conditions (DT_{50} = <8 days). Thifensulfuron-methyl technical material is not flammable, self-igniting or explosive and does not have any oxidising properties.

B.2.3.2 Plant protection product

Thifensulfuron-methyl 50SG - DuPont

Thifensulfuron-methyl 50SG is a water-soluble granule (SG) containing 500 g a.s./kg. It is non-flammable, non-explosive and not an oxidiser. The pH of a 1% concentration of the preparation in water was consistently measured at 9.2 pH units. Based on the results from the accelerated storage data (54°C, 2 weeks) and the results from the 2 year storage stability test, it can be concluded that Thifensulfuron-methyl 50SG will be stable under normal storage conditions for a minimum of 2 years.

Additionally, Thifensulfuron-methyl 50SG plus surfactant (DPX-M6316-296 and DPX-KG691-021) was stored in a water-soluble bag at a temperature of 54°C for a period of 2 weeks. All physical and chemical properties specifications, as defined by "The Manual on the Development and Use of FAO Specifications for Plant Protection Products," were met both prior to and after completion of accelerated storage. Based on accelerated storage data, it can reasonably be assumed that Thifensulfuron methyl 50SG plus surfactant will be stable. However, this will need to be confirmed by conducting an ambient temperature storage stability study for the formulation in the water-soluble packaging, under standard conditions for a period of two years.

Thifensulfuron-methyl + Metsulfuron-methyl, 682 + 68 g/kg - Rotam

Thifensulfuron-methyl + Metsulfuron-methyl, 682 + 68 g/kg WG (FH-009) is an off-white granular solid with no characteristic odour. It is not flammable and has no explosive or oxidising properties. The technical properties demonstrate the product to be a nearly dust-free, free flowing solid that produces a homogeneous dispersion that does not foam when added to water. The formulated product and its commercial container materials have also been shown to be stable under both accelerated storage conditions for14 days at 54°C and at ambient shelf-life conditions for a minimum of 2 years. Its technical properties are such that no problems are expected when the product is used according to label recommendations under normal field conditions.

Thifensulfuron-methyl + Metsulfuron-methyl, 680 + 70 g/kg - Cheminova A/S

Thifensulfuron-methyl + Metsulfuron-methyl, 680 + 70 g/kg WG (CHA 8730) is a beige, opaque granular solid with a moderate creosote like odour. It is not flammable and has no explosive or oxidising properties. The technical properties demonstrate the product to be a nearly dust-free, free flowing solid that produces a homogeneous dispersion that does not foam when added to water. The formulated product and its commercial container materials have also been shown to be stable under both accelerated storage conditions for14 days at 54°C and at ambient shelf-life conditions for 2 years. Its technical properties are such that no problems are expected when the product is used according to label recommendations under normal field conditions.

Following 2 years storage the content of the second active substance, metsulfuron-methyl, was noted to increase from 6.18 % w/w to 6.76 % w/w (an increase of 9.4%). In the CHA Doc. No. 104 TIM (page 18), the Notifier states:

"For the metsulfuron-methyl component, the active ingredient content at the 12 and 14 month time point was greater than that analysed initially. It is probable that the initial value was low. No significant differences in concentration were observed between the 12 month and 24 month analysis which indicated that no degradation of the sample was observed throughout the storage period."

For the accelerated storage stability study the same batch was tested and the same initial value for the metsulfuron-methyl content (6.18 %w/w) was given, the analysis following the 2 weeks accelerated storage at 54 ^{o}C yielded a content of 6.01 %w/w (a difference of 2.75%, which is within the permitted 5% limit). If as the study author indicates that the initial value was low, then the difference in the pre and post storage values could exceed the 5% limit, indicating degradation of the metsulfuron-methyl component and necessitating further studies to identify the degradation products.

It should also be noted that this initial metsulfuron-methyl value lies outside of the tolerance limits (i.e. for the specified 70 g/kg metsulfuron-methyl content, concentrations within the 63 – 77 g/kg range are supported, however the initial metsulfuron-methyl content lies outside of this range at 61.8 g/kg). The Notifier will be required to clarify this issue.

Data Gaps

DuPont

Notifier to provide an ambient temperature storage stability study for the formulation in the water-soluble packaging, under standard conditions for a period of two years.

Rotam

~~1. Suspensibility study – it is noted that in the GAP the proposed minimum and maximum application concentrations are 0.10 g/L and 0.51 g/L. The data submitted by the Notifier for suspensibility were generated using a maximum of 0.3 g/L which does not include the minimum proposed concentration. Data will be required to demonstrate the suspensibility of the formulation at the maximum and minimum concentration levels proposed in the GAP.~~

1. The nominal size range should be reported for the formulation following the 2 year ambient temperature storage stability study; the applicant will be required to provide these data.

~~2. Can the Notifier please confirm the packaging type used in the 2 year ambient temperature storage stability study.~~

Cheminova A/S

For Thifensulfuron-methyl + Metsulfuron-methyl, 680 + 70 g/kg WG it is noted that the metsulfuron-methyl content potentially decreases by >5% (as the study report implies that the initial value was lower than analysed) - the applicant will be requested to clarify this issue and if the active decreases by >5%, then the degradation products must be identified. Additionally, it was noted that the initial content for metsulfuron-methyl lies outside of the tolerance limits – the Notifier is requested to comment on this issue. Member

states are advised to consider these issues further when considering issuing product authorisations.

Task Force (active related)

1. Notifiers to confirm that the surface tension reported in Denny (2006) Report R A6097 18, was conducted using a 1 % dilution.
2. It should be noted that EEC method A15 is only applicable for the determination of the auto flammability for liquid formulations, as the active substance is a solid (WG), data generated using this method cannot be considered supportive – data for the auto flammability generated using an appropriate method is requested.
3. The determination that the formulation decomposes at 162°C contradicts the original DAR reported value of 171.1°C. Please provide further clarification of the melting point and decomposition temperatures for the active substance.

