

ANNEX B

Metam

B.2 Physical and chemical properties

Update June 2008
Revision August 2010

B.2.0 Introductory note [added in August 2010]

This document is based on the updated version of Vol.3 B.2 of the DAR, which was peer-reviewed in June 2008 (PRAPeR 51). Evaluations presented in the addendum to B.2, dated June 2008, which were peer-reviewed and accepted by PRAPeR 51 (June 2008), have been incorporated in this document as well for the sake of completeness. Finally, revisions were made following the evaluation of the resubmission dossier introduced in 2010 according to the legal provisions of Commission Regulation (EC) No. 33/2008 and these are highlighted in yellow.

B.2.1 Physical and chemical properties of the active substance (Annex IIA 2)

In table B.2.1-1 below, the relevant physical and chemical properties are reported for ‘purified metam-sodium’ and for ‘metam-sodium as manufactured’ (TK). It should be noted that the latter is in fact an aqueous solution (SL) of 510 g/L metam-sodium, thus identical to the plant protection product. In addition, some properties are reported for Metam-potassium (purified or aqueous solution 690 g/L) and for the major degradation product MITC (methyl isothiocyanate), as well as for the impurity N,N'-dimethylthiourea (DMTU).

Table B.2.1-1: Physical and chemical properties of metam-sodium, metam-potassium, MITC and DMTU

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.1.1 Melting point, freezing point or solidification point (IIA 2.1.1)	EEC A1 (Capillary method using metal block) GLP	Metam-sodium, 99.9% pure (Batch No. MNA SAP01): Melting point: 86.5 – 90.5 °C	Acceptable	Betteley, 1997 (FCC 152/963829)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	OECD 102 / EEC A1 (Differential scanning calorimetry + Capillary method using metal block) GLP	Metam-potassium solid, 98% pure (Batch No. F081126+ F090212): No clear melting endotherm could be noted on the DSC thermogram. No complete melting was visually observed. At around 150°C, the specimen discoloured and finally left a yellow/brown residue on the tube walls.	Acceptable No clear melting point could be determined for metam-potassium, probably due to decomposition upon heating.	White, 2009b (J17224/A) [added in August 2010]
B.2.1.2 Boiling point (IIA 2.1.2)			Not applicable. See B.2.1.3 (temperature of decomposition).	
B.2.1.3 Temperature of decomposition or sublimation (IIA 2.1.3)	EEC A16 (thermal analysis method: DTA) GLP	Metam-sodium, 97.0% pure (Batch No. MNA-Tox-002): In the auto-flammability test with purified metam-sodium, the test product was heated from ambient temperature to 450 °C with a heating rate of 0.5 °C/min. Boiling of the product was not observed at these temperatures. An exotherm was observed at 150 °C and 215 °C, and a white and black hard solid remained in the cubes. The temperature vs time curve of metam-sodium is an indication for decomposition at 150°C with further decomposition at 215°C.	Acceptable Metam-sodium decomposes at 150°C. Further decomposition occurs at 215°C.	Betteley, 1997 (FCC 152/963829)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	OECD 102 / EEC A1 (Differential scanning calorimetry + Capillary method using metal block) GLP	Metam-potassium solid, 98% pure (Batch No. F081126+ F090212): The complicated DSC thermogram indicated decomposition of the sample. No complete melting was visually observed. At around 150°C, the specimen discoloured and finally left a yellow/brown residue on the tube walls.	Acceptable Metam-potassium (purified; solid) decomposes at a temperature of approximately 150°C.	White, 2009b (J17224/A) [added in August 2010]
B.2.1.4 Relative density (IIA 2.2)	Pycnometer method (ISO R1183) GLP	Metam-sodium, 99.9% pure (Batch No. MNA SAP01): Relative density $D_4^{20} = 1.44$	Acceptable	Betteley, 1997 (FCC 152/963829)
	OECD 109 / EEC A3 GLP	Metam-potassium solid, 98% pure (Batch No. F081126+ F090212): Relative density $D_4^{20} = 1.579$	Acceptable	White, 2009b (J17224/A) [added in August 2010]
B.2.1.5 Vapour pressure (IIA 2.3.1)	EEC A4 (vapour pressure balance method) GLP	Metam-sodium, 99.9% pure (white powder): 5.75×10^{-4} Pa (25°C) (interpolated from measurements in temperature range 19 to 39°C)	Acceptable Results indicate that purified metam-sodium is a moderately volatile substance.	Betteley, 1997 (FCC 152/963829)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	OECD 104 EEC A4 (Gas saturation method) GLP	Methylisothiocyanate (MITC), 99.4% pure (Batch AO17701301): 1739 Pa (20°C) (interpolated from measurements at 15°C and 25°C) <i>Note:</i> In first instance, dynamic method was chosen, but this method was not applicable to test item MITC due to decomposition at elevated temperatures.	Acceptable MITC is considered to be a highly volatile substance.	Lindemann, 2003 (RCC 850435)
	OECD 104 EEC A4 (static method) GLP	N,N'-dimethylthiourea (DMTU), 99.8% pure (Batch n° 422930/1): 832.95 Pa (at 20°C) 912.00 Pa (at 25°C) (extrapolated from measurements in temperature range 70 to 120°C)	Acceptable DMTU is a highly volatile substance.	Habeck, 2009b (C42765) [added in August 2010]

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.1.6 Volatility – Henry's law constant (IIA 2.3.2)	Calculation GLP not relevant (calculation)	Metam-sodium: $H = 1.28 \times 10^{-5} \text{ Pa.m}^3/\text{mol}$ (20 °C) values used for calculation: water solubility at 20°C: 578.29 g/L = $4.476 \times 10^3 \text{ mol/m}^3$ (see point B.2.1.11) vapour pressure at 25°C: $5.75 \times 10^{-2} \text{ Pa}$ (see point B.2.1.5)	Acceptable Metam-sodium is very slightly volatile from water. Values (for water solubility and vapour pressure) taken for calculation are not associated with the same temperature. Therefore, RMS has calculated the vapour pressure at 20°C by interpolation (see B.2.1.5): $3.73 \times 10^{-2} \text{ Pa}$. Corresponding Henry's law constant at 20°C is thus calculated to be $8.34 \times 10^{-6} \text{ Pa.m}^3.\text{mol}^{-1}$ (confirmed by Taminco in 2007). The latter value will be mentioned in the listing of end points.	Taminco, 2004a-2007 (A new calculation was provided in 2007.)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	Calculation GLP not relevant (calculation)	MITC: $H = 14.2 \text{ Pa.m}^3/\text{mol}$ (20 °C) values used for calculation: water solubility at 20°C: 8.94 g/L (see point B.2.1.11) vapour pressure at 20°C: 1739 Pa (see point B.2.1.5)	Acceptable MITC is considered to be moderately volatile from water.	Taminco, 2004b
	Calculation GLP not relevant (calculation)	N,N'-dimethylthiourea (DMTU), 99.8% pure (Batch n° 422930/1): $H = 0.149 \text{ Pa.m}^3/\text{mol}$ (at 20°C) $H = 0.163 \text{ Pa.m}^3/\text{mol}$ (at 25°C) values used for calculation: water solubility at room temperature: 581.98 g/L (see point B.2.1.11) vapour pressure at 20°C / 25°C: 832.95 Pa / 912.00 Pa (see point B.2.1.5)	Acceptable DMTU has a moderate volatility from water.	Habeck, 2009b (C42765) [added in August 2010]
B.2.1.7 Physical state, colour (IIA 2.4.1)	Visual inspection (ASTM D1535-89) GLP	Metam-sodium, 99.0% pure (Batch No. MNA-Tox-002): White crystalline powder (according to Munsell neutral scale N9.5/90%R)	Acceptable	Betteley, 1997 (FCC 152/963829)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	Visual inspection (ASTM D1209-79) Not GLP	Metam-sodium 510 g/L (Coded 32 F 05/03/2001): Yellow clear solution (264 APHA)	Acceptable	Van Hecke et al., 2001a (W/RL/200101/001)
	Visual inspection GLP	Metam-potassium solid, 98% pure (Batch No. F081126+ F090212): Pale yellow amorphous, solid, crystalline powder with a few hard lumps	Acceptable	White, 2009b (J17224/A) [added in August 2010]
	Visual inspection (OPPTS 830.6302 OPPTS 830.6303) GLP	Metam-potassium 53.62% w/w aqueous solution (i.e. soluble concentrate, as manufactured) (Batch V11/01): Clear, light yellow liquid	Acceptable	Ambroz Hahn, 2002a (ABC Study No. 47104)
	Visual inspection	MITC, 97.0% pure (Lot No. 66905-026): Colourless crystalline solid	Acceptable	Flack, 1997 (FCC 153/962827)
B.2.1.8 Odour (IIA 2.4.2)	Organoleptic determination GLP	Metam-sodium, 97.0% pure (Batch No. MNA-Tox-002): Sweet onion-like smell	Acceptable	Betteley, 1997 (FCC 152/963829)
	Organoleptic determination Not GLP	Metam-sodium 510 g/L (Coded 32 F 05/03/2001): Weak CS ₂ and H ₂ S odour	Acceptable	Van Hecke et al., 2001a (W/RL/200101/001)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	Organoleptic determination	Metam-potassium solid, 98% pure (Batch No. F081126+ F090212):	Acceptable	White, 2009b (J17224/A)
	GLP	Slightly acrid, sulphurous odour		[added in August 2010]
	OPPTS 830.6304 (inhalation) GLP	Metam-potassium 53.62% w/w aqueous solution (i.e. soluble concentrate, as manufactured) (Batch V11/01): Pungent odour similar to sulphur	Acceptable	Ambroz Hahn, 2002a (ABC Study No. 47104)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References																						
B.2.1.9 Spectra of the active substance (IIA 2.5.1)	OECD 101 (for UV-VIS spectrum) GLP	Metam-sodium, 99.9% pure (Batch No. MNA SAP01): UV/VIS (scanned range: 190-400 nm) IR (KBr; sample scanned over range 4500-500cm⁻¹) ¹H-NMR (CD₃OD; 400 MHz) MS (EI-MS/MS) The different spectra were found to be in agreement with the proposed chemical structure. <i>UV/VIS absorption characteristics :</i> <table><tr><td></td><td>λ_{max} (nm)</td><td>ϵ (L.mol⁻¹.cm⁻¹)</td></tr><tr><td rowspan="4">Neutral (distilled water)</td><td>205.0</td><td>7502.8</td></tr><tr><td>248.0</td><td>7942.3</td></tr><tr><td>280.0</td><td>9924.0</td></tr><tr><td>at λ 290 nm</td><td>approx. 6000</td></tr><tr><td rowspan="3">Alkaline (0.1 M NaOH) pH > 10</td><td>248.0</td><td>8042.5</td></tr><tr><td>280.0</td><td>9796.8</td></tr><tr><td>at λ 290 nm</td><td>approx. 6000</td></tr><tr><td>Acidic (0.1M HCl) pH < 2</td><td colspan="2">Metam-sodium hydrolysed too fast to measure accurately</td></tr></table> Temperature was not recorded, but the spectra would have been obtained at ambient laboratory temperature (in the region of 25 °C).		λ_{max} (nm)	ϵ (L.mol ⁻¹ .cm ⁻¹)	Neutral (distilled water)	205.0	7502.8	248.0	7942.3	280.0	9924.0	at λ 290 nm	approx. 6000	Alkaline (0.1 M NaOH) pH > 10	248.0	8042.5	280.0	9796.8	at λ 290 nm	approx. 6000	Acidic (0.1M HCl) pH < 2	Metam-sodium hydrolysed too fast to measure accurately		The submitted IR, NMR and MS spectra were acceptable. Some information was missing in the study report for UV/VIS-spectra (precise molar absorption coefficients at 290 nm, temperature and pH values), but acceptable further clarification was provided by the laboratory. No further data are deemed necessary.	Betteley, 1997 (FCC 152/963829)
	λ_{max} (nm)	ϵ (L.mol ⁻¹ .cm ⁻¹)																								
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Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References																								
	No method/guideline referenced Not GLP	Metam-potassium, dried active substance (purity not stated) UV-VIS, MS, IR and ¹ H-NMR spectra were provided. UV-VIS spectrum is similar to that of metam-sodium recorded under neutral conditions (see above, Betteley, 1997)	Study is not GLP and hence, it cannot be relied upon.	De Boever, 2001																								
	OECD 101 (for UV-VIS spectrum) GLP	Metam-potassium solid, 98% pure (Batch No. F081126+ F090212): Following spectra were provided: UV/VIS (scanned range: 190-700 nm) IR (KBr; sample scanned over range 4000-400cm ⁻¹) UV absorption characteristics: <table><tr><td></td><td>λ_{max} (nm)</td><td>ϵ (L.mol⁻¹.cm⁻¹)</td></tr><tr><td rowspan="4">Neutral (pH 6.94)</td><td>206</td><td>8318</td></tr><tr><td>248</td><td>7357</td></tr><tr><td>282</td><td>8954</td></tr><tr><td>at λ 290 nm</td><td>approx. 6400</td></tr><tr><td rowspan="4">Alkaline (pH = 10.88)</td><td>195</td><td>14664</td></tr><tr><td>248</td><td>7397</td></tr><tr><td>282</td><td>8908</td></tr><tr><td>at λ 290 nm</td><td>approx. 6500</td></tr><tr><td>Acidic (pH = 1.90)</td><td colspan="2">Sample was unstable. (no accurate measurement possible due to rapid hydrolysis of metam-potassium)</td></tr></table>		λ_{max} (nm)	ϵ (L.mol ⁻¹ .cm ⁻¹)	Neutral (pH 6.94)	206	8318	248	7357	282	8954	at λ 290 nm	approx. 6400	Alkaline (pH = 10.88)	195	14664	248	7397	282	8908	at λ 290 nm	approx. 6500	Acidic (pH = 1.90)	Sample was unstable. (no accurate measurement possible due to rapid hydrolysis of metam-potassium)		Acceptable UV and IR spectra were provided. The observed characteristic UV absorption maxima (at 248 and 282 nm) are in line with the results observed in the spectral analysis of metam-sodium samples (<i>vide supra</i> ; Betteley, 1997). Extinction coefficients at the trigger wavelength of 290 nm were estimated by the RMS and are above 10 L.mol ⁻¹ .cm ⁻¹ , which is also in accordance with the observations made for metam-sodium.	White, 2009b (J17224/A) (+ report addendum dated June 15, 2010) [added in August 2010]
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Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References																										
B.2.1.10 Spectra of the impurities (IIA 2.5.2)	OECD 101 GLP	MITC, 97.0% pure (Lot No. 66905-026): <i>Following spectra were provided:</i> UV/VIS (scanned range: 190-500 nm) IR (KBr; sample scanned over range 4500-500cm⁻¹) ¹H-NMR (CDCl₃; 400 MHz) MS (EI, 70 eV) The different spectra were found to be in agreement with the chemical structure of MITC. <i>UV/VIS absorption characteristics :</i> <table><tr><td></td><td>λ_{max} (nm)</td><td>ϵ (L.mol⁻¹.cm⁻¹)</td></tr><tr><td rowspan="3">Neutral (distilled water)</td><td>235</td><td>635</td></tr><tr><td>283</td><td>65</td></tr><tr><td>321</td><td>17</td></tr><tr><td rowspan="3">Alkaline (0.1 M NaOH)</td><td>276</td><td>46</td></tr><tr><td>320</td><td>5</td></tr><tr><td>at λ 290 nm</td><td>Not reported, but > 10 based on spectrum</td></tr><tr><td rowspan="4">Acidic (0.1M HCl)</td><td>235</td><td>635</td></tr><tr><td>283</td><td>23</td></tr><tr><td>324</td><td>6</td></tr><tr><td>at λ 290 nm</td><td>Not reported, but > 10 based on spectrum</td></tr></table> The absorption in the wavelength range 200-300 nm was shown to be significantly different / higher in alkaline medium, compared to that observed under neutral and acidic conditions.		λ_{max} (nm)	ϵ (L.mol ⁻¹ .cm ⁻¹)	Neutral (distilled water)	235	635	283	65	321	17	Alkaline (0.1 M NaOH)	276	46	320	5	at λ 290 nm	Not reported, but > 10 based on spectrum	Acidic (0.1M HCl)	235	635	283	23	324	6	at λ 290 nm	Not reported, but > 10 based on spectrum	The submitted UV, IR, NMR and MS spectra for MITC are considered acceptable.	Flack, 1997 (FCC 153/962827)
	λ_{max} (nm)	ϵ (L.mol ⁻¹ .cm ⁻¹)																												
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	at λ 290 nm	Not reported, but > 10 based on spectrum																												

