ANNEX B

Metconazole

B.2 Physical and chemical properties

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

With respect to the test substances used for the determination of the physical and chemical properties, following purity values should be taken into account, unless indicated otherwise :

- for the purified a.s. : 98.6% (83.0% cis-isomer, 15.7% trans-isomer) (lot AC 8879-140B – certificate of analysis)
- for the a.s. as manufactured (TC) : 96% (batch : ST89/088 lot89-01)

Table B.2.1-1 : Physical and chemical properties of Metconazole

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)	- Electrothermal Digital Melting Point Apparatus (Capillary method) - GLP-compliance stated	purified a.s. : melting point range = 100.0 – 108.4 °C	Acceptable. Method used is equivalent to EEC A1.	Mangels, 1995
B.2.1.2 Boiling point (IIA 2.1.2)			Not applicable (metconazole is not a liquid or a low melting substance)	Bashir, 1995
B.2.1.3 Temperature of decomposition or sublimation (IIA 2.1.3)			Not applicable (melting point was determined without decomposition taking place)	

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.1.4 Relative density (IIA 2.2)	- EEC A3 (pycnometer method) - GLP-compliance stated	purified a.s. : D_4^{20} = 1.14	Acceptable	Bashir, 1995
B.2.1.5 Vapour pressure (IIA 2.3.1)	- EEC A4 (vapour pressure balance method) - GLP-compliance stated	purified a.s. : vapour pressure at 20°C = 2.1 x 10^{-8} Pa (extrapolated from measurements at 85, 90, 95 and 100°C)	Acceptable. Metconazole has a very low vapour pressure and volatilisation is not expected to be significant at ambient temperature.	Tremain & An, 2000
B.2.1.6 Volatility – Henry's law constant (IIA 2.3.2)	- Calculation - GLP-compliance not relevant	purified a.s. : vapour pressure at 20°C : 2.1 x 10^{-8} Pa water solubility at 20°C : 30.4 mg/L = 0.095 mol/m^3 $\Rightarrow$ H at 20°C = 2.21 x 10^{-7} Pa.m^3.mol^{-1}	Acceptable	Martin, 2002
B.2.1.7 Physical state, colour (IIA 2.4.1)	- Visual inspection - GLP-compliance stated	purified a.s. : white powdered solid a.s. as manufactured (TC), 98.3% pure (lot AC 10575-61) : white powdered solid	Acceptable	Cevasco, 1996
B.2.1.8 Odour (IIA 2.4.2)	- Olfactory observation - GLP-compliance stated	purified a.s. : odourless a.s. as manufactured (TC), 98.3% pure (lot AC 10575-61) : odourless	Acceptable	Cevasco, 1996

<table>
<tr><th>Study</th><th>Guidelines/Methods and GLP</th><th>Findings</th><th>Evaluation and conclusion</th><th>References</th></tr>
<tr>
<td>B.2.1.9
Spectra of the active substance
(IIA 2.5.1)</td>
<td>- Standard UV/VIS, IR, NMR and MS methodology

- GLP-compliance stated in Tier II</td>
<td>a.s., 98.1% pure (80% cis, 20% trans) (lot AC 12140-17);
purified cis-isomer, 98.8% pure (lot AC 8879-136A);
purified trans-isomer , 98.6% pure (lot AC 9339-122A) :
Following spectra were provided :
UV/VIS (spectra measured between 190-700 nm)
IR (KBr; sample scanned over range 4000 to 600 cm^{-1})
^{1}H-NMR (DMSO-d6)
^{13}C-NMR (DMSO-d6)
MS (both CI and EI)

The different spectra were found to be in agreement with the proposed chemical structures

UV/VIS absorption characteristics :
<table>
<tr><th></th><th>λ_{max} (nm)</th><th>ε ($L.mol^{-1}.cm^{-1}$)</th></tr>
<tr><td>acetonitrile solution</td><td>196
221
226 (shoulder)
262
268</td><td>17700
5900
4600
150
190</td></tr>
</table>
at λ > 290 nm : 2 maxima (determined in pH 7 buffer containing 0.1% acetonitrile; cfr quantum yield study) :
at 310 nm : ε-value = 2686 $L.mol^{-1}.cm^{-1}$
at 372.5 nm : ε-value = 1921 $L.mol^{-1}.cm^{-1}$</td>
<td>Acceptable.
Although study report lacks formal GLP-compliance statement and declaration from Quality Assurance Unit, data integrity and GLP conformity of instruments are assured.</td>
<td>Jones, 2001

Knoch & Martin, 1999 (quantum yield study)</td>
</tr>
<tr>
<td>B.2.1.10
Spectra of the impurities
(IIA 2.5.2)</td>
<td>- Applicant's statement</td>
<td>"Not required, none of the impurities in the active substance are of toxicological, ecotoxicological or environmental concern"</td>
<td>Acceptable</td>
<td></td>
</tr>
</table>

<table>
<tr><th>Study</th><th>Guidelines/Methods and GLP</th><th>Findings</th><th>Evaluation and conclusion</th><th>References</th></tr>
<tr><td>B.2.1.11
Solubility in water
(IIA 2.6)</td><td>- EEC A6 (flask method + HPLC-UV)

- GLP-compliance stated</td><td>purified a.s. :
solubility at 20°C in distilled Milli-Q water (pH ca. 7.5)
• cis/trans mixture (AC 900768) : 30.4 mg/L
• cis-isomers (CL 354801) : 17.1 mg/L
• trans-isomers (CL 354802) : 13.6 mg/L

