# *European Commission*

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

# BAS 750F
# (Mefentrifluconazole)

## Volume 3 – B.2 (PPP) – BAS 750 01 F

Rapporteur Member State : United Kingdom
Co-Rapporteur Member State : France & Austria

# Version History

| When | What |
|---|---|
| April 2017 | Initial DAR |
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# B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT BAS 750 01 F

The physical and chemical properties of the plant protection product BAS 750 01 F (BAS 750 F 100 g/L EC used as name in studies) are detailed in Table 2-1.

**Table 2-1 : Physical and chemical properties of the plant protection product BAS 750 01 F**

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|
| **B.2.1. APPEARANCE** | | | | | | |
| **Physical state and colour**<br>**B.2.1/01** | Visual examination and organoleptic determination | BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD-140113-0006 | **Initial**: Clear yellow liquid with faintly fishy odour<br>**2 weeks at 54°C**: Clear yellow liquid with faintly fishy odour | Acceptable<br>No change in physical state and colour after accelerated storage | Y | [see 2014/1219235 Kroehl T. 2014 a] |
| **B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES** | | | | | | |
| **Explosive properties**<br>**B.2.2/01** | EC A.14 | BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD-140113-0006 | **Mechanical sensitivity: Impact**<br>No reaction observed indicating no explosive properties<br>**Thermal sensitivity: Koenen-Test**<br>No reaction observed indicating no explosive properties | Acceptable<br>Preliminary test had to be stopped due to evaporation of the test item therefore the main test was used.<br>Test method EC A.14 is considered comparable to test methods described in Part I of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria for classification of explosive substances | Y | [see 2014/1133852 Dreisch S. 2014 a] |

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|
| | | | | by CLP.<br>BAS 750 01 F is not classified as an explosive substance according to CLP Regulation (EC) 1272/2008 Annex 1: 2.1. | | |
| **Oxidizing properties**<br>**B.2.2/02** | EC A.21 | BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD-140113-0006 | The mean pressure rise time (14.68 s) for the test item (1:1 mixture with cellulose) is greater than the mean pressure rise time (3.95 s) for the reference item (1:1 mixture of nitric acid 65% with cellulose).<br>BAS 750 01 F has no oxidizing properties. | Acceptable<br>EEC A.21 deemed sufficiently comparable to Test 21 as described in Section 34.4.1 of the UN Recommendations on the Transport of Dangerous Goods used for classification of oxidising liquids.<br>BAS 750 01 F is not classified as an oxidising liquid according to CLP Regulation (EC) 1272/2008 Annex 1. | Y | [see 2014/1133852 Dreisch S. 2014 a] |
| **B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY** | | | | | | |
| **Flash point of the liquids formulations**<br>**B.2.3/01** | EC A.9 | BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD-140113-0006 | Flash point: 128°C | Acceptable<br>With a flash point > 60 °C, BAS 750 01 F is not classified as a flammable liquid according to CLP Regulation (EC) 1272/2008 Annex 1: Part 2.3. | Y | [see 2014/1133852 Dreisch S. 2014 a] |
| **Flammability of solid** | - | - | Not applicable as BAS 750 01 F is not a solid | Acceptable | - | - |

<table>
<tr><th>Test or Study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr><td>formulations<br>B.2.3/02</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Self-heating of formulation<br>B.2.3/03</td><td>EC A.15</td><td>BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD-140113-0006</td><td>Auto-ignition temperature: 375 °C</td><td>Acceptable</td><td>Y</td><td>[see 2014/1133852 Dreisch S. 2014 a]</td></tr>
<tr><td colspan="7">B.2.4. ACIDITY/ALKALINITY AND PH VALUE</td></tr>
<tr><td>pH of the neat aqueous formulation<br>B.2.4/01</td><td>-</td><td>-</td><td>Not applicable to EC formulations</td><td>Acceptable</td><td>-</td><td>-</td></tr>
<tr><td>pH of a 1 % dilution of the solid or non aqueous formulation<br>B.2.4/02</td><td>CIPAC MT 75.3</td><td>BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD-140113-0006</td><td>
<table>
<tr><th></th><th colspan="3">pH value at 23°C</th></tr>
<tr><th></th><th>Initial</th><th>7 days at 0°C</th><th>2 weeks at 54°C</th></tr>
<tr><td>pH of pure water</td><td>5.6</td><td>5.8</td><td>5.8</td></tr>
<tr><td>pH of CIPAC water D</td><td>6.1</td><td>6.3</td><td>6.3</td></tr>
<tr><td>pH at 1.0% in pure water</td><td>6.8</td><td>6.7</td><td>6.8</td></tr>
<tr><td>pH at 1.0% in CIPAC water D</td><td>6.6</td><td>6.6</td><td>6.5</td></tr>
</table>
</td><td>Acceptable<br>Non-significant change in pH on storage</td><td>Y</td><td>[see 2014/1219235 Kroehl T. 2014 a]</td></tr>
<tr><td>Acidity / Alkalinity<br>B.2.4/03</td><td>-</td><td>-</td><td>Only required for preparations which are acidic (pH<4) or alkaline (pH>10).</td><td>Acceptable</td><td>-</td><td>-</td></tr>
<tr><td colspan="7">B.2.5. VISCOSITY AND SURFACE TENSION</td></tr>
<tr><td>Viscosity of the liquid formulation<br>B.2.5/01</td><td>CIPAC MT 192</td><td>BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD-</td><td>The dynamic viscosity in mPa.s is:
<table>
<tr><th>Storage period</th><th>Initial</th><th>After 2 weeks at 54°C</th></tr>
</table>
</td><td>Acceptable<br>Although the formulation has > 10% hydrocarbon</td><td>Y</td><td>[see 2014/1219235 Kroehl T. 2014 a]</td></tr>
</table>

