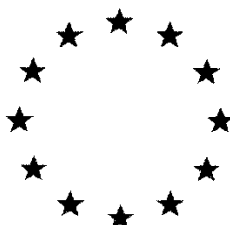


# ***European Commission***



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

**ETHOFUMESATE**

**Volume 3 – B.2 (AS)**

Rapporteur Member State: Austria  
Co-Rapporteur Member State: Denmark

**Version History**

| <b>When</b> | <b>What</b>                |
|-------------|----------------------------|
| 1998        | Initial DAR                |
| 2000        | Addendum 8 to Vol.3 rev. 2 |
| 2015/01     | DRAR                       |
|             |                            |
|             |                            |

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

Throughout this document the original DAR, written by Sweden, is referred to as the DAR and this evaluation, written by Austria, is referred to as the RAR (Renewal assessment report). Studies that were evaluated in the DAR have not been re-evaluated and the results are presented in this report in grey. New information (e.g. historical control data, additional experimental details) or new interpretation of the data has been taken into account or changes compared to the original DAR are written in black.

| Test or Study Annex Point   | Guideline and method              | Test material purity and specification  | Used methods / Results   | Comments (Acceptable / Non acceptable)   | GLP | Reference   |
|---|-----------------------------------|---|--|--|-----|---|
| <b>B.2.1. MELTING POINT AND BOILING POINT</b>                       |                                   |   |  |  |     |   |
| <b>Melting, freezing or solidification point</b><br><b>B.2.1/01</b> | EC A.1, OECD 102 DSC              | Ethofumesate pure<br>Batch n° AE B049913 00<br>1B99 0002<br>purity 99.9 %                         | The melting point of ethofumesate at atmospheric pressure (1013.3 hPa) is 70.7 °C.   | <b>Acceptable</b><br><br>New study was performed since a melting range was stated in the DAR | Y   | <b>Taskforce:</b><br>Smeykal, H.; 2008<br>M-299734-01-1 |
|   | OECD 102                          | Ethofumesate technical concentrate<br>Content: 99.9%<br>capillary method with photocell detection | Melting range: 69.6 - 70.7°C   | EU agreed endpoint<br>DAR 1998   | Y   | <b>UPL:</b><br>Ward, 1990<br>(see DAR)                  |
| <b>Boiling point</b><br><b>B.2.1/02</b>                             | EC A.2, OECD 103 DSC              | Ethofumesate pure<br>Batch n° AE B049913 00<br>1B99 0002<br>purity 99.9 %                         | Ethofumesate boiled under decomposition at atmospheric pressure. The boiling range of ethofumesate under decomposition at atmospheric pressure (1013.3 hPa) is 305 – 320 °C.                 | <b>Acceptable</b><br><br>New study was performed as the former was not according to GLP.     | Y   | <b>Taskforce:</b><br>Smeykal, H.; 2008<br>M-299734-01-1 |
|   | OECD 113 CIPAC MT 113 DSC and TGA | Ethofumesate technical concentrate<br>F/97/010<br>Content: not stated                             | Ethofumesate decomposes before reaching the boiling point. Temperatures of decomposition are: 285°C (Differential Scanning Calorimetric) and 224°C (Thermogravimetric Analysis).             | EU agreed endpoint<br>DAR 1998   | Y   | <b>UPL:</b><br>Werle, 1997<br>(see DAR)                 |
| <b>Decomposition / Sublimation temperature</b><br><b>B.2.1/03</b>   | OECD 113                          | Ethofumesate pure<br>Batch n° AE B049913 00<br>1B99 0002<br>purity 99.9 %                         | Ethofumesate showed an endothermic effect in the temperature range 65 – 90 °C (melting) and an exothermal decomposition in the temperature range 290 – 405 °C with a mean energy of 375 J/g. | <b>Acceptable</b><br><br>New study was performed as the former was not according to GLP.     | Y   | <b>Taskforce:</b><br>Smeykal, H.; 2008<br>M-299734-01-1 |