A preliminary test demonstrated that water solubility is not dependent on pH</td><td>Acceptable.
Metconazole is moderately soluble in water, irrespective of pH.</td><td>Madsen, 1995a</td></tr>
<tr><td>B.2.1.12
Solubility in organic solvents
(IIA 2.7)</td><td>- EEC A6 (flask method + HPLC-UV)

- GLP-compliance stated</td><td>purified a.s. :
solubility at 20°C (g/L) :
<table>
<tr><th></th><th>AC 900768 (cis/trans)</th><th>CL 354801 (cis)</th><th>CL 354802 (trans)</th></tr>
<tr><td>hexane</td><td>1.40</td><td>0.929</td><td>0.483</td></tr>
<tr><td>toluene</td><td>103</td><td>66.2</td><td>38</td></tr>
<tr><td>dichloromethane</td><td>481</td><td>343</td><td>141</td></tr>
<tr><td>methanol</td><td>403</td><td>291</td><td>117</td></tr>
<tr><td>2-propanol</td><td>132</td><td>86.6</td><td>46.7</td></tr>
<tr><td>acetone</td><td>363</td><td>251</td><td>117</td></tr>
<tr><td>ethyl acetate</td><td>260</td><td>173</td><td>90.0</td></tr>
</table></td><td>Acceptable</td><td>Madsen, 1995a</td></tr>
<tr><td></td><td>- Theoretical discussion + calculations

- GLP not relevant</td><td>The solubility in organic solvents of the pure grade of Metconazole is an accurate estimation of the solubility of the technical grade.</td><td>Acceptable</td><td>Martin, 1999</td></tr>
</table>

<table>
<tr><th>Study</th><th>Guidelines/Methods and GLP</th><th>Findings</th><th>Evaluation and conclusion</th><th>References</th></tr>
<tr><td>B.2.1.13
Partition coefficient n-octanol/water
(IIA 2.8)</td><td>- EEC A8 (shake flask method + HPLC-UV)

- GLP-compliance stated</td><td>purified a.s. :
<table><tr><th></th><th>AC 900768 (cis/trans)</th><th>CL 354801 (cis)</th><th>CL 354802 (trans)</th></tr><tr><td>log P_{ow} at 20°C</td><td>3.85</td><td>3.85</td><td>3.8</td></tr></table>
Test water : distilled Milli-Q water (pH 7.2 - 8)

Effect of pH was not investigated since there is no dissociation in water in the environmentally relevant pH-range (see B.2.1.17)</td><td>Acceptable</td><td>Madsen, 1995b</td></tr>
<tr><td>B.2.1.14
Hydrolysis rate at pH 4, 7 and 9 under sterile conditions in the absence of light
(IIA 2.9.1)</td><td>- EEC C7

- GLP-compliance stated for study by Fisk</td><td>technical a.s., 95.3% pure (79.8% cis, 15.5% trans) (batch 89-01) :
Preliminary tests at 50°C at pH 4, 5, 7 and 9 :
• at pH 4, 5 and 7 : hydrolytic stability (<10% hydrolysis of both isomers in 5 d)
⇒ no further tests required

• at pH 9 : results are inconclusive mainly due to inefficiency of extraction process
⇒ additional preliminary test at pH 9 on separate isomers, using direct analysis by HPLC

purified cis-isomers, 96.9% pure (batch 3454/078),
purified trans isomers, 97% pure (batch 88-08) :
Preliminary test at 50°C at pH 9 :
hydrolytic stability of both cis- and trans-isomers (<10% hydrolysis in 5 d)
⇒ no further tests required</td><td>Acceptable. Metconazole is hydrolytically stable under environmentally relevant conditions.
Purity of test substance being less than 98% is not considered to have an impact on the conclusions of the study because of the analytical procedure used for quantification (impurities were not quantified or included in any calculation). Moreover, test results from hydrolysis study are confirmed by results from dark control samples in aqueous photolysis study (cfr. B.2.1.15).</td><td>Fisk, 1991
Mangels, 1996b (discussion paper)</td></tr>
</table>

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)	- US-EPA Subdivision N Series 161-2 (xenon arc light source with UV filter (cut off λ < 290 nm)) - GLP-compliance stated	^{14}C-labelled a.s., radiochemical purity 97.41% (stated) – 99.8% (determined by HPLC) : at 25°C; in pH 5, 7 and 9 buffer (sterile conditions), continuous irradiation for 30d : *Material balance :* total recoveries of applied radioactivity ranged from resp. 98.6 to 100.0% (pH5), 98.4 to 100.7% (pH 7) and 96.4 to 101.8% (pH 9) for the exposed test systems, and from resp. 98.0 to 100.6% (pH 5), 96.3 to 100.0% (pH 7) and 95.0 to 100.0% (pH 9) for the dark controls *Photolysis rate :* pH 5 : k = 0.0252 d^{-1}; DT_{50} = 27.5 d pH 7 : k = 0.0191 d^{-1}; DT_{50} = 36.3 d pH 9 : k = 0.0194 d^{-1}; DT_{50} = 35.8 d Dark control samples displayed no appreciable loss of metconazole throughout the study *Major photolysis products (> 10% of applied radioactivity) :* metconazole photolyzed to multiple more polar degradation products; the only photodegradate exceeding 10% of applied radioactivity was identified as hydroxymetconazole (14.5% after 30 d at pH 7)	Acceptable. Method is in accordance with SETAC-procedures. Metconazole is moderately (pH 5) to slightly (pH 7 and 9) degradable by direct photolysis.	Williams & Heim, 1996