<table>
<tr><th>Test or Study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr><td></td><td></td><td>140113-0006</td><td>
<table>
<tr><td>Temperature (°C)</td><td>20</td><td>40</td><td>20</td><td>40</td></tr>
<tr><td>at D= 10 $s^{-1}$</td><td>82</td><td>34</td><td>84</td><td>38</td></tr>
<tr><td>at D= 100 $s^{-1}$</td><td>82</td><td>34</td><td>84</td><td>38</td></tr>
<tr><td>at D= 400 $s^{-1}$</td><td>82</td><td>34</td><td>84</td><td>38</td></tr>
<tr><td>Flow behaviour</td><td colspan="4">Newtonian, no change in viscosity with change in shear rate at either 20 °C or 40 °C</td></tr>
<tr><td>Kinematic Viscosity* [mm²/s] at D = 100 $s^{-1}$</td><td>83</td><td>35</td><td colspan="2">-</td></tr>
</table>
* Kinematic viscosity [mm²/s] =<br>Dynamic Viscosity [mPa·s] / Density (0.993 at 20°C, 0.978 at 40°C)</td><td>content, the kinematic viscosity > 20.5 $mm^2/s$ at 40°C therefore the product is not classed as a Category 1 aspiration hazard under CLP.</td><td></td><td></td></tr>
<tr><td>Surface tension of the formulation<br>B.2.5/02</td><td>OECD 115<br>EC A.5</td><td>BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD-140113-0006</td><td>
<table>
<tr><th>Test concentration [%]</th><th>Test temperature [°C]</th><th>Surface Tension [mN/m]</th></tr>
<tr><td>0.1 in pure water at 20°C</td><td>20</td><td>31.0</td></tr>
<tr><td>1.5 in pure water at 20°C</td><td>20</td><td>29.1</td></tr>
<tr><td>100 at 25°C</td><td>25</td><td>28.9</td></tr>
</table>
</td><td>Acceptable<br>The preparation is regarded as surface active.</td><td>Y</td><td>[see 2014/1219235 Kroehl T. 2014 a]</td></tr>
<tr><td colspan="7">B.2.6. RELATIVE DENSITY AND BULK DENSITY</td></tr>
<tr><td>Relative density of the liquid formulation<br>B.2.6/01</td><td>EC A.3</td><td>BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD-140113-0006</td><td>Mechanical oscillator method
<table>
<tr><th colspan="2" rowspan="2"></th><th colspan="2">Density</th></tr>
<tr><th>Initial</th><th>2 weeks at 54°C</th></tr>
<tr><td>At 20°C:</td><td>Density [$g/cm^3$]</td><td>0.993</td><td>0.993</td></tr>
<tr><td></td><td>Relative density $D^{20}_4$<br>(= Density / 0.99997 $g/cm^3$)</td><td>0.993</td><td>0.993</td></tr>
</table>
</td><td>Acceptable</td><td>Y</td><td>[see 2014/1219235 Kroehl T. 2014 a]</td></tr>
</table>