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References																		
	OECD 101 (for UV spectrum) GLP	N,N'-dimethylthiourea (DMTU), 99% pure (Lot no. S21210-437): Following spectra were provided: UV/VIS (scanned range: 200-750 nm) IR (KBr; sample scanned over range 4400-450cm⁻¹) ¹H-NMR (CDCl₃; 400 MHz) ¹³C-NMR (CDCl₃; 100 MHz) MS (EI) UV absorption characteristics (at 25.5 ± 0.5°C): <table><thead><tr><th></th><th>λ_{max} (nm)</th><th>ε (L.mol⁻¹.cm⁻¹)</th></tr></thead><tbody><tr><td rowspan="2">Neutral (pH = 7.0) [CH₃OH/ water 90:10 v/v]</td><td>238</td><td>1.27 x 10⁴</td></tr><tr><td>at λ 290 nm</td><td>161</td></tr><tr><td rowspan="2">Alkaline (pH = 12.3) [CH₃OH/ 0.1 M NaOH 90:10 v/v]</td><td>238</td><td>1.28 x 10⁴</td></tr><tr><td>at λ 290 nm</td><td>368</td></tr><tr><td rowspan="2">Acidic (pH = 1.1) [CH₃OH/ 1M HCl 90:10 v/v]</td><td>238</td><td>9.91 x 10³</td></tr><tr><td>at λ 290 nm</td><td>415</td></tr></tbody></table> IR, NMR & mass spectra were consistent with chemical structure.		λ _{max} (nm)	ε (L.mol ⁻¹ .cm ⁻¹)	Neutral (pH = 7.0) [CH ₃ OH/ water 90:10 v/v]	238	1.27 x 10 ⁴	at λ 290 nm	161	Alkaline (pH = 12.3) [CH ₃ OH/ 0.1 M NaOH 90:10 v/v]	238	1.28 x 10 ⁴	at λ 290 nm	368	Acidic (pH = 1.1) [CH ₃ OH/ 1M HCl 90:10 v/v]	238	9.91 x 10 ³	at λ 290 nm	415	Acceptable	O'Connor & Woolley, 2010 (1542/0009R) [added in August 2010]
	λ _{max} (nm)	ε (L.mol ⁻¹ .cm ⁻¹)																				
Neutral (pH = 7.0) [CH ₃ OH/ water 90:10 v/v]	238	1.27 x 10 ⁴																				
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Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.1.11 Solubility in water (IIA 2.6)	EEC A6 (flask method; analysis of metam- sodium conc. by HPLC-UV) GLP	Metam-sodium, 99.9% pure (Batch No. MNA SAP01): 578.29 g/L at 20°C (Distilled water was used; pH of the saturated test solutions ranged from 9.16 – 9.30)	Acceptable Metam-sodium is readily soluble in water. Due to the high water solubility of metam-sodium, the pH of the test solutions was increased.	Betteley, 1997 (FCC 152/963829)
	EEC A6 OECD 105 (Flask method; analysis of metam- sodium conc. by HPLC-UV) GLP	Metam-sodium, 99.2% pure (Batch No. V799R): at pH 5: not measurable, due to hydrolysis; due to high water solubility of metam-sodium, pH of buffer solution could not be maintained at pH 5. pH 9 buffer solution: due to high water solubility of metam-sodium, pH changed to ca. pH 10: 600 g/L at 10°C (pH 10.11) 734 g/L at 20°C (pH 10.12) 701 g/L at 30°C (pH 10.37)	Acceptable Metam-sodium is readily soluble in water. In acidic medium (pH 5), metam- sodium is very rapidly hydrolysed and therefore, water solubility cannot be determined accurately at that pH.	Betteley, 2002a (UCB809/013754)
	EEC A6 (Flask method; analysis of MITC conc. by HPLC-UV) GLP	MITC, 97.0% pure (Lot No. 66905-026): 8.94 g/L at 20°C (pH 7.5)	Acceptable; MITC is readily soluble in water.	Flack, 1997 (FCC 153/962827)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References														
	OECD 105 EEC A6 (simplified flask method; analysis of DMTU conc. by HPLC-UV) GLP	N,N'-dimethylthiourea (DMTU), 99.8% pure (Batch no. 422930/1): ≥ 581.98 g/L at room temperature (pH = 7.3)	Acceptable DMTU is readily soluble in water.	Habeck, 2009a (C42743) [added in August 2010]														
B.2.1.12 Solubility in organic solvents (IIA 2.7)	Method consists of adding measured volumes of solvent to a known mass of test substance until complete dissolution is observed (visual inspection). GLP	Metam-sodium, 99.9% pure (Batch No. MNA SAP01): After each addition of solvent, the cylinder containing the solution was shaken for 30 minutes and its content was checked visually for any undissolved material before the next addition of solvent. <table><tr><td></td><td>solubility at 20°C (g/L)</td></tr><tr><td>n-heptane</td><td>< 0.2126</td></tr><tr><td>Xylene</td><td>< 0.2611</td></tr><tr><td>1,2-dichloroethane</td><td>< 0.2620</td></tr><tr><td>ethyl acetate</td><td>< 0.2032</td></tr><tr><td>acetone</td><td>< 0.2188</td></tr><tr><td>methanol</td><td>33 – 40</td></tr></table>		solubility at 20°C (g/L)	n-heptane	< 0.2126	Xylene	< 0.2611	1,2-dichloroethane	< 0.2620	ethyl acetate	< 0.2032	acetone	< 0.2188	methanol	33 – 40	Acceptable Metam-sodium appears to be readily soluble in methanol, whereas in other organic solvents, its solubility is significantly lower. The exact solubility was not determined in those other organic solvents, but no further data are deemed necessary.	Betteley, 1997 (FCC 152/963829)
	solubility at 20°C (g/L)																	
n-heptane	< 0.2126																	
Xylene	< 0.2611																	
1,2-dichloroethane	< 0.2620																	
ethyl acetate	< 0.2032																	
acetone	< 0.2188																	
methanol	33 – 40																	