| Test or Study Annex Point                             | Guideline and method                         | Test material purity and specification  | Used methods / Results  | Comments (Acceptable / Non acceptable)  | GLP        | Reference   |
|---|--|---|---|---|------------|---|
| <b>B.2.2. VAPOUR PRESSURE, VOLATILITY</b>             |  |   |   |   |            |   |
| <b>Vapour pressure<br/>B.2.2/01</b>                   | EC A.4,<br>OECD 104<br>Gas saturation method | Ethofumesate<br>Batch n° C66/87<br>purity 99.9 %  | Extrapolated:<br>$6.5 \times 10^{-4}$ Pa for 25 °C<br>Measured :<br>$4.0 \times 10^{-3}$ Pa for 40 °C   | EU agreed endpoint<br>DAR 1998  | Y          | <b>Taskforce and UPL:</b><br>Bright, A.A.S.<br>1988<br>M-155198-01-1  |
| <b>Volatility (Henry's Law constant)<br/>B.2.2/02</b> | Calculation                                  | Ethofumesate<br>Batch n° C66/87<br>purity 99.9 %  | Henry's law constant at 25 °C at different pH values:<br>$3.72 \times 10^{-3}$ Pa x m <sup>3</sup> x mol <sup>-1</sup><br>No pH effect because the active substance is not ionisable. | EU agreed endpoint<br>DAR 1998  | N          | <b>Taskforce and UPL:</b><br>Bright, A.S.<br>Stalker, A.M.<br>1994<br>M-158022-01-1   |
| <b>B.2.3. APPEARANCE (PHYSICAL STATE, COLOUR)</b>     |  |   |   |   |            |   |
| <b>Physical state and colour<br/>B.2.3/01</b>         | OPPTS 830.6302,<br>OPPTS 830.6303            | Ethofumesate pure<br>Batch n°<br>AE B049913 00<br>1B99 0002<br>purity 99.9 %<br><br>Ethofumesate<br>TGAI<br>Batch n°<br>AE B049913-01-08<br>purity 98.5 % | Purified active substance :<br>odorless white powder<br><br>Active substance as manufactured :<br>Beige platelets<br>intensive odor (not characteristic)                              | <b>Acceptable</b><br><br>New study was performed as the former was not according to GLP.                            | Y<br><br>Y | <b>Taskforce:</b><br>Ziemer, F.<br>Strunk, B.<br>2012<br>M-431327-01-1<br><br>Ziemer, F.<br>Strunk, B.<br>2012<br>M-431325-01-1 |
|   | visual assessment                            | Ethofumesate<br>TGAI<br>Content: 99.1%  | White crystalline powder  | <b>Acceptable</b><br><br>No information on the pure active substance is required since the purity of TGAI is > 98%. | Y          | <b>UPL:</b><br>Diepenhorst, P.C.<br>2011  |