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|
| | | | At 40°C; Density [g/cm$^3$]; 0.978; --- | | | |
| **Bulk density (pour and tap) of powder or granules**<br>**B.2.6/02** | - | - | Not applicable for an EC formulation | Acceptable | - | - |
| **B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT** | | | | | | |
| **Stability after accelerated storage (54°C during 14 days, 8 weeks at 40°C, 12 weeks at 35°C or 18 weeks at 30°C)**<br>**B.2.7/01** | CIPAC MT 46.3<br>Analytical assay using HPLC method AFL0909/01 | BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD-140113-0006 | Product stored in a 1L-PA/PE-coextruded bottle at 54°C for 14 days<br>Initial / 2 weeks at 54 °C<br>Active ingredient content (g/L): 98.7 / 99.3<br>Pack appearance/corrosion: No influence of the product on the container, no corrosion, seal infact and no peculiarities inside container observed / No influence of the product on the container, no corrosion, seal infact and no peculiarities inside container observed<br>% weight change of pack: - / < 0.01<br>The results for other properties pre- and post-storage are reported in the relevant annex points elsewhere in this table. | Acceptable<br>Change in active substance content upon accelerated storage = 0.6%<br>No degradation of the active substance nor the packaging was observed after accelerated storage.<br>HPLC method AFL0909/01 used to determine the level of the active substance has been acceptably validated in accordance with SANCO/3030/99 rev.4 (ref: DAR Volume 3CP PPP B-5.1.1). | Y | [see 2014/1219235 Kroehl T. 2014 a] |
| **Effect of low temperature on stability of liquid** | CIPAC MT 39.3 | BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD- | After 7 days at 0°C, 3.5 mL turbitiy at bottom but no phase separation was observed.<br>After a further 24 hours standing, one inversion and 1 hour standing, 1.4 mL turbidity at bottom but no phase separation was observed.<br>The results for properties pre- and post-low temperature storage are reported in annex points B.2.4 and B.2.8.6 | Acceptable | Y | [see 2014/1219235 Kroehl T. |

<table>
<tr><th>Test or Study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr><td>formulation<br>B.2.7/02</td><td></td><td>140113-0006</td><td></td><td></td><td></td><td>2014 a]</td></tr>
<tr><td>Shelf life following storage at ambient temperature<br>B.2.7/03</td><td></td><td>BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD-140113-0006</td><td><u>104 week report</u><br><br>Samples stored at 23°C in incubators in PA/PE-coextruded packs, 1L and 250 mL (for physical and analytical measurements respectively).<br><br>
<table>
<tr><th><u>Test</u></th><th><u>Guideline and method</u></th><th></th></tr>
<tr><td>Content of a.i. and relevant impurities</td><td>Active: AFL0909/01<br>Relevant impurities: APL0705/01</td><td>
<table>
<tr><th>Storage time (weeks)</th><th>BAS 750 F (Reg. No. 5834378) [g/L]</th></tr>
<tr><td>Initial</td><td>98.7</td></tr>
<tr><td>12</td><td>97.7</td></tr>
<tr><td>26</td><td>98.7</td></tr>
<tr><td>39</td><td>97.3</td></tr>
<tr><td>52</td><td>99.8</td></tr>
<tr><td>78</td><td>98.9</td></tr>
<tr><td>104</td><td>97.0</td></tr>
</table>
n.d. = not determined<br>* < LOQ (22 mg/kg)</td></tr>
<tr><td>Density</td><td>EC A3</td><td>
<table>
<tr><th>Storage time (weeks)</th><th>Density at 20 °C [g/cm$^3$]</th><th>Relative Density $D^{20}_4$ (= Density / 0.99997 g/cm$^3$)</th></tr>
<tr><td>Initial</td><td>0.993</td><td>0.993</td></tr>
<tr><td>12</td><td>0.993</td><td>0.993</td></tr>
<tr><td>26</td><td>0.993</td><td>0.993</td></tr>
<tr><td>39</td><td>0.993</td><td>0.993</td></tr>
<tr><td>52</td><td>0.993</td><td>0.993</td></tr>
</table>
</td></tr>
</table>
</td><td>Acceptable<br>Change in active substance content upon 2 year ambient storage = 1.7%<br>No degradation of the active substance, the formulation, nor the packaging was observed after 2 year ambient storage.<br>HPLC method AFL0909/01 used to determine the level of the active substance has been acceptably validated in accordance with SANCO/3030/99 rev.4 (ref: DAR Volume 3CP PPP B-5.1.1).<br>Persistence of foaming determined at concentrations covering the in-use range.<br>Emulsifiability, emulsion stability and re-emulsifiability determined at concentrations</td><td>Y</td><td>[see 2016/1296130 Kroehl T. 2016 c]</td></tr>
</table>

<table>
<tr><th>Test or Study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td></td><td>
<table>
<tr><td>78</td><td>0.993</td><td>0.993</td></tr>
<tr><td>104</td><td>0.993</td><td>0.993</td></tr>
</table></td></tr>
<tr><td>Condition<br>Physical state<br>Colour<br>Odour</td><td></td><td>
<table>
<tr><th>Storage time (weeks)</th><th>Condition</th><th>Physical state</th><th>Colour</th><th>Odour</th></tr>
<tr><td>Initial</td><td>Clear liquid</td><td>Liquid</td><td>Yellow</td><td>Faintly fishy</td></tr>
<tr><td>52</td><td>Clear liquid</td><td>Liquid</td><td>Yellow</td><td>Faintly fishy</td></tr>
<tr><td>104</td><td>Clear liquid</td><td>Liquid</td><td>Yellow</td><td>Faintly fishy</td></tr>
</table></td></tr>
<tr><td>pH</td><td>CIPAC MT 75</td><td>
<table>
<tr><th>Storage time (weeks)</th><th colspan="2">Initial</th><th colspan="2">52</th><th colspan="2">104</th></tr>
<tr><td></td><td>Meas. Temp. [°C]</td><td>pH</td><td>Meas. Temp. [°C]</td><td>pH</td><td>Meas. Temp. [°C]</td><td>pH</td></tr>
<tr><td>pH of pure water</td><td>23</td><td>5.6</td><td>25</td><td>5.8</td><td>23</td><td>5.6</td></tr>
<tr><td>pH of CIPAC water D</td><td>23</td><td>6.1</td><td>25</td><td>6.4</td><td>23</td><td>6.3</td></tr>
<tr><td>pH at 1.0% in pure water</td><td>23</td><td>6.8</td><td>25</td><td>6.8</td><td>24</td><td>6.7</td></tr>
<tr><td>pH at 1.0 % in CIPAC water D</td><td>23</td><td>6.6</td><td>25</td><td>6.6</td><td>23</td><td>6.5</td></tr>
</table></td></tr>
</table></td><td>covering the in-use range.</td><td></td><td></td></tr>
</table>