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.1.13 Partition coefficient n-octanol/water (IIA 2.8)	EEC A8 (Shake-flask method) GLP	Metam-sodium, 99.9% pure (Batch No. MNA SAP01): A pH 7 buffer solution was used instead of pure distilled water. $\log P_{ow}$ at 20°C $\leq$ - 2.91 (pH 6.9) Effect of pH (4 to 10) on log Pow of metam-sodium was not investigated, but notifier provided a justification, which is summarized here below: <i>"The water solubility of metam-sodium in different conditions was reported in IIA 2.6 (See B.2.1.11; Betteley, 2002a). The solubility of metam-sodium is very large and hence, the pH of the buffer changed to ca. pH 10 during the solubility tests at pH 5 and pH 9 buffers. It can be concluded from this study that water solubility of metam-sodium was not significantly affected by pH (i.e. it remains a highly water soluble compound), presumably because it is capable of ionising in both acid and base. [...] It was therefore decided that partition coefficient tests at three pH's was unnecessary."</i>	Acceptable Metam-sodium has a log $P_{ow} \leq -2.91$ at 20 °C (pH 6.9) and hence, bioaccumulation in the environment is very unlikely. Effect of pH was not investigated, but notifier provided a justification. Although the RMS does not consider this justification as complete and acceptable, no further data are deemed to be required, since only one form of metam is believed to be significantly present at environmentally relevant pH (i.e. the ionized species methyldithiocarbamate, dissolved as a salt). Moreover, it is noted that metam-sodium will be readily degraded in the aqueous environment (see B.2.1.14) and hence, the log P_{ow} of metam-sodium is expected to have a limited effect on the risk assessment.	Betteley, 1997 (FCC 152/963829)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	EEC A8 (Shake-flask method) GLP	Metam-potassium solid, 98% pure (Batch No. F081126+ F090212): At 19.5 ± 0.5°C: log P _{ow} = - 3.42 (pH 5) log P _{ow} = - 3.44 (pH 7) log P _{ow} = - 3.55 (pH 9) Reported pH values correspond to the pH to which the aqueous phase used in the test was adjusted.	Acceptable The determined partition coefficient values reconfirm that bioaccumulation of metam-(potassium) in the environment is highly unlikely. The log P _{ow} was found to be independent of the pH of the aqueous phase and was in average -3.47.	Kelly, 2009 (J17224/B) [added in August 2010]
	EEC A8 (Shake-flask method) GLP	MITC, 97.0% pure (Lot No. 66905-026): log P _{ow} at 20°C: 1.05 (pH 7.5)	Acceptable; MITC has a log P _{ow} of 1.05 and hence, bioaccumulation of MITC in the environment is not expected.	Flack, 1997 (FCC 153/962827)
	EEC A8 (Shake-flask method) GLP	N,N'-dimethylthiourea (DMTU), 99.8% pure (Batch no. 422930/1): At 20-25°C: log P _{ow} : - 0.23 (pH of the aqueous phase was in range 7.6 – 8.5)	Acceptable DMTU has a low octanol/water partition coefficient and hence, bioaccumulation of DMTU in the environment is considered to be highly unlikely.	Habeck, 2009c (C42754) [added in August 2010]

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.1.14 Hydrolysis rate at pH 4, 7 and 9 under sterile conditions in the absence of light (IIA 2.9.1)	EEC C7 GLP	Metam-sodium 99.9% pure (Batch No. MNA SAP01): conc. 1 g/L (0.01M); analysis by HPLC <i>Incubation at 50°C:</i> pH 7: approx. 10% hydrolysis after 2.4 h and 60% hydrolysis after 5 days pH 9: approx. 10% hydrolysis after 2.4 h and 40% hydrolysis after 5 days ⇒ DT₅₀ of metam-sodium at 25°C can be estimated as between 1 day and 1 year for pH 7 and pH 9. <i>Incubation at 25°C:</i> pH 4: approx. 54% hydrolysis after 2.4 h and 95% hydrolysis after 23 hours ⇒ DT₅₀ of metam-sodium at pH 4 is less than 1 day at 25°C.	Not acceptable as stand-alone document, but acceptable as preliminary test. On the basis of the test results, it can only be concluded that metam-sodium is very rapidly hydrolysing at pH 4 (>50% hydrolysis after 2.4 hrs at 25°C). Furthermore, the test results suggest that metam-sodium is fairly hydrolysing at pH 7 and pH 9, but precise DT₅₀ values are not provided. Moreover, the study is not fully in accordance with EEC C7 (e.g. for pH 7 and 9 only a preliminary test at 50°C was performed; no degradation curve provided, no half-life calculation).	Betteley, 1997 (FCC 152/963829)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	US-EPA Subdivision N Series 161-1 GLP	Aqueous solution containing 30% w/w [methyl ^{14}C]-metam-sodium (Lot no. WRC 9471-45-01); radiochemical purity = 78% (major radioimpurities: 12% DMTU and 2% DMU (1,3-dimethylurea)); At 25°C in pH 5, 7 and 9 buffer; Initial concentrations of metam-sodium in buffered aqueous solutions were in range 57 – 65 mg/L; ⇒ Metam-sodium degrades rapidly in water at 25°C. <i>Estimated half-lives (assuming pseudo-first order kinetics):</i> pH 5: DT_{50} = 1.9 days pH 7: DT_{50} = 2.2 days pH 9: DT_{50} = 4.5 days <i>Major degradation products (≥ 10% of applied radioactivity AR):</i> - <u>MITC (methylothiocyanate):</u> 60% of AR at end of study at pH 7 (5d); 20% of AR at end of studies at pH 5 (1.8 d) and at pH 9 (5.4 d); - <u>MCDT (sodium methylcarbamo(dithioperoxo)thioate):</u> 16% of AR at end of study at pH 9 (5.4 d) $\text{H}_3\text{C}-\text{NH}-\overset{\text{S}}{\underset{\text{S}}{\text{C}}}-\text{S}-\text{S}^- \text{ } ^+\text{Na}$ This compound is detected only at pH 9, because probably formed by reaction of metam-sodium with elementar sulphur [S], which is only significantly formed in basic medium by oxidation of HS^-.	Acceptable Metam-sodium is readily hydrolysed. Moreover, hydrolysis appears to be accelerated with decreasing pH. At low pH (pH 5), MITC and methylamine are the main degradation products. At higher pH (pH 7 and 9), mainly MITC and MCDT are formed.	Ericson, 1990 (RR 90-110B)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
		<i>Minor degradation products:</i> Methylamine (particularly at pH 5); 1 unidentified compound (representing $\pm 5\%$ of AR at start of study and not increasing appreciably). <i>Product identification:</i> By match of HPLC retention times and TLC R_f values with those of reference compounds. Confirmation by mass spectrometry. <i>Mass balance:</i> Average recoveries of radioactivity were 95, 94 and 101% at pH 5, 7 and 9, respectively.		
	No guideline referenced GLP	Metam-sodium, 99,2% pure (Batch No. V799R): 200 mg/L solution, at pH 5, measurement of concentration after 24 hours: - at 10°C: 23.5% metam-sodium remained - at 20°C: 15.2% metam-sodium remained - at 30°C: 0% metam-sodium remained	Not acceptable Very limited information provided in the report; no raw data	Betteley, 2002a (UCB809/013754)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References																
	OECD 111 GLP	[¹⁴C]-Methyl Isothiocyanate (CH₃N=[¹⁴C]=S) (Batch No. 3501-187), radiochemical purity = 98.46%; 30 days incubation at 15°C, 25°C and 50°C; pH 4, 7 and 9 buffer solutions; Test conc. < 0.01 M <i>Estimated half-lives DT₅₀ (days) (assuming first order kinetics):</i> <table><tr><td></td><td>15°C</td><td>25°C</td><td>50°C</td></tr><tr><td>pH 4</td><td>(a)</td><td>≈ 40</td><td>2*</td></tr><tr><td>pH 7</td><td>(a)</td><td>50</td><td>2*</td></tr><tr><td>pH 9</td><td>22</td><td>14</td><td>< 1 day (b)</td></tr></table> *possibly underestimation because of poor resolution of MITC from degradation products in severely degraded samples → DT₅₀ calculated based on decline of MITC in first 7 days of incubation (a) No significant degradation observed → No DT₅₀ calculated (b) Rapid degradation, but kinetics not linear → No DT₅₀ calculated Degradation was found to be more extensive at higher temperatures and higher pH (concomitant with higher hydroxyl ion concentration).		15°C	25°C	50°C	pH 4	(a)	≈ 40	2*	pH 7	(a)	50	2*	pH 9	22	14	< 1 day (b)	Acceptable; MITC is shown to degrade significantly by hydrolysis at every pH and temperature (with the exception of pH 4 and 7 at 15°C). Estimations of half-lives were given and degradation pathways for MITC at pH 4, 7 and 9, respectively, were proposed in the study report. Degradation of MITC was found to be more extensive at higher temperatures and at higher pH (concomitant with higher hydroxyl ion concentration). Major degradation products were identified as dimethylurea (DMU), dimethyl thiourea (DMTU) and methyldithiocarbamic acid (MDTCA, i.e. metam)	Kidd et al., 2005 (Inveresk Report No. 24450)
	15°C	25°C	50°C																	
pH 4	(a)	≈ 40	2*																	
pH 7	(a)	50	2*																	
pH 9	22	14	< 1 day (b)																	

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
		<i>Major degradation products ($\geq 10\%$ of applied radioactivity AR):</i> Dimethylurea, dimethyl thiourea and methyldithiocarbamic acid (MDTCA) <i>Product identification:</i> By match of HPLC retention times with those of reference compounds. Confirmation by mass spectrometry. <i>Mass balance:</i> At pH 4: clear decrease of overall recovery of AR at higher temperature (down to 41% at 50°C), indicating that MITC was degrading to volatile degradates. At pH 7: decrease down to 79% at 50°C. At pH 9: mean recoveries in range 100-118% and no decrease, indicating that degradation of MITC at pH 9 gives rise to non-volatile components.	Besides, there were indications that volatile degradates were formed at pH 4 (and pH 7).	

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.1.15 Direct phototransformation in purified water using artificial light under sterile conditions (IIA 2.9.2)	No guideline referenced GLP	Metam-sodium 99.9% pure (Batch No. MNA SAP01): Irradiation for 5 hours, pH 7 buffer solution: Metam-sodium: 0.24183 h^{-1} Actinometer: 0.15791 h^{-1} Estimated photochemical half-life in the environment (latitude 52°N) = 3 days Due to potential hydrolytic behaviour of metam-sodium over an extended time period at pH 7, the photolysis measurements were not carried out directly on the test substance, but instead, the experiment was conducted on an actinometer adjusted to yield a similar rate of photolysis as the test substance.	Not acceptable Insufficient information provided in the study report, e.g. mass balance, identity of breakdown products, rate constant for dark controls	Betteley, 1997 (FCC 152/963829)
	No guideline referenced Not GLP (publication)	Metam-sodium dihydrate 98% pure Crescent Chemical Half-life: 2.9 - 8.4 min (equivalent to 44 min of midsummer sunlight at latitude 40°N in 10 cm deep water)	Study is not conducted according to GLP (publication) and therefore, it is not relied upon.	Draper en Wakeham, 1993