B.2.4 References relied on

Only new studies relied on for the renewal of Thifensulfuron-methyl are included below. For references referring to studies in the DAR, see the reference list in original DAR.

DuPont active substance data studies

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIA, 2.2/01	Greenwood, J.	2002	Thifensulfuron-methyl pure active ingredient (DPX-M6316): Determination of the density Covance Laboratories (UK) DuPont-6580 GLP: Yes Published: No **DuPont Report No. 6316/PC 31 does not meet current guidelines so new study completed according to current guidelines.**	Y	DuPont
IIA, 2.3.1/01	Ganesh, M.U.	2012	DPX-M6316: Laboratory study of vapour pressure International Institute of Biotechnology and Toxicology (IIBAT) DuPont-31258 GLP: Yes Published: No **Original study 6316/PC-23-CA does not meet current guidelines, so new study completed according to current guidelines.**	Y	DuPont
IIA, 2.3.2/01	Tessier, D.M.	2012	Henry's law constant for	Y	DuPont

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
			Thifensulfuron-methyl DuPont Stine-Haskell Research Center DuPont-34492 GLP: No Published: No **New calculation based on updated vapour pressure values determined in DuPont-31258.**		
IIA, 2.4.1/01	Greenwood, J.	2002	Thifensulfuron-methyl (DPX-M6316) pure active ingredient and technical: Determination of the appearance (colour, physical state and odour) Covance Laboratories (UK) DuPont-6581 GLP: Yes Published: No **DuPont Report No. 6316/PC 31 does not meet current guidelines, so new study completed according to current guidelines.**	Y	DuPont
IIA, 2.4.2/01	Greenwood, J.	2002	Thifensulfuron-methyl (DPX-M6316) pure active ingredient and technical: Determination of the appearance (colour, physical state and odour) Covance Laboratories (UK) DuPont-6581 GLP: Yes Published: No **DuPont Report No. 6316/PC 31 does not meet current guidelines, so new study completed according to current guidelines.**	Y	DuPont
IIA, 2.5.1.1/01	Schmuckler, M.E.	2000	Nuclear magnetic resonance (NMR), mass spectrum (MS), infrared (IR) and ultraviolet/visible (UV) spectra of Thifensulfuron-methyl DuPont Experimental Station DuPont-3537 GLP: Yes Published: No **DuPont Report No. 6316/PC 16 does not meet current guidelines, so new study completed according to current guidelines.**	Y	DuPont
IIA, 2.5.1.2/01	Schmuckler, M.E.	2000	Nuclear magnetic resonance (NMR), mass spectrum (MS),	Y	DuPont

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
			infrared (IR) and ultraviolet/visible (UV) spectra of Thifensulfuron-methyl DuPont Experimental Station DuPont-3537 GLP: Yes Published: No **DuPont Report No. 6316/PC 16 does not meet current guidelines, so new study completed according to current guidelines.**		
IIA, 2.5.1.3/01	Schmuckler, M.E.	2000	Nuclear magnetic resonance (NMR), mass spectrum (MS), infrared (IR) and ultraviolet/visible (UV) spectra of Thifensulfuron-methyl DuPont Experimental Station DuPont-3537 GLP: Yes Published: No **DuPont Report No. 6316/PC 16 does not meet current guidelines, so new study completed according to current guidelines.**	Y	DuPont
IIA, 2.5.1.3/02	Schmuckler, M.E.	2001	Thifensulfuron-methyl (DPX-M6316): ^{13}C-NMR spectrum DuPont Stine-Haskell Research Center DuPont-4261 GLP: No Published: No **DuPont Report No. 6316/PC 16 does not meet current guidelines, so new study completed according to current guidelines.**	Y	DuPont
IIA, 2.5.1.4/01	Schmuckler, M.E.	2000	Nuclear magnetic resonance (NMR), mass spectrum (MS), infrared (IR) and ultraviolet/visible (UV) spectra of Thifensulfuron-methyl DuPont Experimental Station DuPont-3537 GLP: Yes Published: No **DuPont Report No. 6316/PC 16 does not meet current guidelines, so new study completed according to current guidelines.**	Y	DuPont
IIA, 2.5.1.5/01	Schmuckler, M.E.	2000	Nuclear magnetic resonance (NMR), mass spectrum (MS),	Y	DuPont

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
			infrared (IR) and ultraviolet/visible (UV) spectra of Thifensulfuron-methyl DuPont Experimental Station DuPont-3537 GLP: Yes Published: No **DuPont Report No. 6316/PC 16 does not meet current guidelines, so new study completed according to current guidelines**		
IIA, 2.6/01	Greenwood, J.	2002	Thifensulfuron-methyl pure active ingredient (DPX-M6316): Determination of water solubility (un-buffered distilled water) Covance Laboratories (UK) DuPont-6579 GLP: Yes Published: No **Study submitted to provide additional information on water solublity in un-buffered water.**	Y	DuPont
IIA, 2.7/01	Greenwood, J.	2002	Thifensulfuron-methyl technical (DPX-M6316): Determination of the organic solvent solubility Covance Laboratories (UK) DuPont-6582 GLP: Yes Published: No **DuPont Report No. 6316/PC 31 does not meet current guidelines, so new study completed according to current guidelines**	Y	DuPont
IIA, 2.9.1/01	Wardrope, L.	2011	Hydrolysis of [^{14}C]-DPX-M6316 (Thifensulfuron-methyl) as a function of pH Charles River DuPont-30225 GLP: Yes Published: No **DuPont Report No. AMR 224-84, Revision No. 1 does not meet current guidelines, so new study completed according to current guidelines.**	Y	DuPont
IIA, 2.9.2/01	Lentz, N.	2001	Photodegradation of Thifensulfuron-methyl in natural water by simulated sunlight Ricerca, LLC DuPont-6047	Y	DuPont