<table>
<tr><th>Test or Study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th colspan="3">Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>Viscosity</td><td>CIPAC MT 192</td><td>
<table>
<tr><td>Meas. temp (°C)</td><td colspan="4">20</td></tr>
<tr><td></td><td colspan="3">Dynamic viscosity [mPa·s]</td><td>Flow behaviour</td></tr>
<tr><td>Storage time [weeks]</td><td>at D= 10 $s^{-1}$</td><td>at D = 20 $s^{-1}$</td><td>at D= 100 $s^{-1}$</td><td>at D= 400 $s^{-1}$</td><td></td></tr>
<tr><td>Initial</td><td>82</td><td>82*</td><td>82</td><td>82</td><td>Newtonian</td></tr>
<tr><td>52</td><td>82</td><td>81</td><td>81</td><td>80</td><td>Newtonian</td></tr>
<tr><td>104</td><td>75</td><td>77</td><td>79</td><td>79</td><td>Newtonian</td></tr>
</table>
<table>
<tr><td>Meas. temp (°C)</td><td colspan="4">40</td></tr>
<tr><td></td><td colspan="3">Dynamic viscosity [mPa·s]</td><td>Flow behaviour</td></tr>
<tr><td>Storage time [weeks]</td><td>at D= 10 $s^{-1}$</td><td>at D = 20 $s^{-1}$</td><td>at D= 100 $s^{-1}$</td><td>at D= 400 $s^{-1}$</td><td></td></tr>
<tr><td>Initial</td><td>34</td><td>34*</td><td>34</td><td>34</td><td>Newtonian</td></tr>
<tr><td>52</td><td>30</td><td>31</td><td>31</td><td>31</td><td>Newtonian</td></tr>
<tr><td>104</td><td>29</td><td>30</td><td>32</td><td>32</td><td>Newtonian</td></tr>
</table>
*extrapolated
</td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td>Persistence of foaming</td><td>MT 47.2</td><td>
<table>
<tr><td>Test Conc. In CIPAC water D</td><td></td><td>0.1%</td><td>1.5%</td></tr>
<tr><td>Storage time [weeks]</td><td>time</td><td colspan="2">Foam volume [ml]</td></tr>
<tr><td rowspan="4">Initial</td><td>10 sec</td><td>26</td><td>44</td></tr>
<tr><td>1 min</td><td>24</td><td>40</td></tr>
<tr><td>3 min</td><td>20</td><td>38</td></tr>
<tr><td>12 min</td><td>18</td><td>32</td></tr>
<tr><td rowspan="2">52</td><td>10 sec</td><td>26</td><td>44</td></tr>
<tr><td>1 min</td><td>24</td><td>40</td></tr>
</table>
</td><td></td><td></td><td></td></tr>
</table>

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | 3 min | 20 | 38 | |
| | | | 12 min | 18 | 32 | |
| | | 104 | 10 sec | 28 | 44 | |
| | | | 1 min | 26 | 40 | |
| | | | 3 min | 22 | 36 | |
| | | | 12 min | 20 | 30 | |

**Emulsion stability** — MT 36.3

**Test conc.: 0.1%**

| Storage time [weeks] | | Initial | | 52 | | 104 | |
|---|---|---|---|---|---|---|---|
| CIPAC water | | A | D | A | D | A | D |
| Time interval | Description of separation | | | | | | |
| | | Separation [mL] | | | | | |
| 30 seconds | Spontaneous emulsion | completely emulsified; little froth | | | | | |
| 30 minutes | Sediment | 0 | 0 | 0 | 0 | 0 | 0 |
| | Top cream | 0 | 0 | 0 | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 | 0 | 0 | 0 |
| | Bottom oil | | | | | | |
| 2 hours | Sediment | <1* | 0 | 0 | 0 | 0 | 0 |
| | Top cream | 0 | 0 | 0 | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 | 0 | 0 | 0 |
| | Bottom oil | | | | | | |
| 24 hours | Sediment | 0 | 0 | 0 | 0 | 0 | 0 |
| | Top cream | <1 | 0 | 0 | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 | 0 | 0 | 0 |