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	US-EPA Subdivision N Series 161-2 GLP-compliance stated (no GLP certificate, but study before 1993)	[methyl ^{14}C]-metam-sodium (WRC 9902-15-1), radiochemical purity > 95% Irradiation for up to 25 min; at 25°C; Initial concentration of metam-sodium in aqueous pH 7 buffered solutions was 53 mg/L: Irradiated: $k_{\text{overall}} = 0.064 \text{ min}^{-1}$; Dark control: $k_{\text{dark}} = 0.006 \text{ min}^{-1}$ $\rightarrow k_{\text{photolysis}} = 0.058 \text{ min}^{-1}$ $\Rightarrow$ Photochemical half-life: $\text{DT}_{50} = 12 \text{ min}$ (equivalent to 27.8 min of natural sunlight at latitude 38° N) <i>Major degradation products ($\geq 10\%$ of applied radioactivity AR):</i> - <u>N-methylthioformamide (syn- and anti- rotamer):</u> 22% of AR after 25 min $\text{H}_3\text{C}-\text{NH}-\underset{\text{S}}{\underset{\parallel}{\text{C}}}-\text{H}$ - <u>MCDT (sodium methylcarbamodithioperoxo)thioate):</u> 14% of AR after 25 min - <u>MITC (methylisothiocyanate):</u> 16% of AR after 25 min - <u>Methylamine:</u> 18% of AR after 25 min (zero-time sample contained 14% methylamine) <i>Product identification:</i> HPLC with UV-DAD or radioactive flow detector; Identity confirmation by GC-MS and ^1H-NMR spectroscopy. <i>Material balance:</i> Average recovery of radioactivity for the photolysed and dark control samples was 94%.	Acceptable In pH 7 buffered solution metam-sodium is very rapidly degraded by photolysis into N-methylthioformamide, MITC, methylamine and MCDT.	Spurgeon, 1990 (RR 90-091B)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.1.16 Quantum yield of direct phototransformation in water (IIA 2.9.3)	Not GLP (publication)	Metam-sodium dihydrate, 98% pure (Crescent Chemical): Mean quantum yield = 0.36 ± 0.093 (range 0.20 – 0.46)	Study is not conducted according to GLP (publication) and therefore, it is not relied upon. However, further data are not deemed to be necessary. In the environment, metam-sodium will rapidly degrade by hydrolysis and by direct phototransformation (see B.2.1.14 and B.2.1.15). Determination of the quantum yield of direct phototransformation for metam-sodium is therefore considered as not relevant and thus not required.	Draper en Wakeham, 1993 (American Chemical Society, J. Agric. Food Chem., 41, pp. 1129-1133)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.1.17 Dissociation in water – pKa value(s) (IIA 2.9.4)	OECD 112 (potentiostatic titration) GLP	Metam-sodium, 99.2% pure (Batch No.V799R): <i>[revised in June 2008 – peer reviewed in June 2008]</i> <u>pKa_I = 2.99</u> $\text{H}_3\text{C}-\text{NH}_2^+-\underset{\text{S}}{\underset{\parallel}{\text{C}}}-\text{SH} \rightleftharpoons \text{H}_3\text{C}-\text{NH}_2^+-\underset{\text{S}}{\underset{\parallel}{\text{C}}}-\text{S}^- + \text{H}^+$ pKa = 2.99 <u>pKa_{II} = 11.06</u> $\text{H}_3\text{C}-\text{NH}_2^+-\underset{\text{S}}{\underset{\parallel}{\text{C}}}-\text{S}^- \rightleftharpoons \text{H}_3\text{C}-\text{NH}-\underset{\text{S}}{\underset{\parallel}{\text{C}}}-\text{S}^- + \text{H}^+$ pKa = 11.06 “The structure is not dissimilar to that of an amino acid, which exists predominantly in the form of a dipolar ion and can react as an acid or base.”	Acceptable	Betteley, 2002b (UCB810/013755) + Letter ref. 41.152/05/ dd. 23 May 2005 (clarification identity of dissociated species) + additional clarification on identity of dissociated species <i>[added in June 2008 – peer reviewed in June 2008]</i>

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	OECD 112 (titration) GLP	Metam-potassium solid, 98% pure (Batch No. F081126+ F090212): pKa = 6.87	Not acceptable; The pKa value determined for metam-potassium is substantially different from the pKa values determined previously in a study with metam-sodium (<i>vide supra</i> : Betteley, 2002b; pKa _I : 2.99; pKa _{II} : 11.06), which were in accordance with the proposed structures of the ionic species. Given the fact that we are dealing with two salt variants of the same molecule (metam), such large differences are deemed not possible. The abnormal result could not be explained, although the applicant suggested degradation of the test substance as a possible cause.	Kelly, 2009 (J17224/B) [added in August 2010]

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.1.18 Estimated photochemical oxidative degradation (IIA 2.10)	Calculation with Atmospheric Oxidation Program (based on Atkinson method, AOPWIN v1.90) GLP not applicable (calculation)	Metam-sodium: Hydroxyl rate constant = 64.3×10^{-12} cm ³ /molecule-sec ⇒ DT ₅₀ = 1.997 hours (based on 24-hrs day) (assuming a hydroxyl radical concentration of 1.5×10^6 OH radicals/cm ³)	Acceptable Metam-sodium is expected to be very rapidly degraded in air.	Betteley, 2001 (UCB 811/013383)
B.2.1.19 Flammability (IIA 2.11.1)	EEC A10 GLP	Metam-sodium, 97.0% pure (Batch No. MNA-Tox-002): In the presence of the test flame, the test compound melted into a yellow/gold liquid. The compound did not ignite.	Acceptable Metam-sodium (solid, 97% pure) is not considered as highly flammable.	Betteley, 1997 (FCC 152/963829)
B.2.1.20 Auto-flammability (IIA 2.11.2)	EEC A16 (thermal analysis method: DTA) GLP	Metam-sodium, 97.0% pure (Batch No. MNA-Tox-002): The test substance did not self-ignite when heated from ambient temperature to 450 °C.	Acceptable Metam-sodium (solid, 97% pure) is not considered as auto-flammable.	Betteley, 1997 (FCC 152/963829)
	EEC A15 GLP	Metam-sodium 510 g/L (Batch No. V787R/0727SH/32G): No self-ignition of test substance was observed between room temperature and 400 °C.	Acceptable Metam-sodium 510 g/L is not auto-flammable.	Tremain, 2000 (378/046)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	EEC A15 GLP	Metam-potassium 690 g/L (Batch No. 081121T32I): At 342°C, rapid sparking of the samples was observed (stopped after about 1 second). No distinct ignition occurred.	Acceptable Metam-potassium 690 g/L is not auto-flammable.	White, 2009a (J17223) [added in August 2010]
B.2.1.21 Flash point (IIA 2.12)	Statement	Metam-sodium: Statement notifier: “Not relevant: no flammable liquids involved and melting point of active substance is > 40°C.”	According to the FAO specification for Metam-sodium aqueous solutions (Code 20.1Na/13/S/15), the flash point of the preparation should be minimum 66°C, which implies that flash point determination (before and after storage stability test) is required in order to allow verification of compliance with FAO specification. See below for an experimental study.	
	EEC A9 (Pensky Martens Closed Cup) GLP	Metam-sodium 510 g/L (Batch No. 081117T32F): No flash point observed. At a temperature of 51 to 52°C, a change in colour of the test flame was noted. At a temperature of 97°C, sample boiled and extinguished the flame.	Acceptable The preparation Metam-sodium 510 g/L is not flammable (flash point > 97°C). Compliance with the FAO specification (Code 20.1Na/13/S/15) is herewith demonstrated.	Knowles, 2009 (J17220) [added in August 2010]

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	Statement	Metam-potassium: Statement notifier: <i>"Not relevant: no flammable liquids involved and melting point of active substance is > 40°C."</i>	Statement is not accepted. A melting point was not provided for metam-potassium. See below for an experimental study.	
	EEC A9 (Pensky Martens Closed Cup) GLP	Metam-potassium 690 g/L (Batch No. 081121T321): No flash point observed. At a temperature of 102°C, sample boiled and extinguished the flame.	Acceptable Metam-potassium 690 g/L is not flammable (flash point > 102°C).	White, 2009a (J17223) [added in August 2010]
B.2.1.22 Explosive properties (IIA 2.13)	EEC A14 GLP	Metam-sodium, 97.0% pure (Batch No. MNA-Tox-002): No explosion was observed when submitting the test substance to the effect of a flame (thermal sensitivity) or to shock (mechanical sensitivity) or friction (sensitivity to mechanical stimuli).	Acceptable Metam-sodium (solid, 97% pure) is not considered as explosive.	Betteley, 1997 (FCC 152/963829)
	Differential Scanning Calorimetry (DSC) + theoretical assessment GLP	Metam-potassium 690 g/L (Batch No. 081121T321): DSC examination: heating test specimen from 30° to 400°C did not result in a significant exothermic event. Theoretical assessment: Metam-K does not possess chemical groups associated with explosive properties (e.g. -NO ₂ , -NO ₃ , -N ₃ , peroxide, chlorate, perchlorate, nitrate, bromate, chromate) and the rest of the formulation is water, which poses no risk with regard to explosivity.	Acceptable Metam-potassium 690 g/L is not expected to possess explosive properties.	White, 2009a (J17223) [added in August 2010]

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.1.23 Surface tension (IIA 2.14)	EEC A5 (ring method) GLP	Metam-sodium, 97.0% pure (Batch No. MNA-Tox-002): 1 g/L aqueous solution : 72.0 mN/m at 21°C	Acceptable Metam-sodium (solid, 97% pure) is not considered to be a surface-active compound.	Betteley, 1997 (FCC 152/963829)
	EEC A5 (ring method ISO 304) GLP	Metam-sodium 510 g/L (Batch No. V787R/0727SH/32G) Undiluted formulation: 63.0 mN/m at 25 °C	Acceptable The formulation Metam-sodium 510 g/L is not considered as being surface active. It should be noted that this study is actually not required.	Lumsden, 2000a (378/036)
	Method du Nouy (ring method) Not GLP	Metam-potassium solution containing 43.2% w/w active ingredient (Sample ID No. L9709KF) 39.4 mN/m	Results suggest that metam-potassium is a surface-active compound. However, the study is not GLP and hence, it cannot be relied upon.	Van de Putte, 1997 (W/RL/9712/004)
	EEC A5 (Du-Nüoy Tensiometer – ring method) GLP	Metam-potassium 690 g/L (Batch No. 081121T32I): Neat (undiluted) formulation: 51.5 mN/m at 20 °C 1 g/L aqueous solution: 55.1 mN/m at 20 °C	Acceptable Metam-potassium 690 g/L is a surface-active preparation.	White, 2009a (J17223) [added in August 2010]

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.1.24 Oxidising properties (IIA 2.15)	Expert statement GLP	Metam-sodium: Expert statement: <i>"In considering the molecular structure of metam-sodium, it clearly contains no oxygen atoms other than those associated with water of crystallisation. Metam-sodium cannot provide oxygen in a form that can enhance the burning rate of a combustible material and therefore cannot act as an oxidiser."</i>	Statement is considered acceptable. Metam-sodium is not expected to possess oxidising properties.	Betteley, 2001 (UCB 812/013400)
	theoretical assessment GLP not applicable	Metam-potassium 690 g/L (Batch No. 081K21T32I): Metam-K does not possess chemical groups associated with oxidising properties (no oxygen, fluorine or chlorine present). The rest of the formulation is water, which poses no risk with regard to oxidising properties.	Acceptable Metam-potassium 690 g/L is not expected to possess oxidising properties.	White, 2009a (J17223) [added in August 2010]

Summary and conclusions:

Pure metam-sodium is a white crystalline powder with a sweet onion-like smell and a relative density (D_4^{20}) of 1.44. Its melting point is in the range 86.5 – 90.5 °C and decomposition has been observed at 150°C and at 215°C. It is moderately volatile (vapour pressure = $5.75 \cdot 10^{-2}$ Pa at 25°C) and readily soluble in water (578.29 g/L at 20°C) and thus, slightly volatile from water ($H = 8.34 \times 10^{-6}$ Pa.m³.mol⁻¹ at 20°C). Metam-sodium is also readily soluble in methanol, but in other organic solvents, solubility is relatively low (< 0.26 g/L). It is not a surface-active compound (surface tension of 1 g/L aqueous solution at 21°C: 72.0 mN/m). In diluted concentrations, metam-sodium is subject to fast hydrolysis (estimated half-lives at 25°C ranging from few hours to few days). Main degradation products are MITC, methylamine and MCDT (sodium methylcarbamodithioperoxothioate). Hydrolysis appears to be accelerated with decreasing pH. In pH 7-buffered solution, metam-sodium is very rapidly degraded by direct phototransformation into N-methylthioformamide, MITC, methylamine and MCDT (photochemical half-life: $DT_{50} = 12$ min, equivalent to 27.8 min of natural sunlight at latitude 38° N). With a log Pow < -2.9, it is not critical with respect to bioaccumulation. It is not considered as highly flammable or auto-flammable and has no explosive or oxidising properties. Metam-sodium is expected to be very rapidly degraded in air.