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
			GLP: Yes Published: No **DuPont Report No. AMR 511-86 does not meet current guidelines, so new study completed according to current guidelines..**		
IIA, 2.9.3/01	Lentz, N.Y	2001	Photodegradation of Thifensulfuron-methyl in natural water by simulated sunlight Ricerca, LLC DuPont-6047 GLP: Yes Published: No **DuPont Report No. AMR 511-86 does not meet current guidelines, so new study completed according to current guidelines.**	Y	DuPont
IIA 2.9.4/01	Tessier, D.M.	2012	Calculated theoretical half-life of DPX-M6316 (Thifensulfuron-methyl) in the top layer of aqueous systems DuPont Stine-Haskell Research Center GLP: No Published: No DuPont-34893 **Study submitted to satisfy new data point (not required in 1995 dossier).**	Y	DuPont
IIA, 2.14/01	Huntley, K.	2000	Determination of the surface tension of Thifensulfuron-methyl (DPX-M6316) ABC Laboratories, Inc. (Missouri) DuPont-3577 GLP: No Published: No **Study available according to current guidelines.**	Y	DuPont
IIA, 2.15/01	Radhakrishnan, D.	2011	DPX-M6316: Laboratory study of oxidizing properties International Institute of Biotechnology and Toxicology (IIBAT) DuPont-30783 GLP: Yes Published: No **AMR 3100-94 originally submitted was a structural argument only. A new study**	Y	DuPont

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
			(DuPont-30783), which is the experimental determination of the oxidising properties of Thifensulfuron-methyl was completed.		

Task Force (Rotam and Cheminova A/S) active substance data studies

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIA, 2.1.2/01	Comb, T.	2012	Thifensulfuron-methyl (PAI) Physico-Chemical Properties Huntingdon Life Sciences Ltd EU TSM AIR 2 Task Force Report No. DGV0083 GLP, Unpublished **Data gap identified from first EU evaluation**	Y	EU TSM AIR 2 Task Force
IIA, 2.1.3/01	Comb, T.	2012	Thifensulfuron-methyl (PAI) Physico-Chemical Properties Huntingdon Life Sciences Ltd EU TSM AIR 2 Task Force Report No. DGV0083 GLP, Unpublished **Data gap identified from first EU evaluation** ⇒ IIA, 2.1.2/01	Y	EU TSM AIR 2 Task Force
IIA, 2.2/01	Comb, T.	2012	Thifensulfuron-methyl (PAI) Physico-Chemical Properties Huntingdon Life Sciences Ltd EU TSM AIR 2 Task Force Report No. DGV0083 GLP, Unpublished **Previous study not conducted with PAI** ⇒ IIA, 2.1.2/01	Y	EU TSM AIR 2 Task Force
IIA, 2.3.1/01	Comb, T.	2012	Thifensulfuron-methyl (PAI) Physico-Chemical Properties Huntingdon Life Sciences Ltd EU TSM AIR 2 Task Force Report No. DGV0083 GLP, Unpublished **Previous study not GLP** ⇒ IIA, 2.1.2/01	Y	EU TSM AIR 2 Task Force

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIA, 2.4.1/01	Comb, T.	2012	Thifensulfuron-methyl (PAI) Physico-Chemical Properties Huntingdon Life Sciences Ltd EU TSM AIR 2 Task Force Report No. DGV0083 GLP, Unpublished **Data gap identified from first EU evaluation** ⇒ IIA, 2.1.2/01	Y	EU TSM AIR 2 Task Force
IIA, 2.4.1/02	Denny, O.	2006a	Determination of Physical and Chemical Properties of THIFENSULFURON METHYL TECHNICAL – Appearance Anadiag S.A. Rotam Agrochem International Co. Ltd. Report No. R A6097 05 GLP, Unpublished **Previous study not conducted with TGAI**	Y*	ROT
IIA, 2.4.1/03	Pedersen, S.N.	2006	Determination of the storage stability for 14 days at 54°C of Thifensulfuron-methyl technical, Batch No. 844-NO-95 in commercial packaging Cheminova A/S Report No. 006 TIM GLP, Unpublished **Previous study not conducted with TGAI**	Y	CHE
IIA, 2.4.2/01	Denny, O.	2006a	Determination of Physical and Chemical Properties of THIFENSULFURON METHYL TECHNICAL – Appearance Anadiag S.A. Rotam Agrochem International Co. Ltd. Report No. R A6097 05 GLP, Unpublished **Previous study not conducted with TGAI** ⇒ IIA, 2.4.1/02	Y*	ROT
IIA, 2.4.2/02	Pedersen, S.N.	2006	Determination of the storage stability for 14 days at 54°C of Thifensulfuron-methyl technical, Batch No. 844-NO-95 in commercial packaging Cheminova A/S Report No. 006 TIM GLP, Unpublished **Previous study not conducted with TGAI** ⇒ IIA, 2.4.1/03	Y	CHE