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Bottom oil | | | | | | | | | |
| Re-emulsification + 30 seconds | Completely re-dispersed | Yes, homog. emulsion | | | | | | | | |
| 30 minutes after re-emulsification | Sediment | <1* | 0 | 0 | 0 | 0 | 0 | | | |
| | Top cream | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | Bottom cream | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | Top oil | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | Bottom oil | | | | | | | | | |

*traces

**Test conc.: 1.5%**

| Storage time [weeks] | | Initial | | 52 | | 104 | |
|---|---|---|---|---|---|---|---|
| CIPAC water | | A | D | A | D | A | D |
| Time interval | Description of separation | | | | | | |
| | | Separation [mL] | | | | | |
| 30 seconds | Spontaneous emulsion | completely emulsified; little froth | | | | | |
| 30 minutes | Sediment | 0 | 0 | 0 | 0 | 0 | 0 |
| | Top cream | 0 | 0 | 0 | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 | 0 | 0 | 0 |
| | Bottom oil | | | | | | |
| 2 hours | Sediment | <1* | 0 | 0 | 0 | 0 | 0 |
| | Top cream | 0 | 0 | 0 | 0 | 1 | 0 |
| | Bottom cream | 0 | 0 | 0 | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 | 0 | 0 | 1 |
| | Bottom oil | 0 | 0 | 0 | 0 | 0 | 0 |
| 24 hours | Sediment | | | | | | |
| | Top cream | 0 | 0 | 0 | 0 | 0 | 0 |
| | Bottom | <1 | 0 | 1 | 0 | 1 | 0 |
| | | <1 | 0 | 0 | 0 | 0 | 0 |

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | cream<br>Top oil<br>Bottom oil | 0<br>0 | <1<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 1<br>0 |
| | Re-emulsification + 30 seconds | Completely re-dispersed | Yes, homog. emulsion | | | | | |
| | 30 minutes after re-emulsification | Sediment<br>Top cream<br>Bottom cream<br>Top oil<br>Bottom oil | <1*<br>0<br>0<br>0<br>0 | 0<br>0<br>0<br>0<br>0 | 0<br>0<br>0<br>0<br>0 | 0<br>0<br>0<br>0<br>0 | 0<br>0<br>0<br>0<br>0 | 0<br>0<br>0<br>0<br>0 |

*traces

**Packaging appearance (clarity)**

| Storage time [weeks] | Clarity |
|---|---|
| Initial | Clear |
| 52 | Clear |
| 104 | Clear |

**Weight change of unopened container**

| Storage time [weeks] | Weight initial [g] | Weight after storage [g] | Weight change [%] |
|---|---|---|---|
| 52 | 1092.7 | 1093.0 | 0.03 |
| 104 | 1092.3 | 1093.0 | 0.07 |

**Resistance of the packaging material to its contents**

| Storage time [weeks] | Package appearance | | Corrosion |
|---|---|---|---|
| | Initial | After storage | |
| Initial | - | - | No influence of the product on the original container, no corrosion, seal intact and no |

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|
| | | | <table><tr><td></td><td></td><td></td><td></td><td></td><td>peculiarities inside of the original container were observed.</td></tr><tr><td></td><td></td><td>52</td><td>No influence of the product on the original container was observed.</td><td>As initial</td><td>No corrosion, seal intact and no peculiarities inside of the original container were observed.</td></tr><tr><td></td><td></td><td>104</td><td>No influence of the product on the original container was observed.</td><td>Except a slight deformation, no influence of the product on the original container was observed.</td><td>No corrosion, seal intact and no peculiarities inside of the original container were observed.</td></tr></table> | | | |
| **B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT** | | | | | | |
| **B.2.8.1. Wettability** | | | | | | |
| **Wettability of solid formulation**<br>**B.2.8.1/01** | - | - | Not applicable to EC formulations | Acceptable | - | - |
| **B.2.8.2. Persistence foaming** | | | | | | |
| **Persistence of foaming of the diluted** | CIPAC MT 47.2 | BAS 750 F 100 g/L EC (BAS 750 01 F) | <table><tr><td>Test Conc.</td><td></td><td></td><td>0.1%</td><td>1.5%</td></tr><tr><td>Storage Temp.</td><td>Storage time</td><td>time</td><td colspan="2">Foam volume</td></tr></table> | Acceptable<br>Less than 60 mL foam after 1 minute | Y | [see 2014/1219235 Kroehl T. |