Metam-sodium as manufactured is a yellowish clear aqueous solution (containing 510 g/L metam-sodium) with a weak CS₂ and H₂S odour. It is not surface-active and not auto-flammable. Flash point was determined to be > 97°C and thus, compliance with FAO specification (Code 20.1Na/13/S/15) (requiring flash point ≥ 66°C) was demonstrated.

Metam-potassium is another variant (salt) of metam. Based on the chemical similarity with metam-sodium, it is expected that hydrolysis, photolysis, octanol-water partition, dissociation in water, flammability, explosive and oxidising properties of metam-potassium will be comparable to that/those of Metam-sodium.

Purified metam-potassium is a pale yellow, crystalline/amorphous powder with a slightly acrid, sulphurous odour and a relative density (D₄²⁰) of 1.58. It decomposes (before melting) at a temperature of approximately 150°C. The determined octanol/water partition coefficient (log Pow of -3.47) reconfirms that bioaccumulation of metam-(potassium) in the environment is not to be expected.

Metam-potassium as manufactured is a clear, light yellow liquid (aqueous solution containing 690 g/L metam-potassium) with a pungent, sulphurous odour. The solution is surface-active (surface tension of neat/undiluted preparation and 1g/L aqueous solution: 51.5 and 55.1 mN/m at 20°C, respectively). Furthermore, the aqueous solution is not flammable (flash point > 102°C), not auto-flammable and is not expected to possess explosive or oxidising properties.

MITC (impurity/main degradation product of metam):

Purified MITC is a colourless, crystalline solid. It is highly volatile (vapour pressure at 20°C: 1739 Pa) and readily soluble in water (8.94 g/L at 20°C) and thus, moderately volatile from water (H = 14.2 Pa.m³/mol at 20 °C). MITC has a log Pow of 1.05 and hence, bioaccumulation of MITC in the environment is not expected. Hydrolysis of MITC was found to be significant and appeared to be more extensive at higher temperatures and at higher pH (concomitant with higher hydroxyl ion concentration). Estimated half-lives at 25°C were 40, 50 and 11 days at pH 4, pH 7 and pH 9, respectively. Major degradation products were identified as dimethylurea (DMU), N,N'-dimethyl thiourea (DMTU) and methyldithiocarbamic acid (MDTCA, i.e. metam). Furthermore, there were indications that volatile degradation products were formed at pH 4 (and pH 7).

DMTU (impurity):

DMTU is a highly volatile substance (vapour pressure of 832.95 Pa at 20°C). It is moderately volatile from water (H = 0.149 Pa.m³/mol at 20°C), in which it is readily soluble (≥ 581.98 g/L at room temperature). Its low octanol/water partition coefficient (log Pow = - 0.23) indicates that bioaccumulation of DMTU in the environment is not to be expected.

B.2.2. Physical, chemical and technical properties of the plant protection product(s) (Annex IIIA 2)Table B.2.2-1: Physical, chemical and technical properties of **METAM-SODIUM 510 g/L** (Soluble Concentrate (SL))(Note: in addition, some provided information for **METAM-POTASSIUM 690 g/L** aqueous solution has been evaluated and reported)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.2.1 Physical state, colour (IIIA 2.1)	Visual inspection (ASTM D1209-79) Not GLP	Metam-sodium 510 g/L (Coded 32 F 05/03/2001): Yellow clear solution (264 APHA)	Acceptable	Van Hecke et al., 2001a (W/RL/200101/001)
	Visual inspection (OPPTS 830.6302 OPPTS 830.6303) GLP	Metam-potassium 53.62% w/w aqueous solution (i.e. soluble concentrate, as manufactured) (Batch V11/01): Clear, light yellow liquid	Acceptable	Ambroz Hahn, 2002a (ABC Study No. 47104)
B.2.2.2 Odour (IIIA 2.1)	Organoleptic determination Not GLP	Metam-sodium 510 g/L (Coded 32 F 05/03/2001): Weak CS ₂ and H ₂ S odour	Acceptable	Van Hecke et al., 2001a (W/RL/200101/001)
	OPPTS 830.6304 (inhalation) GLP	Metam-potassium 53.62% w/w aqueous solution (i.e. soluble concentrate, as manufactured) (Batch V11/01): Pungent odour similar to sulphur	Acceptable	Ambroz Hahn, 2002a (ABC Study No. 47104)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.2.3 Explosive properties (IIIA 2.2.1)	Statement GLP not relevant (statement)	Metam-sodium 510 g/L: Statement notifier: <i>"The a.s. has shown not to exhibit any explosive properties under the test conditions described in the guideline." (Sec B.2.1.22) "As the a.s. comprises over 40% of the aqueous formulation, and water is not explosive, it can be concluded that the formulation as a whole does not exhibit any explosive properties."</i>	Statement is considered to be acceptable. The formulation Metam-sodium 510 g/L is not expected to have explosive properties.	
	Differential Scanning Calorimetry (DSC) + theoretical assessment GLP	Metam-potassium 690 g/L (Batch No. 081121/32I): DSC examination: heating test specimen from 30° to 400°C did not result in a significant exothermic event. Theoretical assessment: Metam-K does not possess chemical groups associated with explosive properties (e.g. -NO ₂ , -NO ₃ , -N ₃ , peroxide, chlorate, perchlorate, nitrate, bromate, chromate) and the rest of the formulation is water, which poses no risk with regard to explosivity.	Acceptable Metam-potassium 690 g/L is not expected to possess explosive properties.	White, 2009a (J17223) [added in August 2010]
B.2.2.4 Oxidizing properties (IIIA 2.2.2)	Expert statement GLP	Metam-sodium: Expert statement: <i>"In considering the molecular structure of metam-sodium, it clearly contains no oxygen atoms other than those associated with water of crystallisation. Metam-sodium cannot provide oxygen in a form that can enhance the burning rate of a combustible material and therefore cannot act as an oxidiser."</i>	The expert statement concerns the oxidising potential of purified/solid metam-sodium. However, taken into account the fact that the preparation is an aqueous solution of metam-sodium, it is considered unlikely that the preparation would have oxidising properties. Therefore, no further data are deemed necessary.	Betteley, 2001 (UCB 812/013400)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	theoretical assessment GLP not applicable	Metam-potassium 690 g/L (Batch No. 081121T32I): Metam-K does not possess chemical groups associated with oxidising properties (no oxygen, fluorine or chlorine present). The rest of the formulation is water, which poses no risk with regard to oxidising properties.	Acceptable Metam-potassium 690 g/L is not expected to possess oxidising properties.	White, 2009a (J17223) [added in August 2010]
B.2.2.5 Flash point (IIIA 2.3)	Statement GLP not relevant (statement)	Metam-sodium 510 g/L: Statement notifier: “Not required. The formulation does not contain flammable solvents.”	According to the FAO specification for Metam-sodium aqueous solutions (Code 20.1Na/13/S/15), the flash point of the preparation should be minimum 66°C, which implies that flash point determination (before and after storage stability test) is required in order to allow verification of compliance with FAO specification. See below for an experimental study.	
	EEC A9 (Pensky Martens Closed Cup) GLP	Metam-sodium 510 g/L (Batch No. 081117T32F): No flash point observed. At a temperature of 51 to 52°C, a change in colour of the test flame was noted. At a temperature of 97°C, sample boiled and extinguished the flame.	Acceptable The preparation Metam-sodium 510 g/L is not flammable (flash point > 97°C). Compliance with the FAO specification (Code 20.1Na/13/S/15) is herewith demonstrated.	Knowles, 2009 (J17220) [added in August 2010]

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	EEC A9 (Pensky Martens Closed Cup) GLP	Metam-potassium 690 g/L (Batch No. 081121T32I): No flash point observed. At a temperature of 102°C, sample boiled and extinguished the flame.	Acceptable Metam-potassium 690 g/L is not flammable (flash point > 102°C).	White, 2009a (J17223) [added in August 2010]
B.2.2.6 Flammability (IIIA 2.3)			Not required, as Metam-sodium 510 g/L is a liquid preparation.	
B.2.2.7 Auto-flammability (IIIA 2.3)	EEC A15 GLP	Metam-sodium 510 g/L (Batch No. V787R/0727SH/32G) No self ignition of test substance was observed between room temperature and 400 °C.	Acceptable Metam-sodium 510 g/L is not auto-flammable.	Tremain, 2000 (378/046)
	EEC A15 GLP	Metam-potassium 690 g/L (Batch No. 081121T32I): At 342°C, rapid sparking of the samples was observed (stopped after about 1 second). No distinct ignition occurred.	Acceptable Metam-potassium 690 g/L is not auto-flammable.	White, 2009a (J17223) [added in August 2010]
B.2.2.8 Acidity or alkalinity and pH value (IIIA 2.4.1)	CIPAC MT 75.3 GLP	Metam-sodium 43.0% w/w (Batch No. V820-2A2432F): pH = 9.6	Acceptable	Tognucci, 2003 (RCC 846139)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	In-house method 09E3415 (based on CIPAC MT 31) Not GLP	Metam-sodium 510 g/L (Batch No. 32F 05/03/2001): Alkalinity expressed as % NaOH: 0.016 Alkalinity expressed as % mono-methylamine: 0.012%	Study is not GLP and hence, it cannot be relied upon. However, acidity/alkalinity data are not required, as pH of the preparation is between 4 and 10 (see above).	Van Hecke et al., 2001b (W/RL/200101/002)
B.2.2.9 pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	CIPAC MT 75.3 GLP	Metam-sodium 510 g/L (Batch No. 32 F0704): 1% (w/v) aqueous solution of test substance: pH = 8.11 at 21.5°C	Acceptable	Howes, 2003 (PFX 001/032863)
	OPPTS 830.7000 GLP	Metam-potassium 53.62% w/w aqueous solution (i.e. soluble concentrate, as manufactured) (Batch V11/01): 1% (w/w) aqueous solution of test substance: pH = 7.69 at 25°C	Acceptable	Ambroz Hahn, 2002a (ABC Study No. 47104)
B.2.2.10 Kinematic viscosity (IIIA 2.5.1)			Not relevant; Ultra Low Volume use is not intended for the preparation Metam-sodium 510 g/L.	
B.2.2.11 Viscosity (IIIA 2.5.2)	OECD 114 (capillary viscometer) GLP	Metam-sodium 510 g/L aqueous solution (Batch No. V779R/0315SH/32G): 3.54 mm ² /s at 20°C 2.03 mm ² /s at 40°C	The study is acceptable. Metam-sodium 510 g/L (SL) can be regarded as a Newtonian liquid.	Lumsden, 2000b (378/037)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References													
	OPPTS 830.7100 (rotational viscometer) GLP	Metam-potassium 53.62% w/w aqueous solution (Batch V11/01): <table><tr><th>Temperature (°C)</th><th>rpm</th><th>Viscosity (mPa.s)</th></tr><tr><td rowspan="2">20</td><td>50</td><td>3.7</td></tr><tr><td>100</td><td>3.8</td></tr><tr><td rowspan="2">40</td><td>50</td><td>2.8</td></tr><tr><td>100</td><td>2.6</td></tr></table>	Temperature (°C)	rpm	Viscosity (mPa.s)	20	50	3.7	100	3.8	40	50	2.8	100	2.6	Acceptable; The preparation Metam-potassium (54% aqueous solution) can be regarded as a Newtonian fluid.	Ambroz Hahn, 2002b (ABC Study No. 47106)
Temperature (°C)	rpm	Viscosity (mPa.s)															
20	50	3.7															
	100	3.8															
40	50	2.8															
	100	2.6															
B.2.2.12 Surface tension (IIIA 2.5.3)	EEC A5 (ring method ISO 304) GLP	Metam-sodium 510 g/L (Batch No. V787R/0727SH/32G): 63.0 mN/m at 25 °C	Acceptable The formulation Metam-sodium 510 g/L is not considered as being surface active. It should be noted that determination of the surface tension is actually not triggered, since an aspiration hazard (cfr. R65) is not to be considered (formulation does not contain more than 10% hydrocarbons).	Lumsden, 2000a (378/036)													
	Method du Nouy (ring method) Not GLP	Metam-potassium solution containing 43.2% w/w active ingredient (Sample ID No. L9709KF): 39.4 mN/m	Study is not GLP and hence, it cannot be relied upon.	Van de Putte, 1997 (W/RL/9712/004)													