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIA, 2.5.1/01	Comb, T.	2012	Thifensulfuron-methyl (PAI) Physico-Chemical Properties Huntingdon Life Sciences Ltd EU TSM AIR 2 Task Force Report No. DGV0083 GLP, Unpublished **Data gap identified from first EU evaluation** ⇒ IIA, 2.1.2/01	Y	EU TSM AIR 2 Task Force
IIA, 2.7/01	Denny, O.	2006b	Determination of Physical and Chemical Properties of THIFENSULFURON METHYL TECHNICAL – Solubility in organic solvents Anadiag S.A. Rotam Agrochem International Co. Ltd. Report No. R A6097 08 GLP, Unpublished **Previous study not conducted with TGAI**	Y*	ROT
IIA, 2.7/02	Dardemann, D.J	2009	Determination of the Solubility of Thifensulfuron-Methyl in different organic Solvents Stähler International GmbH & Co. KG Cheminova A/S Report No. 130 TIM GLP, Unpublished **Previous study not conducted with TGAI**	Y	CHE
IIA, 2.9.1/01	Simmonds, M. & Buntain, I	2012	[^{14}C]-Thifensulfuron-methyl: Hydrolysis in sterile buffer at pH 4, 7 and 9 Battelle UK Ltd. Cheminova A/S, Report No. 260 TIM GLP, Unpublished **To support Efate data requirements** ⇒ IIA, 7.5/01	Y	EU TSM AIR 2 Task Force
IIA, 2.9.2/01	Oddy, A.	2012	[^{14}C]-Thifensulfuron-methyl: Aqueous Photolysis and Quantum Yield Determination in Sterile Buffer Solution Battelle UK Ltd. Cheminova A/S, Report No. 284 TIM GLP, Unpublished **To support Efate data requirements** ⇒ IIA, 7.6/01	Y	EU TSM AIR 2 Task Force

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIA, 2.9.3/01	Oddy, A.	2012	[^{14}C]-Thifensulfuron-methyl: Aqueous Photolysis and Quantum Yield Determination in Sterile Buffer Solution Battelle UK Ltd. Cheminova A/S, Report No. 284 TIM GLP, Unpublished **To support Efate data requirements** ⇒ IIA, 7.6/01	Y	EU TSM AIR 2 Task Force
IIA, 2.11.1/01	Denny, O.	2006c	Determination of Physical and Chemical Properties of THIFENSULFURON METHYL TECHNICAL – Flammability Anadiag S.A. Rotam Agrochem International Co. Ltd. Report No. R A6097 15 GLP, Unpublished **Previous study not conducted with TGAI**	Y	EU TSM AIR 2 Task Force
IIA, 2.11.2/01	Denny, O.	2006d	Determination of Physical and Chemical Properties of THIFENSULFURON METHYL TECHNICAL – Autoflammability Anadiag S.A. Rotam Agrochem International Co. Ltd. Report No. R A6097 16 GLP, Unpublished **Previous study not conducted with TGAI**	Y	EU TSM AIR 2 Task Force
IIA, 2.13/01	Denny, O.	2006e	Determination of Physical and Chemical Properties of THIFENSULFURON METHYL TECHNICAL – Explosive properties Anadiag S.A. Rotam Agrochem International Co. Ltd. Report No. R A6097 17 GLP, Unpublished **Previous study not conducted with TGAI**	Y	EU TSM AIR 2 Task Force
IIA, 2.14/01	Denny, O.	2006f	Determination of Physical and Chemical Properties of THIFENSULFURON METHYL TECHNICAL – Surface tension Anadiag S.A. Rotam Agrochem International Co. Ltd. Report No. R A6097 18 GLP, Unpublished **Data gap identified from first EU evaluation**	Y	EU TSM AIR 2 Task Force

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIA, 2.15/01	Denny, O.	2006g	Determination of Physical and Chemical Properties of THIFENSULFURON METHYL TECHNICAL – Oxidising properties Anadiag S.A. Rotam Agrochem International Co. Ltd. Report No. R A6097 19 GLP, Unpublished **Previous study not conducted with TGAI**	Y	EU TSM AIR 2 Task Force

*Annex II study submitted in some Member States in support of national authorisations. However, study not previously submitted to support Annex I listing therefore data protection claimed.

Plant Protection Product - Thifensulfuron-methyl 50SG (DuPont)

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.1/01	Bloemer, D.S.	2003	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.2.1/01	Macdonald, E., Craig, W.B.	2003	Thifensulfuron-methyl 50SG soluble granules herbicide formulation: Laboratory study of explosive ane oxidizing properties, flammability of solids and relative self-ignition Inveresk Research DuPont-11738 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.2.2/01	Macdonald, E., Craig, W.B.	2003	Thifensulfuron-methyl 50SG soluble granules herbicide formulation: Laboratory study of explosive ane oxidizing properties, flammability of solids and relative self-ignition Inveresk Research DuPont-11738 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.1/02	Saravanan, V.	2013	Thifensulfuron methyl 50SG water soluble granule formulation (DPX-M6316): Laboratory study of physical and chemical properties in water soluble bag with 0.1% w/v Trend 90 spray tank adjuvant Advinus Therapeutics Limited DuPont-36400 GLP: Yes Published: No	Y	DuPont
IIIA, 2.3.2/01	Macdonald, E., Craig, W.B.	2003	Thifensulfuron-methyl 50SG soluble granules herbicide formulation: Laboratory study of	Y	DuPont

			explosive ane oxidizing properties, flammability of solids and relative self-ignition Inveresk Research DuPont-11738 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**		

Annex point	**Author**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Y/N**	**Owner**
IIIA, 2.3.3/01	Macdonald, E., Craig, W.B.	2003	Thifensulfuron-methyl 50SG soluble granules herbicide formulation: Laboratory study of explosive ane oxidizing properties, flammability of solids and relative self-ignition Inveresk Research DuPont-11738 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.4.2/01	Bloemer, D.S.	2003	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.1/02	Saravanan, V	2013	Thifensulfuron methyl 50SG water soluble granule formulation (DPX-M6316): Laboratory study of physical and chemical properties in water soluble bag with 0.1% w/v Trend 90 spray tank adjuvant Advinus Therapeutics Limited DuPont-36400 GLP: Yes Published: No	Y	DuPont