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)	- OECD Guidance doc. on direct phototransformation of chemicals in water (1997) (Heraeus Suntest apparatus : xenon arc lamp with UV-filter (cut off λ < 290 nm) + uranyl nitrate/oxalic acid actinometer)) - GLP-compliance stated	^{14}C-labelled a.s., radiochemical purity 99.2% : at 20°C, in pH 7 buffer (sterile conditions, 0.1% acetonitrile co-solvent) : *quantum yield :* $\phi = 2.19 \times 10^{-7}$ (calculated by QUANTAUS program) *environmental direct photolysis half-life :* using Frank & Klöpffer model (simulation conditions : stagnant water with area of 100 m² and depth of 1 m, no suspended sediment, pH 5.5, 10^{-7} mol/L ROO-radical, 10^{-14} mol/L OH-radical, 10^{-10} mol/L RO-radical, 10^{-10} mol/L singlet oxygen, assumed irradiation time of 16.5 hrs for June and 7.6 hrs for December, assumed water temperatures of 20°C for June and 3°C for December) : $t_{1/2}$ ranges from 2.7×10^{9} d for ROO-radical to 2.7×10^{23} d for OH-radical in June and from 3.6×10^{10} d for ROO-radical to 3.6×10^{24} d for OH-radical in December	Acceptable. Method is in accordance with ECETOC Technical reports 3 and 12. ϕ-value confirms that photodegradation is not expected to be a major route of dissipation of Metconazole in aquatic systems.	Knoch & Martin, 1999
B.2.1.17 Dissociation in water – pKa value(s) (IIA 2.9.4)	- OECD 112 (spectrophotometric method) - GLP-compliance stated	purified a.s. : at 29.4°C : pKa_1 = 11.38 (dissociation of the proton that is bonded to the oxygen of the hydroxyl moiety) pKa_2 = 1.08 (protonation of any one of the 3 nitrogen atoms on the triazole ring)	Acceptable	Madsen & Barton, 1995 Kroehl, 2003 (report amendment)

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) - GLP-compliance not relevant	overall OH rate constant K_{OH} = 19.6914 x 10^{-12} cm^3/molecules.sec ⇒ estimated half-life in troposphere = 6.5 hr or 0.543 d (using a 12 hr day with global OH-concentration of 1.5 x 10^6 OH radicals/cm^3)	Acceptable	Mangels, 1996a
B.2.1.19 Flammability (IIA 2.11.1)	- EEC A10 - GLP-compliance stated	a.s. as manufactured (TC) : test substance could not be ignited with a flame ⇒ a.s. is not considered as highly flammable	Acceptable	van Helvoirt, 1990b
B.2.1.20 Auto-flammability (IIA 2.11.2)	- EEC A16 - GLP-compliance stated	a.s. as manufactured (TC) : no self ignition of test substance was observed between room temperature and melting point ⇒ a.s. is not considered as auto-flammable	Acceptable	van Helvoirt, 1990a
B.2.1.21 Flash point (IIA 2.12)			Not applicable (melting point > 40°C)	

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.1.22 Explosive properties (IIA 2.13)	- EEC A14 - GLP-compliance stated	a.s. as manufactured (TC) : • Koenen Steel Tube test : not explosive when exposed to thermal stress (no deformation of test tubes) • BAM Fall Hammer test : not explosive when exposed to mechanical stress by shock (no traces of vigorous reaction) • BAM Friction test : not explosive when exposed to mechanical stress by friction (test substance reacts i.e. decomposes into a black residue, but no traces of vigorous reaction) ⇒ a.s. does not present explosive properties	Acceptable	van Helvoirt, 1990c
B.2.1.23 Surface tension (IIA 2.14)	- EEC A5 (ring method) - GLP-compliance stated	purified a.s. : σ = 65.0 mN/m at 22°C (10 ppm solution) ⇒ a.s. is not surface active	Not acceptable : surface tension was not determined at 90% of saturation concentration	Bashir, 1995
	- EEC A5 (plate method) - GLP-compliance stated	a.s. as manufactured (TC), 97.4% pure (batch AC 10925-24B) : σ = 64.8 mN/m at 20°C (90% of saturation concentration) ⇒ a.s. is not surface active	Acceptable	Kaestel, 2003
B.2.1.24 Oxidizing properties (IIA 2.15)	- EEC A17 - GLP-compliance stated	a.s. as manufactured (TC) : • max. burning rate of reference mixtures = 2.63 mm/s (barium nitrate/cellulose 60/40 % w/w); combustion through the whole pile • max. burning rate of test mixtures = 1.82 mm/s (test substance/cellulose 10/90 % w/w); combustion at the surface of the pile only ⇒ a.s. does not present oxidizing properties	Acceptable	van Helvoirt, 1990d