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	EEC A5 (Du-Nüoy Tensiometer – ring method) GLP	Metam-potassium 690 g/L (Batch No. 081121T32I): Neat (undiluted) formulation: 51.5 mN/m at 20 °C 1 g/L aqueous solution: 55.1 mN/m at 20 °C	Acceptable Metam-potassium 690 g/L is a surface-active preparation.	White, 2009a (J17223) cf. IIA 2.14 [added in August 2010]
B.2.2.13 Relative density (IIIA 2.6.1)	EEC A3 (pycnometer; ISO 758) GLP	Metam-sodium 510 g/L (Batch No. V787R/0727SH/32G): $D_4^{20} = 1.21$ (at 20.0 ± 0.5 °C)	Acceptable	Lumsden, 2000c (378/038)
	EEC A3 (pycnometer) GLP	Metam-potassium 53.62% w/w aqueous solution (Batch V11/01): $D_4^{20} = 1.278$ (at 20°C)	Acceptable	Ambroz Hahn, 2002a (ABC Study No. 47104)
B.2.2.14 Bulk or tap density (IIIA 2.6.2)			Not required for liquid preparations	

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References															
B.2.2.15 Stability after storage for 14 days at 54°C (IIIA 2.7.1)	CIPAC MT 46.3 + methods as indicated under individual points GLP	Metam-sodium 43.0%w/w (Batch No. V820-2A2432F); stored in HDPE bottles (with screw cap) for 14 days at 54°C: <table><tr><th>arameter</th><th>initial</th><th>after storage (14d, 54°C)</th></tr><tr><td>Appearance (visual inspection + nasal inhalation)</td><td>Clear yellowish liquid of low viscosity; Faint odour</td><td>Clear yellowish liquid with low viscosity; Strong smell of hydrogensulfide; No obvious alteration of bottles.</td></tr><tr><td>Content of a.i. (UCB method 09E3411; based on CIPAC 20/13/M/1.3)</td><td>42.0% w/w (510.1 g/L)</td><td>42.3% w/w (513.6 g/L)</td></tr><tr><td>pH (CIPAC MT 75.3)</td><td>9.6</td><td>8.9</td></tr><tr><td>Solution stability (CIPAC MT 41; standard water D; 18 hrs at 20°C)</td><td>No visible sediment or solid particles</td><td>No visible sediment or solid particles</td></tr></table>	arameter	initial	after storage (14d, 54°C)	Appearance (visual inspection + nasal inhalation)	Clear yellowish liquid of low viscosity; Faint odour	Clear yellowish liquid with low viscosity; Strong smell of hydrogensulfide; No obvious alteration of bottles.	Content of a.i. (UCB method 09E3411; based on CIPAC 20/13/M/1.3)	42.0% w/w (510.1 g/L)	42.3% w/w (513.6 g/L)	pH (CIPAC MT 75.3)	9.6	8.9	Solution stability (CIPAC MT 41; standard water D; 18 hrs at 20°C)	No visible sediment or solid particles	No visible sediment or solid particles	Acceptable Content of a.i. does not significantly change upon accelerated storage. Only significant change observed was the more intense smell of hydrogensulfide after storage. The results indicate that preparation Metam-sodium 510 g/L remains stable during storage for 14 days at 54°C.	Tognucci, 2003 (RCC 846139)
arameter	initial	after storage (14d, 54°C)																	
Appearance (visual inspection + nasal inhalation)	Clear yellowish liquid of low viscosity; Faint odour	Clear yellowish liquid with low viscosity; Strong smell of hydrogensulfide; No obvious alteration of bottles.																	
Content of a.i. (UCB method 09E3411; based on CIPAC 20/13/M/1.3)	42.0% w/w (510.1 g/L)	42.3% w/w (513.6 g/L)																	
pH (CIPAC MT 75.3)	9.6	8.9																	
Solution stability (CIPAC MT 41; standard water D; 18 hrs at 20°C)	No visible sediment or solid particles	No visible sediment or solid particles																	
B.2.2.16 Stability after storage			Alternative temperature/ time conditions are not																

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
for other periods and temperatures (IIIA 2.7.1)			required as preparation is not heat-sensitive (see B.2.2.15).	
B.2.2.17 Minimum content after heat stability testing (IIIA 2.7.1)			No reduction of metam-sodium content was observed (see B.2.2.15). Hence, no statement is required.	
B.2.2.18 Effect of low temperatures on stability (IIIA 2.7.2)	CIPAC MT 39.2 GLP	Metam-sodium 510 g/L (Batch No. V787R/0727SH/32G): No sediment, precipitate or separation was observed before or after storage. ⇒ Metam-sodium 510 g/L is physically stable to storage at $0 \pm 1^\circ\text{C}$ for 48 hours.	Not acceptable Effect of low temperature on stability was determined after 48 hours at 0°C (CIPAC MT 39.2), whereas FAO/WHO prescribes use of CIPAC MT 39.3 for SL (7 days at 0°C).	Lumsden, 2000d (378/039)
	CIPAC MT 39.2 GLP	Metam-potassium, 53.62% w/w aqueous solution (Batch V11/01): No phase separation was observed after storage. ⇒ Metam-potassium 54% w/w is physically stable to storage at $0 \pm 1^\circ\text{C}$ for 48 hours.	Not acceptable Effect of low temperature on stability was determined after 48 hours at 0°C (CIPAC MT 39.2), whereas FAO/WHO prescribes use of CIPAC MT 39.3 for SL (7 days at 0°C).	Sarff, 2002 (ABC Report No. 47105-A)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	CIPAC MT 39.3 GLP	Metam-sodium 510 g/L (Batch No. G560053078): No visual change of the clear solution after storage; no separated material observed. ⇒ Metam-sodium 510 g/L is physically stable to storage at 0 °C for 7 days.	Acceptable	Widmer, 2005a (RCC A21701)
	CIPAC MT 39.3 GLP	Metam-potassium 690 g/L (Batch No. G560039845): No visual change of the clear solution after storage; no separated material observed. ⇒ Metam-potassium 690 g/L is physically stable to storage at 0 °C for 7 days.	Acceptable	Widmer, 2005b (RCC A21712)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References															
B.2.2.19 Shelf life at ambient temperature (IIIA 2.7.3)	GIFAP Monograph No. 17 + methods as indicated under individual points Not GLP	Metam-sodium 510 g/L (Batch No. 32F05032001, 32F07032001, 32F08032001); Storage in HDPE containers of 250 mL with screw cap for 2 years at ambient temperature; The storage temperature was monitored during the test and the variation was reported (fluctuation between -0.3°C and 32°C). <table><tr><th>Parameter</th><th>initial</th><th>after storage (2 years)</th></tr><tr><td>Appearance (visual inspection + nasal inhalation)</td><td>- Clear, yellowish liquid with weak CS₂ and H₂S odour; - No crystallisation or precipitation; - No significant interaction between formulation and packaging; - Loss of weight: max. 1.72%</td><td></td></tr><tr><td>Density (kg/L) (method 09E3412)</td><td>1.21</td><td>1.21</td></tr><tr><td>Content of a.i. (g/L) (UCB method 09E3411; based on CIPAC 20/13/M/1.3)</td><td>1st batch: 506.7 2nd batch: 500.9 3rd batch: 498.1 (Average: 501.9)</td><td>1st batch: 493.7 2nd batch: 471.7 3rd batch: 492.0 (Average 485.8) (i.e. 3.2% decrease in average)</td></tr><tr><td>pH (method 09E3413 based on CIPAC MT 75)</td><td>8.7 (average)</td><td>9.5 (average)</td></tr></table>	Parameter	initial	after storage (2 years)	Appearance (visual inspection + nasal inhalation)	- Clear, yellowish liquid with weak CS ₂ and H ₂ S odour; - No crystallisation or precipitation; - No significant interaction between formulation and packaging; - Loss of weight: max. 1.72%		Density (kg/L) (method 09E3412)	1.21	1.21	Content of a.i. (g/L) (UCB method 09E3411; based on CIPAC 20/13/M/1.3)	1 st batch: 506.7 2 nd batch: 500.9 3 rd batch: 498.1 (Average: 501.9)	1 st batch: 493.7 2 nd batch: 471.7 3 rd batch: 492.0 (Average 485.8) (i.e. 3.2% decrease in average)	pH (method 09E3413 based on CIPAC MT 75)	8.7 (average)	9.5 (average)	Acceptable A slight decrease of active ingredient content was observed. However, the average decrease (over the three batches) is below 5% and moreover, the relatively high decrease (i.e. 5.8%) for the 2 nd batch material is probably due to the sample container not being hermetically closed and dissipation of volatile product through the screw cap. This assumption is supported by the results obtained for this sample container in the loss-of-weight test. No significant change in appearance and no interaction with the package was observed. pH was in the range 8.6 – 9.9. Metam-sodium 510 g/L is considered to be stable for 2 years at ambient temperatures. GLP storage stability study with analysis of the relevant impurities before and after storage (cf. data gap identified in EFSA conclusion of 26 November	Van Hecke et al., 2003a (W/RL/200303001)
Parameter	initial	after storage (2 years)																	
Appearance (visual inspection + nasal inhalation)	- Clear, yellowish liquid with weak CS ₂ and H ₂ S odour; - No crystallisation or precipitation; - No significant interaction between formulation and packaging; - Loss of weight: max. 1.72%																		
Density (kg/L) (method 09E3412)	1.21	1.21																	
Content of a.i. (g/L) (UCB method 09E3411; based on CIPAC 20/13/M/1.3)	1 st batch: 506.7 2 nd batch: 500.9 3 rd batch: 498.1 (Average: 501.9)	1 st batch: 493.7 2 nd batch: 471.7 3 rd batch: 492.0 (Average 485.8) (i.e. 3.2% decrease in average)																	
pH (method 09E3413 based on CIPAC MT 75)	8.7 (average)	9.5 (average)																	

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References												
	GIFAP Monograph No. 17 + methods as indicated under individual points GLP	Metam-potassium, 53.8% w/w aqueous solution (Batch No. V819); Storage in 125 mL HDPE bottles with screw caps over period of 2 years at 25°C / 60% r.H. and 30°C / 60% r.H. <table><tr><th>Parameter</th><th>initial</th><th>after storage for 2 years at 25°C</th><th>after storage for 2 years at 30°C</th></tr><tr><td>Appearance (visual inspection)</td><td colspan="3">Clear, slightly yellowish liquid</td></tr><tr><td>Content of a.i. (% w/w) (UCB method 09E3D1; based on CIPAC 20/13/M/1.3)</td><td>53.1</td><td>52.3</td><td>52.1</td></tr></table>	Parameter	initial	after storage for 2 years at 25°C	after storage for 2 years at 30°C	Appearance (visual inspection)	Clear, slightly yellowish liquid			Content of a.i. (% w/w) (UCB method 09E3D1; based on CIPAC 20/13/M/1.3)	53.1	52.3	52.1	Metam-potassium 690 g/L appears to remain stable after storage for 2 years at 25°C or 30°C. However, it should be noted that pH was not investigated. GLP storage stability study with analysis of the relevant impurities before and after storage (cf. data gap identified in EFSA conclusion of 26 November 2008) is ongoing.	Tognucci, 2004 (RCC 846298)
Parameter	initial	after storage for 2 years at 25°C	after storage for 2 years at 30°C													
Appearance (visual inspection)	Clear, slightly yellowish liquid															
Content of a.i. (% w/w) (UCB method 09E3D1; based on CIPAC 20/13/M/1.3)	53.1	52.3	52.1													
B.2.2.20 Wettability (IIIA 2.8.1)			Not required for liquid formulation													