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|
| **formulation**<br>**B.2.8.2/01** | | Batch No.: FD-140113-0006 | [°C] / [weeks] / [ml]<br>- / Initial / 10 sec: 26, 46<br>- / Initial / 1 min: 24, 44<br>- / Initial / 3 min: 20, 44<br>- / Initial / 12 min: 18, 36<br>54 / 2 / 10 sec: 20, 42<br>54 / 2 / 1 min: 18, 42<br>54 / 2 / 3 min: 16, 40<br>54 / 2 / 12 min: 16, 36 | Persistence of foaming determined at concentrations covering the in-use range. | | 2014 a] |
| **B.2.8.3. Suspensibility** | | | | | | |
| **Suspensibility of water dispersible formulation**<br>**B.2.8.3/01** | - | - | Not applicable to an EC formulation | Acceptable | - | - |
| **Spontaneity of dispersion of water dispersible formulation**<br>**B.2.8.3/02** | - | - | Not applicable to an EC formulation | Acceptable | - | - |
| **Dispersion stability of SE, OD or EG formulation**<br>**B.2.8.3/03** | - | - | Not applicable to an EC formulation | Acceptable | - | - |
| **B.2.8.4. Degree of dissolution and dilution stability** | | | | | | |
| **Degree of dissolution of water soluble** | - | - | Not applicable to an EC formulation | Acceptable | - | - |

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|
| **formulation B.2.8.4/01** | | | | | | |
| **Dilution stability of water soluble formulation B.2.8.4/02** | - | - | Not applicable to an EC formulation | Acceptable | - | - |
| **B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability** | | | | | | |
| **B.2.8.5.1. Particle size distribution** | | | | | | |
| **Wet sieve test of water dispersible formulation B.2.8.5.1/01** | - | - | Not applicable to an EC formulation | Acceptable | - | - |
| **Size distribution of particles of powder or suspension concentrate formulation B.2.8.5.1/02** | - | - | Not applicable to an EC formulation | Acceptable | - | - |
| **Nominal size range of granule B.2.8.5.1/03** | - | - | Not applicable to an EC formulation | Acceptable | - | - |
| **B.2.8.5.2. Dust content** | | | | | | |
| **Dust content of granular formulation B.2.8.5.2/01** | - | - | Not applicable to an EC formulation | Acceptable | - | - |
| **B.2.8.5.3. Attrition** | | | | | | |
| **Attrition characteristics of granules and tablets** | - | - | Not applicable to an EC formulation | Acceptable | - | - |

<table>
<tr><th>Test or Study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr><td>B.2.8.5.3/01</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="7">B.2.8.5.4. Hardness and integrity</td></tr>
<tr><td>Hardness of tablets<br>B.2.8.5.4/01</td><td>-</td><td>-</td><td>Not applicable to an EC formulation</td><td>Acceptable</td><td>-</td><td>-</td></tr>
<tr><td>Integrity of tablets<br>B.2.8.5.4/02</td><td>-</td><td>-</td><td>Not applicable to an EC formulation</td><td>Acceptable</td><td>-</td><td>-</td></tr>
<tr><td colspan="7">B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability</td></tr>
<tr><td>Emulsifiability, emulsion stability and re-emulsifiability of formulation<br>B.2.8.6/01</td><td>CIPAC MT 36.3</td><td>BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD-140113-0006</td><td>Concentration 0.1 % in CIPAC water A
<table>
<tr><td></td><td></td><td>Initial</td><td>7 days at 0°C</td><td>2 weeks at 54°C</td></tr>
<tr><td>Time interval</td><td colspan="4">Volume [mL]</td></tr>
<tr><td>30 seconds</td><td>Spontaneous emulsion</td><td>yes, homog. emulsion, little froth</td><td>yes, homog. emulsion, little froth</td><td>yes, homog. emulsion, little froth</td></tr>
<tr><td rowspan="5">30 minutes</td><td>Sediment</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Top cream</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Bottom cream</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Top oil</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Bottom oil</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td rowspan="5">2 hours</td><td>Sediment</td><td><1*</td><td>0</td><td><1*</td></tr>
<tr><td>Top cream</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Bottom cream</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Top oil</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Bottom oil</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td rowspan="5">24 hours</td><td>Sediment</td><td><1</td><td>0</td><td>0</td></tr>
<tr><td>Top cream</td><td>0</td><td>0**</td><td>0</td></tr>
<tr><td>Bottom cream</td><td>0</td><td>0</td><td><1*</td></tr>
<tr><td>Top oil</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Bottom oil</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Re-emulsification +</td><td></td><td>yes, homog. emulsion</td><td>yes, homog. emulsion</td><td>yes, homog. emulsion</td></tr>
</table></td><td>Acceptable<br><br>Less than 2 mL cream after 30 minutes, trace of oil. Re-emulsification complete after 30 minutes.<br><br>Stability observed in both CIPAC A and D waters.<br><br>Emulsifiability, emulsion stability and re-emulsifiability determined at concentrations covering the in-use range.</td><td></td><td></td></tr>
</table>