Summary and conclusions

Metconazole (BAS 555 F), a fungicide belonging to the chemical family of triazoles, is an odourless white powdered solid with a melting point range of 100.0 to 108.4°C and a relative density at 20°C of 1.14. Its very low vapour pressure (2.1×10^{-8} Pa at 20°C) and Henry's law constant (2.21×10^{-7} $Pa.m^3.mol^{-1}$ at 20°C) indicate that Metconazole is very slightly volatile. Its pKa values of 11.38 and 1.08 indicate that no dissociation occurs in the environmentally relevant pH-range. Metconazole is moderately soluble in water (30.4 mg/L at 20°C, no effect of pH) and readily soluble in organic solvents. Its octanol/water partition coefficient (log P_{ow} = 3.85 at 20°C, no effect of pH) indicates a potential for bioaccumulation in the environment. Metconazole is hydrolytically stable under environmentally relevant conditions (pH 4 to 9), but is moderately (pH 5) to slightly (pH 7 and 9) degradable by direct photolysis in aqueous solution (DT_{50} = 36.3 d at 25°C and pH 7). The a.s. is not highly flammable, not self heating and exhibits no explosive or oxidizing properties.

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 **CARAMBA 60 SL®** (Soluble concentrate : 60 g/L Metconazole)

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.2.1 Physical state, colour (IIIA 2.1)	- Internal method DF/044 : visual inspection - GLP-compliance stated	batch 005 : clear, colourless to slightly yellowish liquid, free from sediment	Acceptable	Schmidt, 2000
B.2.2.2 Odour (IIIA 2.1)	- EPA OPPTS 830.6304	batch F004498 : fusel-like smell	Acceptable	Schmidt, 1999
B.2.2.3 Explosive properties (IIIA 2.2.1)	- NOTOX expert statement, based on EEC A14 - GLP-compliance stated (Krips, 1996a)	“From the structural formula of Metconazole and the composition of Metconazole 60 g/L it can be concluded that the substance is not explosive. The substance does not contain any chemically instable or highly energetic groups that might lead to an explosion.”	Acceptable (cfr. B.2.1.22 and MSDS of formulants)	Krips, 1996a in : Perlitz, 1996
B.2.2.4 Oxidizing properties (IIIA 2.2.2)	- NOTOX expert statement, based on EEC A17 - GLP-compliance stated (Krips, 1996b)	"From the structural formula of Metconazole and the composition of Metconazole 60 g/L it can be concluded that the substance has no oxidizing properties. The substance does not contain any molecule group that might act as an oxidizing agent."	Acceptable (cfr. B.2.1.24 and MSDS of formulants)	Krips, 1996b in : Perlitz, 1996

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.2.5 Flash point (IIIA 2.3)	- Internal method DF/010, equivalent to EEC A9 (Abel-Pensky closed cup) - GLP-compliance stated	batch 005 : flash point = 43°C (corrected to an atmospheric pressure of 1013 mbar)	Acceptable CARAMBA 60 SL® is to be classified as "flammable".	Schmidt, 2000
B.2.2.6 Flammability (IIIA 2.3)			Not applicable (liquid preparation)	
B.2.2.7 Auto-flammability (IIIA 2.3)	- EEC A15 (ASTM E659-78) - GLP-compliance stated (Weaver, 1996)	batch 005 : auto-ignition temperature = 289°C (atmospheric pressure : 1024 mbar)	Acceptable	Weaver, 1996 in : Perlitz, 1996
B.2.2.8 Acidity or alkalinity and pH value (IIIA 2.4.1)			Not applicable (4 < pH < 10) (see B.2.2.9)	
B.2.2.9 pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	- Internal method CEC/006, equivalent to CIPAC MT 75.2 - GLP-compliance stated	batch 005 : 1% in CIPAC water D : pH = 6.5	Acceptable. Use of CIPAC water D instead of freshly boiled distilled water (as indicated by MT 75.2) is not considered to have a significant impact on the result, given the pKa-values of Metconazole and the nature of the formulants.	Schmidt, 2000

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.2.10 Kinematic viscosity (IIIA 2.5.1)	- CIPAC MT 22.1 - GLP-compliance stated	batch F0100899 : at 25°C : ν = 10.6 mm²/s at 40°C : ν = 6.1 mm²/s	Acceptable	Baker, 2000
B.2.2.11 Viscosity (IIIA 2.5.2)		see B.2.2.10		
B.2.2.12 Surface tension (IIIA 2.5.3)	- EEC A5 - GLP-compliance stated	batch F0100899 : undiluted product at 25°C : σ = 26.6 mN/m undiluted product at 40°C : σ = 24.9 mN/m 1% v/v aqueous dilution at 25°C : σ = 33.2 mN/m 1% v/v aqueous dilution at 40°C : σ = 31.2 mN/m ⇒ CARAMBA 60 SL® is surface active	Acceptable.	Baker, 2000
B.2.2.13 Relative density (IIIA 2.6.1	- Internal method DF/007, equivalent to EEC A3 (oscillating density meter) - GLP-compliance stated	batch 005 : D_4^{20} = 0.888	Acceptable	Schmidt, 2000
B.2.2.14 Bulk or tap density (IIIA 2.6.2)			Not applicable (liquid preparation)	

<table>
<tr><th>Study</th><th>Guidelines/Methods and GLP</th><th>Findings</th><th>Evaluation and conclusion</th><th>References</th></tr>
<tr><td>B.2.2.15
Stability after storage for 14 days at 54°C (IIIA 2.7.1)</td><td>- CIPAC MT 46