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.2.21 Persistent foaming (IIIA 2.8.2)	CIPAC MT 47 Not GLP	Metam-sodium 510 g/L (Lot No. G330026113): 5% (v/v) in standard water C: 0 ml foam after 10 s, 1, 3 and 10 min.	Not required, as metam-sodium 510 g/L is not intended to be diluted with water before use (in the sense that no spray solution is to be prepared; In the case of drip irrigation with metam the dilution with water only takes place during the actual application, i.e. in the tubes of the irrigation system with instantaneous application).	Van Hecke et al., 2003b (W/RL/200303/002)
	CIPAC MT 47.2 GLP	Metam-potassium 690 g/L (Batch No. 081121T321): At 30°C, diluted in standard water D: 0.1 % w/v: no foam observed after 10 seconds 2.0 % w/v: no foam observed after 10 seconds	Acceptable No persistent foam is formed when Metam-potassium 690 g/L is diluted in water. However, it should be noted that strictly speaking, this test is not required, as metam-potassium 690 g/L is not intended to be diluted with water before use (in the sense that no spray solution is to be prepared).	Knowles, 2009 (J17221) [added in August 2010]
B.2.2.22 Suspensibility (IIIA 2.8.3)			Not required for SL	

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References						
B.2.2.23 Spontaneity of dispersion (IIIA 2.8.3)			Not required for SL							
B.2.2.24 Dilution stability (IIIA 2.8.4)	CIPAC MT 41 GLP	Metam-sodium 43.0%w/w (Batch No. V820-2A2432F): <table><tr><th>Parameter</th><th>initial</th><th>after storage (14d, 54°C)</th></tr><tr><td>Solution stability (CIPAC MT 41; standard water D; 18 hrs at 20°C)</td><td>No visible sediment or solid particles</td><td>No visible sediment or solid particles</td></tr></table>	Parameter	initial	after storage (14d, 54°C)	Solution stability (CIPAC MT 41; standard water D; 18 hrs at 20°C)	No visible sediment or solid particles	No visible sediment or solid particles	Acceptable The preparation metam-sodium 510 g/L is a stable aqueous solution (SL) and remains stable after accelerated storage (14 days at 54°C).	Tognucci, 2003 (RCC 846139)
Parameter	initial	after storage (14d, 54°C)								
Solution stability (CIPAC MT 41; standard water D; 18 hrs at 20°C)	No visible sediment or solid particles	No visible sediment or solid particles								
B.2.2.25 Dry sieve test and wet sieve test (IIIA 2.8.5)	CIPAC CODE 20/13/M/1.5 Non-GLP	Metam-sodium, 510 g/L: Residue remaining on a 125µm sieve (7 cm diameter): <0.0014 % w/w	Acceptable The amount of insoluble material retained on a 125µm test sieve meets the FAO spec. (i.e. max. 0.2% w/w).	Van Herreweghe, 2007 (Report no. W/RL/200706/001) [added in June 2008 – peer reviewed in June 2008]						

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
	CIPAC CODE 20/13/M/1.5 Non-GLP	Metam-potassium, 690 g/L: Residue remaining on a 125µm sieve (7 cm diameter): <0.0016% w/w	Acceptable The amount of insoluble material retained on a 125µm test sieve meets the FAO spec. (i.e. max. 0.2% w/w).	Van Herreweghe, 2007 (Report no. W/RL/200706/002) <i>[added in June 2008 – peer reviewed in June 2008]</i>
B.2.2.26 Size distribution of particles – Nominal size range of granules (IIIA 2.8.6.1)				
B.2.2.27 Dust content and particle size of dust (IIIA 2.8.6.2)			Not applicable (metam-sodium 510 g/L is not a granular preparation)	
B.2.2.28 Friability and attrition characteristics of granules (IIIA 2.8.6.3)			Not applicable (metam-sodium 510 g/L is not a granular preparation)	
B.2.2.29 Emulsifiability, emulsion stability, re-emulsifiability (IIIA 2.8.7.1)			Not required for SL	
B.2.2.30 Stability of dilute			Not required for SL	

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
emulsions and of preparations which are emulsions (IIIA 2.8.7.2)				
B.2.2.31 Flowability (IIIA 2.8.8.1)			Not applicable (metam-sodium 510 g/L is not a granular preparation)	
B.2.2.32 Pourability (including rinsed residue) (IIIA 2.8.8.2)			Not required for SL	
B.2.2.33 Dustability following accelerated storage (IIIA 2.8.8.3)			Not applicable (metam-sodium 510 g/L is not a DP)	
B.2.2.34 Physical compatibility of tank mixes (IIIA 2.9.1)	Statement	<i>"Not required - no tank mixes"</i>	Not applicable (no tank mixes)	
B.2.2.35 Chemical compatibility of tank mixes (IIIA 2.9.2)	Statement	<i>"Not required - no tank mixes"</i>	Not applicable (no tank mixes)	

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.2.36 Distribution and adhesion to seeds (IIIA 2.10)			Not applicable (Metam-sodium 510 g/L is not intended for seed treatment)	

Summary and conclusions:

The preparation **Metam-sodium 510 g/L** (*soluble concentrate, SL*) is identical to the technical product **active ingredient** as manufactured. It is a clear, yellowish solution with a weak CS₂ and H₂S odour and has a relative density (D₄²⁰) of 1.21 (at 20°C). Furthermore, metam-sodium 510 g/L is not considered auto-flammable and is not expected to have explosive or oxidising properties. The preparation has a pH around 9.6 and is not surface-active. No significant physical/chemical changes were observed after storage for 14 days at 54°C or for 7 days at 0°C. Moreover, the preparation was shown to remain stable after storage for 2 years at ambient conditions.

Flash point determination is still required in order to allow verification of compliance with the current FAO specification.

The flash point was determined to be > 97°C and thus, compliance with FAO specification (Code 20.1Na/13/S/15) (requiring flash point ≥ 66°C) was demonstrated. The amount of insoluble material retained on a 125µm test sieve meets the FAO spec. (i.e. max. 0.2% w/w).

A GLP storage stability study with analysis of the relevant impurities before and after storage (cf. data gap identified in EFSA conclusion of 26 November 2008) is ongoing.

In addition, some studies were provided for the preparation **Metam-potassium 690 g/L** (*soluble concentrate, SL*): viscosity, relative density, effect of low temperature on stability, 2 years shelf life study.

The preparation **Metam-potassium 690 g/L** (*soluble concentrate, SL*) is identical to the technical metam-potassium as manufactured. It is a clear, light yellow liquid with a pungent, sulphurous odour and a relative density of 1.278 (at 20°C). The preparation has Newtonian fluid behaviour and is surface-active (surface tension of neat formulation and 1g/L aqueous solution: 51.5 and 55.1 mN/m at 20°C, respectively). A 1% (w/w) aqueous dilution has a pH of 7.69 (at 25°C). Furthermore, the preparation is not flammable (flash point > 102°C), not auto-flammable and no explosive or oxidising properties are to be expected.

Metam-potassium 690 g/L was found to be physically stable to storage at 0 °C for 7 days. The preparation was also shown to remain stable after storage for 2 years at ambient conditions. No persistent foam is formed when the preparation is diluted in water.

The amount of insoluble material retained on a 125µm test sieve meets the FAO spec. (i.e. max. 0.2% w/w).

A GLP storage stability study with analysis of the relevant impurities before and after storage (cf. data gap identified in EFSA conclusion of 26 November 2008) is ongoing.

B.2.3 References relied on [revised in August 2010]

After evaluation of the resubmission dossier, the RMS verified again the complete list of references relied on. Beside the new references relied upon from the resubmission dossier (highlighted in yellow), also references to previously accepted relevant studies (including those on metam-potassium and MITC) were added.

B.2.3.1 Physical and chemical properties of the active substance (and of MITC and DMTC)

Annex point / reference number	Author(s)	Date	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 2.1.1 /01 IIA 2.1.3 /01 IIA 2.2 /01 IIA 2.3.1 /01	Betteley JMT	1997-12-08	Metam sodium – Physicochemical properties Huntingdon Life Sciences, FCC 152/963829 GLP Not published	Y	Taminco, FMC Foret
IIA 2.1.1/02 IIA 2.1.3 IIA 2.2/02	White G.A.	2009-11-04	Determination of physical properties for purified (solid) Metam-K G.C. Laboratories Ltd., England Report No. J17224/A GLP: yes Not published	Y	Taminco
IIA 2.3.1 /02	Lindemann M	2003-11-07	Determination of the vapour pressure of methyl isothiocyanate RCC Ltd., 850435 GLP Not published	Y	Taminco
IIA 2.3.1/03 IIA 2.3.2/03	Habeck C.	2009-06-02	N,N-Dimethylthiourea: Determination of the vapor pressure Harlan Laboratories Ltd., Itingen, Switzerland Report No. C42765 GLP: yes Not published	Y	Taminco
IIA 2.3.2 /01	Taminco	2004a 2007	Calculation of Henry constant for Metam-sodium Not GLP Not published	Y	Taminco
IIA 2.3.2 /02	Taminco	2004b	Calculation of Henry constant for Methylisothiocyanate (MITC) Not GLP Not published	Y	Taminco
IIA 2.4.1 /01 IIA 2.4.2 /01	Betteley JMT	1997-12-08	Metam sodium – Physicochemical properties Huntingdon Life Sciences, FCC 152/963829 GLP Not published	Y	Taminco, FMC Foret

Annex point / reference number	Author(s)	Date	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 2.4.1 /02 IIA 2.4.2 /02	Van Hecke S, Van de Putte M, Demuynck M	2001-03-19	Metam 510 g/l – Description of the physical state, color and odor UCB Research Laboratory, W/RL/200101/001 Not GLP Not published	Y	Taminco
IIA 2.4.1/05 IIA 2.4.2/04	White G.A.	2009-11-04	Determination of physical properties for purified (solid) Metam-K G.C. Laboratories Ltd., England Report No. J17224/A GLP: yes Not published	Y	Taminco
IIA 2.4.1 /03 IIA 2.4.2 /03	Ambroz Hahn J	2002-01-25	Determination of color, physical state, odor, density, and pH for metam-potassium 54% ABC Laboratories, 47104 GLP Not published	Y	Taminco
IIA 2.4.1 /04	Flack I	1997-05-08	Methyl isothiocyanate – Physical and chemical properties Huntingdon Life Sciences, FCC 153/962827 GLP Not published	Y	Taminco, FMC Foret
IIA 2.5.1 /01	Betteley JMT	1997-12-08	Metam sodium – Physicochemical properties Huntingdon Life Sciences, FCC 152/963829 GLP Not published	Y	Taminco, FMC Foret
IIA 2.5.1/03	White G.A.	2009-11-04	Determination of physical properties for purified (solid) Metam-K G.C. Laboratories Ltd., England Report No. J17224/A GLP: yes Not published	Y	Taminco
IIA 2.5.2/01	O'Connor B.J., Woolley S.M.	2010-06-14	DMTU (N,N') : Determination of spectra Harlan Laboratories Ltd., England Report No. 1542/0009R GLP: yes Not published	Y	Taminco
IIA 2.5.2 (submitted under IIA 2.5.1/03)	Flack I	1997-05-08	Methyl isothiocyanate – Physical and chemical properties Huntingdon Life Sciences, FCC 153/962827 GLP Not published	Y	Taminco, FMC Foret
IIA 2.5.1/01	Betteley JMT	1997-12-08	Metam sodium – Physicochemical properties Huntingdon Life Sciences, FCC 152/963829 GLP Not published	Y	Taminco, FMC Foret