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| 30 seconds | | | | |
| 30 minutes after re-emulsification | Sediment | <1* | 0 | 0 |
| | Top cream | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 |
| | Bottom oil | 0 | 0 | 0 |

* traces; ** schlieren at top

Concentration 1.5 % in CIPAC water A

| | | Initial | 7 days at 0°C | 2 weeks at 54°C |
|---|---|---|---|---|
| Time interval | Volume [mL] | | | |
| 30 seconds | Spontaneous emulsion | yes, homog. emulsion, little froth | yes, homog. emulsion, little froth | yes, homog. emulsion, little froth |
| 30 minutes | Sediment | 0 | 0 | 0 |
| | Top cream | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 |
| | Bottom oil | 0 | 0 | 0 |
| 2 hours | Sediment | <1* | <1 | <1* |
| | Top cream | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 |
| | Bottom oil | 0 | 0 | 0 |
| 24 hours | Sediment | 0 | 0 | 0 |
| | Top cream | <1 | 1 | 1 |
| | Bottom cream | <1 | 0 | 0 |
| | Top oil | 0 | 0 | 0 |
| | Bottom oil | 0 | 0 | 0 |
| Re-emulsification + 30 seconds | | yes, homog. emulsion | yes, homog. emulsion | yes, homog. emulsion |
| 30 minutes after re-emulsification | Sediment | <1* | 0 | 0 |
| | Top cream | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 |

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| | Top oil | 0 | 0 | 0 |
| | Bottom oil | 0 | 0 | 0 |

* traces

Concentration 0.1 % in CIPAC water D

| | | Initial | 7 days at 0°C | 2 weeks at 54°C |
|---|---|---|---|---|
| Time interval | Volume [mL] | | | |
| 30 seconds | Spontaneous emulsion | yes, homog. emulsion, little froth | yes, homog. emulsion, little froth | yes, homog. emulsion, little froth |
| 30 minutes | Sediment | 0 | 0 | 0 |
| | Top cream | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 |
| | Bottom oil | 0 | 0 | 0 |
| 2 hours | Sediment | 0 | 0 | 0 |
| | Top cream | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 |
| | Bottom oil | 0 | 0 | 0 |
| 24 hours | Sediment | 0 | 0 | 0 |
| | Top cream | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 |
| | Top oil | 0 | <1* | <1* |
| | Bottom oil | 0 | 0 | 0 |
| Re-emulsification + 30 seconds | | yes, homog. emulsion | yes, homog. emulsion | yes, homog. emulsion |
| 030 minutes after re-emulsification | Sediment | 0 | 0 | 0 |
| | Top cream | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 |
| | Bottom oil | 0 | 0 | 0 |

* traces

Concentration 1.5 % in CIPAC water D

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|

| | | Initial | 7 days at 0°C | 2 weeks at 54°C |
|---|---|---|---|---|
| Time interval | Volume [mL] | | | |
| 30 seconds | Spontaneous emulsion | yes, homog. emulsion, little froth | yes, homog. emulsion, little froth | yes, homog. emulsion, little froth |
| 30 minutes | Sediment | 0 | 0 | 0 |
| | Top cream | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 |
| | Bottom oil | 0 | 0 | 0 |
| 2 hours | Sediment | 0 | 0 | 0 |
| | Top cream | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 |
| | Bottom oil | 0 | 0 | 0 |
| 24 hours | Sediment | 0 | 0 | 0 |
| | Top cream | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 |
| | Top oil | <1 | 1 | 1 |
| | Bottom oil | 0 | 0 | 0 |
| Re-emulsification + 30 seconds | | yes, homog. emulsion | yes, homog. emulsion | yes, homog. emulsion |
| 30 minutes after re-emulsification | Sediment | 0 | 0 | 0 |
| | Top cream | 0 | 0 | 0 |
| | Bottom cream | 0 | 0 | 0 |
| | Top oil | 0 | 0 | 0 |
| | Bottom oil | 0 | 0 | 0 |

## B.2.8.7. Flowability, pourability and dustability

| | | | | | | |
|---|---|---|---|---|---|---|
| **Flowability of granular formulation**<br>**B.2.8.7/01** | - | - | Not applicable to an EC formulation | Acceptable | - | - |