- GLP-compliance stated</td><td>batch 005 in commercial packaging (HDPE bottle):
<table>
<tr><th></th><th>before storage</th><th>after 14 d at 54°C</th></tr>
<tr><td>metconazole content (g/L)
(FAMS 074-01)</td><td>60.4
(cis/trans % : 83/17)</td><td>60.4
(cis/trans % : 83/17)</td></tr>
<tr><td>water content (% w/w)
(CEA/038 ≈ MT 30.1)</td><td>0.09</td><td>0.10</td></tr>
<tr><td>appearance
(DF/044)</td><td colspan="2">clear, colourless to slightly yellowish liquid, free from sediment</td></tr>
<tr><td>pH 1%
(CEC/006 ≈ MT 75.2, in water D)</td><td>6.5</td><td>6.5</td></tr>
<tr><td>dilution stability
(DF/055 ≈ MT 41, in water D)
• after 30 min
• after 18 h</td><td>

turbidity, no sediment
idem</td><td>

turbidity, no sediment
idem</td></tr>
<tr><td>persistent foaming
(mL foam)
(DF/017 ≈ MT 47)</td><td>after 10 sec : 24
after 1 min : 1
after 3 min : 0</td><td>after 10 sec : 24
after 1 min : 1
after 3 min : 0</td></tr>
<tr><td>density (g/mL)
(DF/007 ≈ EEC A3)</td><td>0.888</td><td>0.888</td></tr>
<tr><td>packaging
(visual inspection)</td><td>-</td><td>no change besides slight paneling</td></tr>
</table>
⇒ CARAMBA 60 SL® is chemically and physically stable for 2 weeks at 54°C; no signs of degradation of the active substance and isomer ratio is constant</td><td>Acceptable</td><td>Schmidt, 2000</td></tr>
</table>

<table>
<tr><th>Study</th><th>Guidelines/Methods and GLP</th><th>Findings</th><th>Evaluation and conclusion</th><th>References</th></tr>
<tr>
<td>B.2.2.16
Stability after storage for other periods and temperatures
(IIIA 2.7.1)</td>
<td>- CIPAC MT 46

- GLP-compliance stated</td>
<td>batch 005 in commercial packaging (HDPE bottle):
<table>
<tr><th></th><th>before storage</th><th>after 8 weeks at 40°C</th></tr>
<tr><td>metconazole content (g/L)
(FAMS 074-01)</td><td>60.4
(cis/trans % : 83/17)</td><td>60.2
(cis/trans % : 83/17)</td></tr>
<tr><td>water content (% w/w)
(CEA/038 ≈ MT 30.1)</td><td>0.09</td><td>0.11</td></tr>
<tr><td>appearance
(DF/044)</td><td colspan="2">clear, colourless to slightly yellowish liquid, free from sediment</td></tr>
<tr><td>pH 1%
(CEC/006 ≈ MT 75.2, in water D)</td><td>6.5</td><td>6.6</td></tr>
<tr><td>dilution stability
(DF/055 ≈ MT 41, in water D)
• after 30 min
• after 18 h</td><td>

turbidity, no sediment
idem</td><td>

turbidity, no sediment
idem</td></tr>
<tr><td>persistent foaming
(mL foam)
(DF/017 ≈ MT 47)</td><td>after 10 sec : 24
after 1 min : 1
after 3 min : 0</td><td>after 10 sec : 25
after 1 min : 1
after 3 min : 0</td></tr>
<tr><td>density (g/mL)
(DF/007 ≈ EEC A3)</td><td>0.888</td><td>0.889</td></tr>
<tr><td>packaging
(visual inspection)</td><td>-</td><td>no change besides slight paneling</td></tr>
</table>
⇒ CARAMBA 60 SL® is stable for 8 weeks at 40°C</td>
<td>Acceptable as supplementary information</td>
<td>Schmidt, 2000</td>
</tr>
</table>

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.2.17 Minimum content after heat stability testing (IIIA 2.7.1)		see B.2.2.15, B.2.2.16		
B.2.2.18 Effect of low temperatures on stability (IIIA 2.7.2)	- Internal method DF/009, equivalent to CIPAC MT 39.1 - GLP-compliance stated	after storage at 0°C : after 1 h : no sediment, some clouding after 7 d : no crystals, some clouding after 7 d + 3 h at 20°C : light fluffy sediment remains (0.8 mL) ⇒ CARAMBA 60 SL® is stable at low temperature	Acceptable	Schmidt, 2000

<table>
<tr><th>Study</th><th>Guidelines/Methods and GLP</th><th>Findings</th><th>Evaluation and conclusion</th><th>References</th></tr>
<tr><td>B.2.2.19
Shelf life at ambient temperature
(IIIA 2.7.3)</td><td>- GIFAP N° 17