Annex point / reference number	Author(s)	Date	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 2.6 /02	Betteley J	2002-02-12	Metam-sodium – Solubility in water (pH 5 and pH 9) Huntingdon Life Sciences, UCB809/013754 GLP Not published	Y	Taminco
IIA 2.6	Flack I	1997-05-08	Methyl isothiocyanate – Physical and chemical properties Huntingdon Life Sciences, FCC 153/962827 GLP Not published	Y	Taminco, FMC Foret
IIA 2.6/03	Habeck C.	2009-05-19	N,N'Dimethylthiourea: Determination of the water solubility Harlan Laboratories Ltd., Itingen, Switzerland Report No. C42743 GLP: yes Not published	Y	Taminco
IIA 2.7 /01 IIA 2.8 /01 IIA 2.9.1 /01	Betteley JMT	1997-12-08	Metam sodium – Physicochemical properties Huntingdon Life Sciences, FCC 152/963829 GLP Not published	Y	Taminco, FMC Foret
IIA 2.8/02	Kelly K.	2009-09-29	Determination of dissociation constant and partition coefficient for purified (solid) Metam-K G. C. Laboratories Ltd., England Report No. J17224/B GLP: yes Not published	Y	Taminco
IIA 2.8	Flack I	1997-05-08	Methyl isothiocyanate – Physical and chemical properties Huntingdon Life Sciences, FCC 153/962827 GLP Not published	Y	Taminco, FMC Foret
IIA 2.8/03	Habeck C.	2009-06-10	N,N'-Dimethylthiourea: determination of the partition coefficient (n-Octanol / Water) Harlan Laboratories Ltd., Itingen, Switzerland Report No. C42754 GLP: yes Not published	Y	Taminco
IIA 2.9.1 /02	Ericson JL	1990-08-21	Metam-Sodium - Hydrolysis at pH 5, 7 and 9 ICI Americas, RR 90-110B GLP Not published	Y	USA TF

Annex point / reference number	Author(s)	Date	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 2.9.1 /04	Kidd GD, Lowrie C, Davidson J	2005-09-01	Hydrolytic Stability of [¹⁴ C]-MITC in Buffered Aqueous Solution (amendment 1, 30-09-2005) Inveresk, 24450, project 206802 GLP Not published	Y	Taminco
IIA 2.9.2 /03	Spurgeon C	1990-04-30	Metam-Sodium - Aqueous Photolysis at 25°C ICI Americas, RR 90-091B GLP Not published	Y	USA TF
IIA 2.9.4 /01	Betteley J	2002-02-12	Metam sodium – Dissociation constant Huntingdon Life Sciences, UCB810/013755 GLP Not published	Y	Taminco
IIA 2.10 /01	Betteley J	2001-10-02	Metam sodium – Oxidative photodegradation (calculation) Huntingdon Life Sciences, UCB811/013383 GLP Not published	Y	Taminco, FMC Foret, Lainco
IIA 2.11.1 /01 IIA 2.11.2 /01	Betteley JMT	1997-12-08	Metam sodium – Physicochemical properties Huntingdon Life Sciences, FCC 152/963829 GLP Not published	Y	Taminco, FMC Foret
IIA 2.11.2 /02	Tremain SP	2000-11-14	Metam-sodium: Determination of Auto-ignition temperature (liquids and gases) Safeparm, SPL 378/046 GLP Not published	Y	Taminco
IIA 2.11.2/03	White G.A.	2009-02-12	Determination of autoflammability, flash point, explosive properties, and surface tension of Metam-K 690 g/l (Technical) product G.C. Laboratories Ltd., England Report No. J17223 GLP: yes Not published	Y	Taminco
IIA 2.12/02	Knowles R.	2009-01-19	Determination of the flash point of the Metam-sodium 510 g/l formulation G.C. Laboratories Ltd., England Report No. J17220 GLP: yes Not published	Y	Taminco

Annex point / reference number	Author(s)	Date	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 2.12/03	White G.A.	2009-02-12	Determination of autoflammability, flash point, explosive properties, and surface tension of Metam-K 690 g/l (Technical) product G.C. Laboratories Ltd., England Report No. J17223 GLP: yes Not published	Y	Taminco
IIA 2.13 /01	Betteley JMT	1997-12-08	Metam sodium – Physicochemical properties Huntingdon Life Sciences, FCC 152/963829 GLP Not published	Y	Taminco, FMC Foret
IIA 2.13/02	White G.A.	2009-02-12	Determination of autoflammability, flash point, explosive properties, and surface tension of Metam-K 690 g/l (Technical) product G.C. Laboratories Ltd., England Report No. J17223 GLP: yes Not published	Y	Taminco
IIA 2.14 /01	Betteley JMT	1997-12-08	Metam sodium – Physicochemical properties Huntingdon Life Sciences, FCC 152/963829 GLP Not published	Y	Taminco, FMC Foret
IIA 2.14 /02	Lumsden AM	2000-06-01	Metam sodium 510 g/l aqueous solution: determination of surface tension Safepharm Laboratories Limited, SPL 378/036 GLP Not published	Y	Taminco
IIA 2.14/04	White G.A.	2009-02-12	Determination of autoflammability, flash point, explosive properties, and surface tension of Metam-K 690 g/l (Technical) product G.C. Laboratories Ltd., England Report No. J17223 GLP: yes Not published	Y	Taminco
IIA 2.15 /01	Betteley J	2001-07-25	Metam sodium – Oxidising properties Huntingdon Life Sciences UCB 812/013400 GLP Not published	Y	Taminco

Annex point / reference number	Author(s)	Date	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 2.15/02	White G.A.	2009-02-12	Determination of autoflammability, flash point, explosive properties, and surface tension of Metam-K 690 g/l (Technical) product G.C. Laboratories Ltd., England Report No. J17223 GLP: yes Not published	Y	Taminco

B.2.3.2 Physical and chemical properties of the plant protection products METAM-SODIUM 510 g/L and METAM-POTASSIUM 690 g/L

Annex point / reference number	Author(s)	Date	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIIA 2.1 /01	Van Hecke S, Van de Putte M, Demuynck M	2001-03-19	Metam 510 g/l – Description of the physical state, color and odor UCB Research Laboratory, W/RL/200101/001 Not GLP Not published	Y	Taminco
IIIA 2.1 /02	Ambroz Hahn J	2002-01-25	Determination of color, physical state, odor, density, and pH for metam-potassium 54% ABC Laboratories, 47104 Published Not GLP	Y	Taminco
IIIA 2.2.1 (submitted under IIA 2.13/02)	White G.A.	2009-02-12	Determination of autoflammability, flash point, explosive properties, and surface tension of Metam-K 690 g/l (Technical) product G.C. Laboratories Ltd., England Report No. J17223 GLP: yes Not published	Y	Taminco
IIIA 2.2.2	Betteley J	2001-07-25	Metam sodium – Oxidising properties Huntingdon Life Sciences, UCB 812/013400 GLP Not Published	Y	Taminco, FMC Foret, Lainco
IIIA 2.2.2 (submitted under IIA 2.15/02)	White G.A.	2009-02-12	Determination of autoflammability, flash point, explosive properties, and surface tension of Metam-K 690 g/l (Technical) product G.C. Laboratories Ltd., England Report No. J17223 GLP: yes Not published	Y	Taminco
IIIA 2.3 (submitted under IIA 2.12/02)	Knowles R.J.	2009-01-19	Determination of the flash point of the Metam-sodium 510 g/l formulation G.C. Laboratories Ltd., England Report No. J17220 GLP: yes Not published	Y	Taminco
IIIA 2.3 (submitted under IIA 2.11.2/03 and IIA 2.12/03)	White G.A.	2009-02-12	Determination of autoflammability, flash point, explosive properties, and surface tension of Metam-K 690 g/l (Technical) product G.C. Laboratories Ltd., England Report No. J17223 GLP: yes Not published	Y	Taminco

Annex point / reference number	Author(s)	Date	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIIA 2.3	Tremain SP	2000-11-14	Metam-sodium: Determination of Auto-ignition temperature (liquids and gases) Safepharm, SPL 378/046 GLP Not Published	Y	Taminco, FMC Foret, Lainco
IIIA 2.4.1 /01	Tognucci A	2003-03-31	Accelerated storage stability of Metam-sodium RCC Ltd, 846139 GLP Not Published	Y	Taminco
IIIA 2.4.2 /01	Howes D	2003-05-14	Metam-sodium 510 g/l – pH of a 1% aqueous solution Huntingdon Life Sciences, PFX 001/032863 GLP Not Published	Y	Taminco
IIIA 2.4.2 /02	Ambroz Hahn J	2002-01-25	Determination of color, physical state, odor, density, and pH for metam-potassium 54% ABC Laboratories, 47104 Published Not GLP	Y	Taminco
IIIA 2.5.2 /01	Lumsden AM	2000-06-02	Metam sodium 510 g/l aqueous solution: determination of viscosity Safepharm Laboratories Limited, SPL Project No. 378/037 GLP Not Published	Y	Taminco
IIIA 2.5.2 /02	Ambroz Hahn J	2002-02-28	Determination of viscosity for metam-potassium 54% ABC Laboratories, 47106 Published Not GLP	Y	Taminco
IIIA 2.6.1 /01	Lumsden AM	2000-06-02	Metam sodium 510 g/l aqueous solution: determination of relative density Safepharm Laboratories Limited, SPL Project No. 378/038 GLP Not Published	Y	Taminco
IIIA 2.6.1 /02	Ambroz Hahn J	2002-01-25	Determination of color, physical state, odor, density, and pH for metam-potassium 54% ABC Laboratories, 47104 Published Not GLP	Y	Taminco
IIIA 2.7 /1	Tognucci A	2003-03-31	Accelerated storage stability of Metam-sodium RCC Ltd, 846139 GLP Not Published	Y	Taminco

Annex point / reference number	Author(s)	Date	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIIA 2.7.2 /03	Widmer H	2005-09-15	Low temperature stability of Metam sodium 510 g/l RCC Ltd., A21701 GLP Not Published	Y	Taminco
IIIA 2.7.2 /04	Widmer H	2005-09-15	Low temperature stability of Metam potassium 690 g/l RCC Ltd., A217121 Published Not GLP	Y	Taminco
IIIA 2.7.3 /01	Van Hecke S, Blom P, Demunck M	2003-04-17	Metam sodium 510 g/l aqueous solution. Shelf Life. Taminco Research Laboratory W/RL/200303001 Not GLP Not Published	Y	Taminco
IIIA 2.7.3 /02	Tognucci A	2004-12-23	Determination of the storage stability of metam potassium (shelf life) RCC Ltd., 846298 Published Not GLP	Y	Taminco
IIIA 2.8.4	Tognucci A	2003-03-31	Accelerated storage stability of Metam-sodium RCC Ltd, 846139 GLP Not Published	Y	Taminco
IIIA 2.8.5	Van Herreweghe B	2007-06-05	Metam sodium 510 g/l – Insoluble Material Taminco N.V. Report W/RL/200706/001 Non GLP Not published	Y	Taminco
IIIA 2.8.5	Van Herreweghe B	2007-06-05	Metam potassium 690 g/l – Insoluble Material Taminco N.V. Report W/RL/200706/002 Non GLP Not published	Y	Taminco