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.6.2/01	Bloemer, D.S.	2003	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.7.1/01	Bloemer, D.S.	2003	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.7.1/02	Saravanan, V.	2013	Thifensulfuron methyl 50SG water soluble granule formulation (DPX-M6316): Laboratory study of physical and chemical properties in water soluble bag with 0.1% w/v Trend 90 spray tank adjuvant Advinus Therapeutics Limited DuPont-36400 GLP: Yes Published: No	Y	DuPont
IIIA, 2.7.3/01	Bloemer, D.S.	2003	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.7.3/02	Saravanan, V.	2013	Thifensulfuron methyl 50SG water soluble granule formulation (DPX M6316): Laboratory study of physical and chemical properties in water soluble bag with 0.1% w/v Trend 90 spray tank adjuvant Advinus Therapeutics Limited DuPont-36400 GLP: Yes Published: No	Y	DuPont
IIIA, 2.7.5/01	Bloemer, D.S.	2005	Thifensulfuron-methyl 50SG water-soluble granular herbicide formulation: Laboratory study of shelf life stability DuPont Stine-Haskell Research Center DuPont-11987 GLP: No Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.8.1/01	Bloemer, D.S.	2003	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.8.2/01	Bloemer, D.S.	2003	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.8.2/02	Robson, D.D.	2012	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986, Supplement No. 1 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.8.2/03	Saravanan, V.	2013	Thifensulfuron methyl 50SG water soluble granule formulation (DPX M6316): Laboratory study of physical and chemical properties in water soluble bag with 0.1% w/v Trend 90 spray tank adjuvant Advinus Therapeutics Limited DuPont-36400 GLP: Yes Published: No	Y	DuPont
IIIA, 2.8.4/01	Bloemer, D.S.	2003	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.8.4/02	Saravanan, V.	2013	Thifensulfuron methyl 50SG water soluble granule formulation (DPX M6316): Laboratory study of physical and chemical properties in water soluble bag with 0.1% w/v Trend 90 spray tank adjuvant Advinus Therapeutics Limited DuPont-36400 GLP: Yes Published: No	Y	DuPont

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.8.5.2/01	Bloemer, D.S.	2003	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.8.6.2/01	Bloemer, D.S.	2003	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.8.6.3/01	Bloemer, D.S.	2003	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA, 2.8.6.5/01	Bloemer, D.S.	2003	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.8.8.1/01	Bloemer, D.S.	2003	Thifensulfuron-methyl 50SG water soluble granular herbicide: Laboratory study of physical and chemical properties DuPont Stine-Haskell Research Center DuPont-11986 GLP: Yes Published: No **50SG formulation not reviewed by the EU.**	Y	DuPont
IIIA 2.15/01	Saravanan, V.	2013	Thifensulfuron methyl 50SG water soluble granule formulation (DPX M6316): Laboratory study of physical and chemical properties in water soluble bag with 0.1% w/v Trend 90 spray tank adjuvant Advinus Therapeutics Limited DuPont-36400 GLP: Yes Published: No	Y	DuPont

Plant Protection Product - Thifensulfuron-methyl + Metsulfuron-methyl, 680 + 70 g/kg – (680 g/kg Water dispersible granule)
(Cheminova A/S)

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.1/01	White, D.F., Mullee, D.M.	2006a	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of Accelerated Storage Stability (CIPAC MT 46.3) and Physico-Chemical Characteristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 20 TIM GLP, Unpublished **Study required to support Section 1 data**	Y*	CHE
IIIA, 2.1/02	White, D. F., Wooley, S. M.	2008	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of long term storage stability and physico-chemical characterristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 104 TIM GLP, Unpublished **Study required to support Section 1 data**	Y	CHE
IIIA, 2.2.1/01	Høgh, E.	2007a	Expert statement on the explosive properties of Thifensulfuron-methyl 680 g/kg + Metsulfuron-methyl 70 g/kg WG Cheminova A/S Cheminova A/S Report No.: 68 TIM GLP, Unpublished **Study required to support Section 1 data**	Y*	CHE
IIIA, 2.2.2/01	Høgh, E.	2007b	Expert statement on the oxidizing properties of Thifensulfuron-methyl 680 g/kg + Metsulfuron-methyl 70 g/kg WG Cheminova A/S Cheminova A/S Report No.: 69 TIM GLP, Unpublished **Study required to support Section 1 data**	Y*	CHE
IIIA, 2.3.2/01	Comb, A.L.	2006	Thifensulfuron-methyl 680 g/kg + Metsulfuron-methyl 70 g/kg WG : Flammability (Solids) and Relative Self-ignition Temperature for Solids Huntingdon Life Sciences Ltd.	Y*	CHE

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
			Cheminova A/S Study No.: CHV/0145 Cheminova A/S Report No.: 8 TIM GLP, Unpublished **Study required to support Section 1 data**		
IIIA, 2.3.3/01	Comb, A.L.	2006	Thifensulfuron-methyl 680 g/kg + Metsulfuron-methyl 70 g/kg WG : Flammability (Solids) and Relative Self-ignition Temperature for Solids Huntingdon Life Sciences Ltd. Cheminova A/S Study No.: CHV/0145 Cheminova A/S Report No.: 8 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.3.2/01	Y*	CHE
IIIA, 2.4.1/01	White, D. F., Mullee, D. M.	2006a	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of Accelerated Storage Stability (CIPAC MT 46.3) and Physico-Chemical Characteristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 20 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/01	Y*	CHE
IIIA, 2.4.1/02	White, D. F., Wooley, S. M.	2008	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of long term storage stability and physico-chemical characterristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 104 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/02	Y	CHE
IIIA, 2.4.2/01	White, D.F., Mullee, D.M.	2006a	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of Accelerated Storage Stability (CIPAC MT 46.3) and Physico-Chemical Characteristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 20	Y*	CHE