- GLP-compliance stated</td><td>batch 005 in commercial packaging (HDPE bottle):
<table>
<tr><th></th><th>before storage</th><th>after 3 yr at 20°C</th><th>after 3 yr at 30°C</th></tr>
<tr><td>metconazole content (g/L)
(FAMS 074-01)</td><td>60.4
(cis/trans : 83/17)</td><td>61.0
(cis/trans : 83/17)</td><td>61.6
(cis/trans : 83/17)</td></tr>
<tr><td>water content (% w/w)
(CEA/038 ≈ MT 30.1)</td><td>0.09</td><td>0.23</td><td>0.27</td></tr>
<tr><td>appearance
(DF/044)</td><td colspan="3">clear, colourless to slightly yellowish liquid, free from sediment</td></tr>
<tr><td>pH 1%
(CEC/006 ≈ MT 75.2, in water D)</td><td>6.5</td><td>6.7</td><td>6.7</td></tr>
<tr><td>dilution stability
(DF/055 ≈ MT 41, in water D)
• after 30 min
• after 18 h</td><td>

turbidity, no sediment
idem</td><td>

turbidity, no sediment
idem</td><td>

turbidity, no sediment
idem</td></tr>
<tr><td>persistent foaming (mL foam)
(DF/017 ≈ MT 47)</td><td>10 s : 24
1 min : 1
3 min : 0</td><td>10 s : 25
1 min : 1
3 min : 0</td><td>10 s : 25
1 min : 1
3 min : 0</td></tr>
<tr><td>density (g/mL)
(DF/007 ≈ EEC A3)</td><td>0.888</td><td>0.890</td><td>0.891</td></tr>
<tr><td>packaging
(visual inspection)</td><td>-</td><td>no change</td><td>no change</td></tr>
</table>
⇒ CARAMBA 60 SL® is stable for 3 years at 20 and 30°C</td><td>Acceptable.
Shelf life of min. 3 years is recommended.</td><td>Schmidt, 2000</td></tr>
</table>

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.2.20 Wettability (IIIA 2.8.1)			Not applicable (liquid preparation)	
B.2.2.21 Persistent foaming (IIIA 2.8.2)	- Internal method DF/017, equivalent to CIPAC MT 47.1 - GLP-compliance stated	dilution of preparation with CIPAC water C to a conc. of 1% w/v : after 10 s : 24 mL foam after 1 min : 1 mL foam after 3 min : 0 mL foam	Acceptable according to CIPAC MT 47, but use of water C and MT 47.1 does not comply with current FAO/WHO guidelines. However, as results in water D using MT 47.2 are not expected to lead to significantly different conclusions, this can be dealt with at MS level, if deemed necessary.	Schmidt, 2000
B.2.2.22 Suspensibility (IIIA 2.8.3)			Not applicable (preparation is not a water dispersible product).	
B.2.2.23 Spontaneity of dispersion (IIIA 2.8.3)			Not applicable (preparation is not a water dispersible product)	
B.2.2.24 Dilution stability (IIIA 2.8.4)	- Internal method DF/055, equivalent to CIPAC MT 41 - GLP-compliance stated	dilution of preparation with CIPAC water D to a conc. of 5% v/v : after 30 min : turbidity, no sediment after 18 h : turbidity, no sediment	Acceptable. Considering that the max. recommended conc. of use is 0.75% v/v, test concentration represents a worst case.	Schmidt, 2000

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.2.25 Dry sieve test and wet sieve test (IIIA 2.8.5)			Not applicable (preparation is neither a dustable powder, nor a water dispersible product)	
B.2.2.26 Size distribution of particles – Nominal size range of granules (IIIA 2.8.6.1)			Not applicable (preparation is neither a powder nor a granule)	
B.2.2.27 Dust content and particle size of dust (IIIA 2.8.6.2)			Not applicable (preparation is not a granule)	
B.2.2.28 Friability and attrition characteristics of granules (IIIA 2.8.6.3)			Not applicable (preparation is not a granule)	
B.2.2.29 Emulsifiability, emulsion stability, re-emulsifiability (IIIA 2.8.7.1)			Not applicable (preparation does not form emulsions)	
B.2.2.30 Stability of dilute emulsions (IIIA 2.8.7.2)			Not applicable (preparation does not form emulsions)	

Study	Guidelines/Methods and GLP	Findings	Evaluation and conclusion	References
B.2.2.31 Flowability (IIIA 2.8.8.1)			Not applicable (preparation is not a granule)	
B.2.2.32 Pourability (including rinsed residue) (IIIA 2.8.8.2)			Not applicable (preparation is not a suspension)	
B.2.2.33 Dustability following accelerated storage (IIIA 2.8.8.3)			Not applicable (preparation is not a dustable powder)	
B.2.2.34 Physical compatibility of tank mixes (IIIA 2.9.1)	- Internal method RLA12646 : visual assessment immediately after mixing in water D, after 30 min and after 120 min, followed by sieving (45 µm and 106 µm)	batch R144-578-15 : under laboratory test conditions (static test), CARAMBA 60 SL® was found to be physically compatible with : Fastac 100 SC, Mageos (WG), Karate Zeon (SC), Fastac 100 EC, Amistar (SC), BAS 528 00 F (EC), Starane (EC), Konker R (SC), Konker (SC) and BAS 540 00 F (SC) The products were tested at the highest recommended use rates and both orders of addition showed satisfactory compatibility.	Acceptable	Horsler, 2002
B.2.2.35 Chemical compatibility of tank mixes (IIIA 2.9.2)		No chemical incompatibility was noted during the testing for physical compatibility (see B.2.2.34)	Acceptable	

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

Summary and conclusions

CARAMBA 60 SL®, a 60 g/L soluble concentrate (SL), is a clear, colourless to slightly yellowish liquid with a fusel-like odour. The pH of its aqueous dilution is essentially neutral. It is not explosive, not oxidizing and has an auto-ignition temperature of 289°C. It has a flash point of 43°C and therefore is classified as flammable.

CARAMBA 60 SL® may be used as a solo product, but it was also shown to exhibit physical and chemical compatibility when combined with various mixture partners of different formulation types.