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|
| **Pourability of suspensions**<br>**B.2.8.7/02** | - | - | Not applicable to an EC formulation | Acceptable | - | - |
| **Dustability of dustable powders after accelerated storage**<br>**B.2.8.7/03** | - | - | Not applicable to an EC formulation | Acceptable | - | - |
| **B.2.9. PHYSICAL AND CHEMICAL COMPATIBILITY WITH OTHER PRODUCTS INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED** | | | | | | |
| **Physical and chemical compatibility of tank mixtures**<br>**B.2.9/01** | ASTM method: E 1518-05 | BAS 750 F 100 g/L EC (BAS 750 01 F)<br>Batch No.: FD-140113-0006 | In total 16 mixtures of BAS 750 01 F with following plant protection products BAS 274 03 F Bravo® (SC), BAS 500 06 F Comet 200® (EC), BAS 700 09 F Imtrex® (EC), BAS 703 07 F Priaxor® (EC), BAS 560 00 F Flexity® (EC), BAS 9314 1 F Proline® (EC), BAS 421 12 F Corbel® (EC), BAS 067 00 W Cerone® (SL), BAS 008 00 D Turbo® (GR), BAS 122 08 W Medax Top® (SC), BAS 139 00 W Medax Max® (WG), BAS 044 26 H Duplosan DP® (SL), BAS 812 00 H Biathlon Plus® (WG), BAS 9517 0 H Ariane C® (EC), BAS 9438 1 H Axial 50® (EC), BAS 9126 0 S Adigor® (EC), BAS 9377 0 H Atlantis® (WG), BAS 9101 0 S Actirob B® (EC), BAS 9005 0 I Pirimor-Granulat® (GR) and BAS 314 03 I Sumicidin Alpha® (EC) were tested. All mixtures were determined to be physically compatible and can be used in spray applications. In all mixtures no lumping and no flocculation occurred.<br>The mixtures appeared to be homogeneous. Therefore BAS 750 01 F is apparently physically compatible with the tested products.<br>No indication of any chemical reaction between the mixed products was observed. Therefore BAS 750 01 F is apparently chemically compatible with the tested products. | Acceptable<br>It is noted that foaming occurs and the use of an anti-foam agent is recommended in tank mixing with BAS 044 26 H Duplosan DP® (SL) and also with BAS 9314 1 F Proline® (EC).<br>It is also noted that the following tank mixes are only compatible with use of an agitator: BAS 274 03 F, BAS 500 06 F, BAS 703 07 F, BAS 560 00 F, BAS 008 00 D & BAS 122 08 W & BAS 421 12 F, BAS 139 00 W, BAS 812 00 H, BAS 9377 0 H | Y | [see 2015/1240031 Wegkamp H.-G.. 2015 a] |

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|---|---|---|---|---|
| **B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS** | | | | | | |
| **Distribution and adhesion to seeds**<br>**B.2.9.10/01** | - | - | Not applicable to an EC formulation | Acceptable | - | - |
| **B.2.11. OTHER STUDIES** | | | | | | |
| | | | | Not applicable | | |

**Summary**

BAS 750 01 F is a clear yellow liquid with a faintly fishy odour. It not classified as explosive, oxidising, highly flammable or as an aspiration hazard in accordance with the CLP Regulation. It has a flashpoint of 128 °C and an auto ignition temperature of 375 °C. It has a pH of around 6.5 in 1% aqueous solution. It is stable after low temperature (7 days at 0 °C), accelerated (2 weeks at 54 °C) and 2 year ambient storage. It has an acceptable level of persistent foam within the concentration range 0.1 – 1.5% which covers lowest-highest in-use concentration. It has an acceptable emulsifiability, emulsion stability and re-emulsifiability in both CIPAC A and D waters determined at concentrations covering the in-use range. It is physically and chemically compatible with 19 other plant protection products in tank mixes.

## B.2.12. REFERENCES RELIED ON

| Data Point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| KCP 2.1/1<br><br>KCP 2.4/1<br><br>KCP 2.5/1<br><br>KCP 2.6/1<br><br>KCP 2.7/3<br><br>KCP 2.8.2/1<br><br>KCP 2.8.6/1 | Kroehl T. | 2014 a | Physical and chemical properties of BAS 750 01 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C)<br><br>2014/1219235<br><br>BASF SE, Limburgerhof, Germany Fed.Rep.<br><br>yes<br><br>Unpublished | No | Yes | Data for first Approval | BASF | N.A. |
| KCP 2.2/1<br><br>KCP 2.3/1 | Dreisch S. | 2014 a | Determination of physico-chemical properties according to Directive 94/37/EC (Regulation (EC) No. 440/2008)<br><br>2014/1133852<br><br>consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.<br><br>yes | No | Yes | Data for first Approval | BASF | N.A. |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | Unpublished | | | | | |
| KCP 2.9/1 | Wegkamp H.-G. | 2015 a | Physical and chemical compatibility in aqueous tank mixtures of BAS 750 01 F<br><br>2015/1240031<br><br>BASF SE, Limburgerhof, Germany Fed.Rep.<br><br>no<br><br>Unpublished | No | No | Not applicable | BASF | N.A |
| KCP 2.7/2 | Kroehl T. | 2016 c | Chemical and physical stability of formula BAS 750 01 F when stored for up to 3 years in PA/PE-coextruded packs - 104 week report<br><br>BASF SE, Limburgerhof, Germany Fed.Rep.<br><br>2016/1296130<br><br>yes<br><br>Unpublished | No | Yes | Data for first Approval | BASF | N.A |