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
			TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/01		
IIIA, 2.4.2/02	White, D. F., Wooley, S. M.	2008	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of long term storage stability and physico-chemical characterristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 104 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/02	Y*	CHE
IIIA, 2.6.2/01	White, D. F., Mullee, D. M.	2006b	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of Flowability (CIPAC MT172) and Bulk Density (CIPAC MT169) Safepharm Laboratories Ltd Cheminova A/S Study No.: 0545/522 Cheminova A/S Report No.: 7 TIM GLP, Unpublished **Study required to support Section 1 data**	Y*	CHE
IIIA, 2.7.1/01	White, D.F., Mullee, D.M.	2006a	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of Accelerated Storage Stability (CIPAC MT 46.3) and Physico-Chemical Characteristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 20 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/01	Y*	CHE
IIIA, 2.7.1/02	Kusk, T.	2007	Determination of storage Stability for 14 days at 54°C of Thifensulfuron-methyl 68% w/w + Metsulfuron-methyl 7% w/w WG Formulation in commercial Packaging Cheminova A/S Cheminova A/S Report No.: 67 TIM GLP, Unpublished **Study required to support Section 1 data**	Y*	CHE

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.7.5/01	White, D. F., Wooley, S. M.	2008	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of long term storage stability and physico-chemical characterristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 104 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/02	Y	CHE
IIIA, 2.7.5/02	Hinz, B.	2010	Determination of the long term storage stability of Thifensulfuron-methyl + Metsulfuron-methyl 68% w/w (680 g/kg) + 7% w/w (70 g/kg) WG formualtion in commercial packaging Cheminova A/S Cheminova A/S report No.: 104 supplemntary GLP, Upublished **Study required to support Section 1 data**	Y	CHE
IIIA, 2.8.1/01	White, D.F., Mullee, D.M.	2006a	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of Accelerated Storage Stability (CIPAC MT 46.3) and Physico-Chemical Characteristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 20 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/01	Y*	CHE
IIIA, 2.8.2/01	Kusk, T.	2007	Determination of storage Stability for 14 days at 54°C of Thifensulfuron-methyl 68% w/w + Metsulfuron-methyl 7% w/w WG Formulation in commercial Packaging Cheminova A/S Cheminova A/S Report No.: 67 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.7.1/02	Y*	CHE
IIIA, 2.8.2/02	Hinz, B.	2010	Determination of the long term storage stability of Thifensulfuron-methyl + Metsulfuron-methyl 68% w/w (680 g/kg) + 7% w/w (70 g/kg) WG formualtion in	Y	CHE

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
			commercial packaging Cheminova A/S Cheminova A/S report No.: 104 supplemntary GLP, Upublished **Study required to support Section 1 data** ⇒ IIIA, 2.7.5/02		
IIIA, 2.8.3.1/01	Kusk, T.	2007	Determination of storage Stability for 14 days at 54°C of Thifensulfuron-methyl 68% w/w + Metsulfuron-methyl 7% w/w WG Formulation in commercial Packaging Cheminova A/S Cheminova A/S Report No.: 67 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.7.1/02	Y*	CHE
IIIA, 2.8.3.1/02	Hinz, B.	2010	Determination of the long term storage stability of Thifensulfuron-methyl + Metsulfuron-methyl 68% w/w (680 g/kg) + 7% w/w (70 g/kg) WG formualtion in commercial packaging Cheminova A/S Cheminova A/S report No.: 104 supplemntary GLP, Upublished **Study required to support Section 1 data** ⇒ IIIA, 2.7.5/02	Y	CHE
IIIA, 2.8.3.2/01	Kusk, T.	2007	Determination of storage Stability for 14 days at 54°C of Thifensulfuron-methyl 68% w/w + Metsulfuron-methyl 7% w/w WG Formulation in commercial Packaging Cheminova A/S Cheminova A/S Report No.: 67 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.7.1/02	Y*	CHE
IIIA, 2.8.3.2/02	Hinz, B.	2010	Determination of the long term storage stability of Thifensulfuron-methyl + Metsulfuron-methyl 68% w/w (680 g/kg) + 7% w/w (70 g/kg) WG formualtion in commercial packaging Cheminova A/S Cheminova A/S report No.: 104 supplemntary	Y	CHE

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
			GLP, Upublished **Study required to support Section 1 data** ⇒ IIIA, 2.7.5/02		
IIIA, 2.8.5.2/01	White, D.F., Mullee, D.M.	2006a	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of Accelerated Storage Stability (CIPAC MT 46.3) and Physico-Chemical Characteristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 20 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/01	Y*	CHE
IIIA, 2.8.5.2/02	White, D. F., Wooley, S. M.	2008	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of long term storage stability and physico-chemical characterristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 104 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/02	Y	CHE
IIIA, 2.8.6.2/01	White, D.F., Mullee, D.M.	2006a	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of Accelerated Storage Stability (CIPAC MT 46.3) and Physico-Chemical Characteristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 20 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/01	Y*	CHE
IIIA, 2.8.6.2/02	White, D. F., Wooley, S. M.	2008	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of long term storage stability and physico-chemical characterristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 104 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/02	Y	CHE

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.8.6.3/01	White, D.F., Mullee, D.M.	2006a	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of Accelerated Storage Stability (CIPAC MT 46.3) and Physico-Chemical Characteristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 20 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/01	Y*	CHE
IIIA, 2.8.6.3/02	White, D. F., Wooley, S. M.	2008	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of long term storage stability and physico-chemical characterristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 104 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/02	Y	CHE
IIIA, 2.8.6.5/01	White, D.F., Mullee, D.M.	2006a	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of Accelerated Storage Stability (CIPAC MT 46.3) and Physico-Chemical Characteristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 20 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/01	Y*	CHE
IIIA, 2.8.6.5/02	White, D. F., Wooley, S. M.	2008	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of long term storage stability and physico-chemical characterristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 104 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/02	Y	CHE
IIIA, 2.8.8.1/01	White, D. F., Mullee, D. M.	2006b	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of Flowability (CIPAC MT172) and	Y*	CHE