Its technical properties indicate that no particular problems are to be expected in the field when it is used as recommended. Accelerated and long term storage stability tests indicate that CARAMBA 60 SL® will exhibit good chemical and physical stability under commercial storage conditions. A minimum shelf life of 3 years can be recommended in suitable packs (e.g. HDPE). Its low temperature stability is acceptable.

B.2.3 References relied on

B.2.3.1 Physical and chemical properties of the active substance

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 2.1.1/1	Mangels G.	1995	AC 900,768 (WL 148271): Determination of the melting point American Cyanamid Company; Princeton NJ 08543-0400; United States of America MK-303-002 Yes unpublished	N	BASF
II A 2.2/1	Bashir M.	1995	Product chemistry determination for CL 900,768 (Boiling point, surface tension and relative density) Corning Hazleton Wisconsin Inc.; Madison WI 53704; United States of America MK-301-003 Yes unpublished	N	BASF
II A 2.3.1/1	Tremain S.,An D.	2000	Metconazole (AC 900768): Determination of vapour pressure Safepharm Laboratories Ltd.; Derby DE1 2BT; United Kingdom MK-306-002 Yes unpublished	N	BASF
II A 2.3.2/1	Martin C.A.	2002	BAS 555 F (Metconazole): Calculation of Henry's law constant BASF Corporation Agro Research; Princeton NJ 08543-0400; United States of America MK-336-001 No unpublished	Y	BASF
II A 2.4.1/1	Cevasco A.A.	1996	Product chemistry determinations for Metconazole CL 900,768 (TGAI and PAI): Color, physical state and odor Corning Hazleton Inc; Vienna VA 22182; United States of America MK-301-004 Yes unpublished	N	BASF
II A 2.4.2/1	Cevasco A.A.	1996	Product chemistry determinations for Metconazole CL 900,768 (TGAI and PAI): Color, physical state and odor Corning Hazleton Inc; Vienna VA 22182; United States of America MK-301-004 Yes unpublished	N	BASF

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 2.5.1/1	Jones M.T.	2001	Metconazole Spectral database (Report amendment 3) BASF Corporation Agro Research; Princeton NJ 08543-0400; United States of America MK-360-005 Yes unpublished	N	BASF
II A 2.6/1	Madsen S.	1995a	Solvent solubility of AC 900,768 (WL 148,271) ABC Laboratories Inc.; Columbia, Missouri 65202; United States of America MK-312-004 Yes unpublished	N	BASF
II A 2.7/1	Madsen S.	1995a	Solvent solubility of AC 900,768 (WL 148,271) ABC Laboratories Inc.; Columbia, Missouri 65202; United States of America MK-312-004 Yes unpublished	N	BASF
II A 2.7/2	Martin C.A.	1999	Solvent solubility of Metconazole (AC 900768) Technical grade American Cyanamid Company; Princeton NJ 08543-0400; United States of America MK-312-005 No unpublished	N	BASF
II A 2.8/1	Madsen S.	1995b	Octanol/Water partition coefficient of AC 900,768 (WL 148,271) ABC Laboratories Inc.; Columbia, Missouri 65202; United States of America MK-315-001 Yes unpublished	N	BASF
II A 2.9.1/1	Fisk P.R.	1991	WL148271 (KNF-S-474m): Hydrolysis as a function of pH Sittingbourne Research Centre; Kent ME9 8AG; United Kingdom MK-322-001 Yes unpublished	N	BASF
II A 2.9.1/2	Mangels G.	1996b	Hydrolysis of Metconazole American Cyanamid Company; Princeton NJ 08543-0400; United States of America MK-322-002 No unpublished	N	BASF

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 2.9.2/1	Williams M.D.,Heim L.G.	1996	Determination of the aqueous photolysis rate with AC 900,768 (WL 148,271) ABC Laboratories Inc.; Columbia, Missouri 65202; United States of America MK-324-001 Yes unpublished	N	BASF
II A 2.9.2/2	Knoch E.,Martin C.A.	1999	Metconazole AC (900768): Determination of the direct phototransformation in buffered medium at pH 7 Institut Fresenius, Chemische und Biologische Laboratorien GmbH; Taunusstein; Germany Fed. Rep. MK-324-003 Yes unpublished	N	BASF
II A 2.9.3/1	Knoch E.,Martin C.A.	1999	Metconazole AC (900768): Determination of the direct phototransformation in buffered medium at pH 7 Institut Fresenius, Chemische und Biologische Laboratorien GmbH; Taunusstein; Germany Fed. Rep. MK-324-003 Yes unpublished	N	BASF
II A 2.9.4/1	Madsen S.,Barton T.E.	1995	Dissociation constant determination of AC 900,768 (WL 148,271) ABC Laboratories Inc.; Columbia, Missouri 65202; United States of America MK-320-001 Yes unpublished	N	BASF
II A 2.9.4/2	Kroehl T.	2003	Report amendment to MK-320-001 “Dissociation constant determination of AC 900,768 (WL 148,271)”, only valid in combinaion with MK-320-01 DocID 2003/1016614 No unpublished	Y	BASF
II A 2.10/1	Mangels G.	1996a	Metconazole (AC 900768): Estimation of the photochemical oxidation rate in the atmosphere American Cyanamid Company; Princeton NJ 08543-0400; United States of America MK-324-002 No unpublished	N	BASF

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 2.11.1/1	Van Helvoirt J.A.	1990b	Determination of the flammability of WL148271 RCC Notox B.V.; Hertogenbosch; Netherlands MK-330-001 Yes unpublished	N	BASF
II A 2.11.2/1	Van Helvoirt J.A.	1990a	Determination of the auto-flammability of WL148271 RCC Notox B.V.; Hertogenbosch; Netherlands MK-330-002 Yes unpublished	N	BASF
II A 2.13/1	Van Helvoirt J.A.	1990c	Determination of explosive properties of WL148271 RCC Notox B.V.; Hertogenbosch; Netherlands MK-334-001 Yes unpublished	N	BASF
II A 2.14/1	Bashir M.	1995	Product chemistry determination for CL 900,768 (Boiling point, surface tension and relative density) Corning Hazleton Wisconsin Inc.; Madison WI 53704; United States of America MK-301-003 Yes unpublished	N	BASF
II A 2.14/2	Kaestel R.	2003	Surface tension of Metconazol (TC) BASF AG; Agrarzentrum, Limburgerhof DocID 2003/1020352 Yes unpublished	Y	BASF
II A 2.15/1	Van Helvoirt J.A.	1990d	Determination of the oxidising properties of WL148271 RCC Notox B.V.; Hertogenbosch; Netherlands MK-356-001 Yes unpublished	N	BASF

B.2.3.2 Physical and chemical properties of the plant protection product

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
III A 2.1/1	Schmidt F.	2000	Metconazole (CL 900768) 60 G/L SL (SF09381): determination of physical/chemical stability data in polyethylene bottles Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. MK-323-003 Yes unpublished	N	BASF
III A 2.1/2	Schmidt F.	1999	Metconazole (CL900768) 60 G/L SL (SF09381): Odor Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. MK-390-020 No unpublished	N	BASF
III A 2.2.1/1	Perlitz M.	1996	Metconazole (CL900768) 60 G/L SL (SF09381): Determination of explosive properties, oxidizing properties and auto ignition temperature RCC Notox B.V.; Hertogenbosch; Netherlands MK-334-002 Yes unpublished	N	BASF
III A 2.2.2/1	Perlitz M.	1996	Metconazole (CL900768) 60 G/L SL (SF09381): Determination of explosive properties, oxidizing properties and auto ignition temperature RCC Notox B.V.; Hertogenbosch; Netherlands MK-334-002 Yes unpublished	N	BASF
III A 2.3/1	Schmidt F.	2000	Metconazole (CL 900768) 60 G/L SL (SF09381): determination of physical/chemical stability data in polyethylene bottles Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. MK-323-003 Yes unpublished	N	BASF
III A 2.3/2	Perlitz M.	1996	Metconazole (CL900768) 60 G/L SL (SF09381): Determination of explosive properties, oxidizing properties and auto ignition temperature RCC Notox B.V.; Hertogenbosch; Netherlands MK-334-002 Yes unpublished	N	BASF

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
III A 2.4/1	Schmidt F.	2000	Metconazole (CL 900768) 60 G/L SL (SF09381): determination of physical/chemical stability data in polyethylene bottles Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. MK-323-003 Yes unpublished	N	BASF
III A 2.5.1/1	Baker I.P.	2000	Surface tension and viscosity data for metconazole 60 g/l SL formula reference SF09381 - final report Cyanamid of Great Britain Ltd.; Gosport; United Kingdom MK-342-001/ MK-340-001 Yes unpublished	N	BASF
III A 2.5.3/1	Baker I.P.	2000	Surface tension and viscosity data for metconazole 60 g/l SL formula reference SF09381 - final report Cyanamid of Great Britain Ltd.; Gosport; United Kingdom MK-342-001/ MK-340-001 Yes unpublished	N	BASF
III A 2.6.1/1	Schmidt F.	2000	Metconazole (CL 900768) 60 G/L SL (SF09381): determination of physical/chemical stability data in polyethylene bottles Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. MK-323-003 Yes unpublished	N	BASF
III A 2.7.1/1	Schmidt F.	2000	Metconazole (CL 900768) 60 G/L SL (SF09381): determination of physical/chemical stability data in polyethylene bottles Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. MK-323-003 Yes unpublished	N	BASF
III A 2.7.2/1	Schmidt F.	2000	Metconazole (CL 900768) 60 G/L SL (SF09381): determination of physical/chemical stability data in polyethylene bottles Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. MK-323-003 Yes unpublished	N	BASF

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
III A 2.7.3/1	Schmidt F.	2000	Metconazole (CL 900768) 60 G/L SL (SF09381): determination of physical/chemical stability data in polyethylene bottles Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. MK-323-003 Yes unpublished	N	BASF
III A 2.8.2/1	Schmidt F.	2000	Metconazole (CL 900768) 60 G/L SL (SF09381): determination of physical/chemical stability data in polyethylene bottles Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. MK-323-003 Yes unpublished	N	BASF
III A 2.8.4/1	Schmidt F.	2000	Metconazole (CL 900768) 60 G/L SL (SF09381): determination of physical/chemical stability data in polyethylene bottles Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. MK-323-003 Yes unpublished	N	BASF
III A 2.9.1/1	Horsler C.W.	2002	Metconazole 60g/L SL (BAS 555 00 F) and Metconazole 90g/L SL (BAS 555 01 F): Compatibility of tank mixes BASF Agro Research Gosport; Gosport; United Kingdom MK-390-024 No unpublished	Y	BASF