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
			Bulk Density (CIPAC MT169) Safepharm Laboratories Ltd Cheminova A/S Study No.: 0545/522 Cheminova A/S Report No.: 7 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.6.2/01		
IIIA, 2.13/01	White, D.F., Mullee, D.M.	2006a	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of Accelerated Storage Stability (CIPAC MT 46.3) and Physico-Chemical Characteristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 20 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/01	Y*	CHE
IIIA, 2.13/02	White, D. F., Wooley, S. M.	2008	Thifensulfuron-methyl + Metsulfuron-methyl 680 + 70 g/kg WG : Determination of long term storage stability and physico-chemical characterristics Safepharm Laboratories Ltd Cheminova A/S Report No.: 104 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.1/02	Y	CHE
IIIA, 2.14/01	Kusk, T.	2007	Determination of storage Stability for 14 days at 54°C of Thifensulfuron-methyl 68% w/w + Metsulfuron-methyl 7% w/w WG Formulation in commercial Packaging Cheminova A/S Cheminova A/S Report No.: 67 TIM GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA, 2.7.1/02	Y*	CHE

*Annex III study not submitted in all EU Member States therefore data protection can be claimed following Annex I renewal in those Member States where the study has not previously been granted data protection

Plant Protection Product - Thifensulfuron-methyl + Metsulfuron-methyl, 680 + 70 (682 g/kg Water dispersible granule) (Rotam)

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.1/01	Denny, O.	2006a	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Accelerated storage stability Anadiag S.A. Rotam Ltd. Report No.: RA6148 23 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.1/03	Denny, O.	2009	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Shelf life at ambient temperature Anadiag S.A. Rotam Ltd. Report No.: RA6148 SL GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.2.1/01	Denny, O.	2006c	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Explosive properties Anadiag S.A. Rotam Ltd. Report No.: RA6148 05 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.2.2/01	Denny, O.	2006d	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Oxidising properties Anadiag S.A. Rotam Ltd. Report No.: RA6148 06 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.3.2/01	Denny, O.	2006e	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Flammability Anadiag S.A. Rotam Ltd. Report No.: RA614807 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.3.3/01	Denny, O.	2006f	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Autoflammability Anadiag S.A. Rotam Ltd. Report No.: RA614808 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.3.3/02	Srinivasan, A.	2013	Study on the physico-chemical properties of thifensulfuron-methyl 682 g/kg + metsulfuron-methyl 68 g/kg water dispersible granule Rotam Research Laboratory (RRL) Rotam Ltd. Report No.: 0993 GLP, Unpublished	Y*	ROT
IIIA, 2.4.1/01	Denny, O.	2006g	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Acidity/ alkalinity Anadiag S.A. Rotam Ltd. Report No.: RA614809 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.4.1/02	Denny, O.	2006a	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Accelerated storage stability Anadiag S.A. Rotam Ltd. Report No.: RA614823 GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/01	Y*	ROT

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.4.1/03	Denny, O.	2009	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Shelf life at ambient temperature Anadiag S.A. Rotam Ltd. Report No.: RA6148 SL GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/03	Y*	ROT
IIIA, 2.4.2/01	Denny, O.	2006h	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- pH of a dilution Anadiag S.A. Rotam Ltd. Report No.: RA6148 10 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.4.2/02	Denny, O.	2006a	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Accelerated storage stability Anadiag S.A. Rotam Ltd. Report No.: RA6148 23 GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/01	Y*	ROT
IIIA, 2.4.2/03	Denny, O.	2009	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Shelf life at ambient temperature Anadiag S.A. Rotam Ltd. Report No.: RA6148 SL GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/03	Y*	ROT

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.6.2/01	Denny, O.	2006i	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Bulk density Anadiag S.A. Rotam Ltd. Report No.: RA6148 11 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.7.1/01	Denny, O.	2006j	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation – Thifensulfuron-methyl content Anadiag S.A. Rotam Ltd. Report No.: RA6148 01 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.7.1/02	Denny, O.	2006a	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Accelerated storage stability Anadiag S.A. Rotam Ltd. Report No.: RA6148 23 GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/01	Y*	ROT
IIIA, 2.7.5/01	Denny, O.	2009	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Shelf life at ambient temperature Anadiag S.A. Rotam Ltd. Report No.: RA6148 SL GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/03	Y*	ROT

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.7.5/02	Demangel, B.	2010a	Determination of the content and the suspensibility of formulation forming suspensions on dilution with water on thifensulfuron-methyl and metsulfuron-methyl WG formulation stored for 3 years at 20 ± 2°C (ambient conditions) in compliance with good laboratory practice Anadiag S.A. Rotam Agrochem International Co. Ltd Report No. 09-918024-014 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.8.1/01	Denny, O.	2006k	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Wettability Anadiag S.A. Rotam Ltd. Report No. RA6148 12 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.8.1/02	Demangel, B.	2010b	Physico chemical tests on thifensulfuron-methyl and metsulfuron-methyl WG formulation stored for 3 years at 20 ± 2°C (ambient conditions) in compliance with good laboratory practice Anadiag S.A. Rotam Agrochem International Co. Ltd Report No.: 09-918024-013 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.8.2/01	Denny, O.	2006a	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Accelerated storage stability Anadiag S.A. Rotam Ltd. Report No.: RA6148 23 GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/01	Y*	ROT

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA, 2.8.2/02	Denny, O.	2006l	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Persistent foaming Anadiag S.A. Rotam Ltd. Report No.: RA6148 13 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.8.2/03	Denny, O.	2009	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Shelf life at ambient temperature Anadiag S.A. Rotam Ltd. Report No.: RA6148 SL GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/03	Y*	ROT
IIIA, 2.8.2/03	Demangel, B.	2010b	Physico chemical tests on thifensulfuron-methyl and metsulfuron-methyl WG formulation stored for 3 years at 20 ± 2°C (ambient conditions) in compliance with good laboratory practice Anadiag S.A. Rotam Agrochem International Co. Ltd Report No.: 09-918024-013 GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.8.1/02	Y*	ROT
IIIA, 2.8.3.1/01	Denny, O.	2006a	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Accelerated storage stability Anadiag S.A. Rotam Ltd. Report No.: RA6148 23 GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/01	Y*	ROT

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IIIA, 2.8.3.1/02	Denny, O.	2006m	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Suspensibility based on Thifensulfuron-methyl Anadiag S.A. Rotam Ltd. Report No.: RA6148 14 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.8.3.1/03	Denny, O.	2009	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Shelf life at ambient temperature Anadiag S.A. Rotam Ltd. Report No.: RA6148 SL GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/03	Y*	ROT
IIIA, 2.8.3.1/04	Demangel, B.	2010a	Determination of the content and the suspensibility of formulation forming suspensions on dilution with water on thifensulfuron-methyl and metsulfuron-methyl WG formulation stored for 3 years at 20 ± 2°C (ambient conditions) in compliance with good laboratory practice Anadiag S.A. Rotam Agrochem International Co. Ltd Report No.: 09-918024-014 GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.7.5/02	Y*	ROT
IIIA, 2.8.3.1/05	Srinivasan, A.	2013	Study on the physico-chemical properties of thifensulfuron-methyl 682 g/kg + metsulfuron-methyl 68 g/kg water dispersible granule Rotam Research Laboratory (RRL) Rotam Ltd. Report No.: 0993 GLP, Unpublished	Y*	ROT

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IIIA, 2.8.3.2/01	Denny, O.	2006a	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Accelerated storage stability Anadiag S.A. Rotam Ltd. Report No.: RA6148 23 GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.7.5/02	Y*	ROT
IIIA, 2.8.3.2/02	Denny, O.	2006n	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Spontaneity of dispersion based on Thifensulfuron-methyl Anadiag S.A. Rotam Ltd. Report No.: RA6148 16 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.8.3.2/03	Denny, O.	2009	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Shelf life at ambient temperature Anadiag S.A. Rotam Ltd. Report No.: RA6148 SL GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.7.5/02	Y*	ROT
IIIA, 2.8.5.2/01	Denny, O.	2006a	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Accelerated storage stability Anadiag S.A. Rotam Ltd. Report No.: RA6148 23 GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/01	Y*	ROT

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IIIA, 2.8.5.2/02	Denny, O.	2006o	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Shelf life at ambient temperature Anadiag S.A. Rotam Ltd. Report No.: RA6148 18 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.8.5.2/03	Denny, O.	2009	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Shelf life at ambient temperature Anadiag S.A. Rotam Ltd. Report No.: RA6148 SL GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/03	Y*	ROT
IIIA, 2.8.6.2/01	Denny, O.	2006p	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Size disribution Anadiag S.A. Rotam Ltd. Report No.: RA6148 19 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.8.6.2/02	Srinivasan, A.	2013	Study on the physico-chemical properties of thifensulfuron-methyl 682 g/kg + metsulfuron-methyl 68 g/kg water dispersible granule Rotam Research Laboratory (RRL) Rotam Ltd. Report No.: 0993 GLP, Unpublished	Y*	ROT

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IIIA, 2.8.6.3/01	Denny, O.	2006a	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Accelerated storage stability Anadiag S.A. Rotam Ltd. Report No.: RA6148 23 GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/01	Y*	ROT
IIIA, 2.8.6.3/02	Denny, O.	2006q	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Dustiness of granules Anadiag S.A. Rotam Ltd. Report No.: RA6148 20 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.8.6.3/03	Denny, O.	2009	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Shelf life at ambient temperature Anadiag S.A. Rotam Ltd. Report No.: RA6148 SL GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/03	Y*	ROT
IIIA, 2.8.6.5/01	Denny, O.	2006r	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Friability and attrition resistance Anadiag S.A. Rotam Ltd. Report No.: RA6148 21 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT

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IIIA, 2.8.6.5/01	Demangel, B.	2010b	Physico chemical tests on thifensulfuron-methyl and metsulfuron-methyl WG formulation stored for 3 years at 20 ± 2°C (ambient conditions) in compliance with good laboratory practice Anadiag S.A. Rotam Agrochem International Co. Ltd Report No.: 09-918024-013 GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.8.1/02	Y*	ROT
IIIA, 2.8.8.1/01	Denny, O.	2006s	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Flowability Anadiag S.A. Rotam Ltd. Report No.: RA6148 22 GLP, Unpublished **Study required to support Section 1 data**	Y*	ROT
IIIA, 2.13/01	Denny, O.	2009	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Shelf life at ambient temperature Anadiag S.A. Rotam Ltd. Report No.: RA6148 SL GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/03	Y*	ROT
IIIA, 2.14/01	Denny, O.	2009	Determination of physical and chemical properties of a thifensulfuron-methyl and metsulfuron-methyl WG formulation- Shelf life at ambient temperature Anadiag S.A. Rotam Ltd. Report No.: RA6148 SL GLP, Unpublished **Study required to support Section 1 data** ⇒ IIIA 2.1/03	Y*	ROT

*Annex III study not submitted in all EU Member States therefore data protection can be claimed following Annex I renewal in those Member States where the study has not previously been granted data protection