| Test or Study Annex Point  | Guideline and method          | Test material purity and specification                                       | Used methods / Results                                 |   | Comments (Acceptable / Non acceptable)   | GLP | Reference  |
|--|-------------------------------|--|--|---|--|-----|--|
| B.2.4. SPECTRA (UV/VIS, IR, NMR, MS), MOLAR EXTINCTION AT RELEVANT WAVELENGTHS, OPTICAL PURITY |                               |  |  |   |  |     |  |
| Ultraviolet/visible (UV/VIS)<br>B.2.4/01   | OECD 101<br>OPPTS<br>830.7050 | Ethofumesate pure<br>Batch n°<br>AE B049913 00<br>1B99 0002<br>purity 99.9 % | UV/VIS (methanol)                                      |   | Acceptable   | Y   | Taskforce:<br>Wiche, A.<br>Bogdoll, B<br>2012<br>M-435863-01-1 |
|  |                               |  | Wavelength [nm]  | Molar extinction coefficient [L/mol x cm] | New study was performed as the former was not according to GLP and acetonitrile and chloroform, respectively was used as solvent.<br><br>According to OECD 101 a suitable organic solvent should be used (methanol preferred) if it is not possible to obtain sufficient concentrations in any of the aqueous media. |     |  |
|  |                               |  | 203  | 19441                                     |  |     |  |
|  |                               |  | 228  | 7228                                      |  |     |  |
|  |                               |  | 281  | 2797                                      |  |     |  |
|  |                               |  | 291  | 1412                                      |  |     |  |
|  |                               |  | UV/VIS (methanol + HCl c <sub>HCl</sub> = 0.1 mol/L)   |   |  |     |  |
|  |                               |  | Wavelength [nm]  | Molar extinction coefficient [L/mol x cm] |  |     |  |
|  |                               |  | 202  | 24122                                     |  |     |  |
|  |                               |  | 227  | 7339                                      |  |     |  |
|  |                               |  | 280  | 2797                                      |  |     |  |
|  |                               |  | 291  | 1357                                      |  |     |  |
|  |                               |  | UV/VIS (methanol + NaOH c <sub>NaOH</sub> = 0.1 mol/L) |   |  |     |  |
|  |                               |  | Wavelength [nm]  | Molar extinction coefficient [L/mol x cm] |  |     |  |
|  |                               |  | 227  | 7339                                      |  |     |  |
|  |                               |  | 280  | 2853                                      |  |     |  |
|  |                               |  | 291  | 1357                                      |  |     |  |
|  |                               |  | At 290 nm ε > 1000 L/mol x cm                          |   |  |     |  |

| Test or Study Annex Point                            | Guideline and method                                 | Test material purity and specification                      | Used methods / Results      |   | Comments (Acceptable / Non acceptable) | GLP                              | Reference   |
|--|--|---|-----------------------------|---|--|----------------------------------|---|
|  |  | Ethofumesate standard: 99.6%                                | Neutral in methanol         |   | Acceptable                             | Y                                | UPL:<br>Bhandari, N.M. (2013)<br><br>Document provided in the confidential part Volume 4 since information on purity of batches and impurities is provided as well. |
|  |  |   | Wavelength [nm]             | Molar extinction coefficient [L/mol x cm] |  |                                  |   |
|  |  |   | 202.5                       | 17362.4                                   |  |                                  |   |
|  |  |   | 227                         | 6716.4                                    |  |                                  |   |
|  |  |   | 280.5                       | 2545.6                                    |  |                                  |   |
|  |  |   | Acidic (methanol + HCl)     |   |  |                                  |   |
|  |  |   | Wavelength [nm]             | Molar extinction coefficient [L/mol x cm] |  |                                  |   |
|  |  |   | 202.0                       | 18872.3                                   |  |                                  |   |
|  |  |   | 227                         | 6663.4                                    |  |                                  |   |
|  |  |   | 280.5                       | 2529.7                                    |  |                                  |   |
|  |  |   | Basic (methanol + NaOH)     |   |  |                                  |   |
|  |  |   | Wavelength [nm]             | Molar extinction coefficient [L/mol x cm] |  |                                  |   |
|  |  |   | 212                         | 6434.0                                    |  |                                  |   |
|  |  |   | 227                         | 6549.6                                    |  |                                  |   |
|  |  |   | 280.0                       | 2557.0                                    |  |                                  |   |
|  |  |   | at 290 nm ε>1000 L/mol x cm |   |  |                                  |   |
|  |  |   | Infrared (IR)<br>B.2.4/02   | OECD 101<br>OPPTS<br>830.7050             |  |                                  |   |
| Ethofumesate pure<br>purity 99.9 %                   | IR spectrum confirmed the structure of Ethofumesate. |   |                             |   | EU agreed endpoint<br>DAR 1998         | N                                | UPL:<br>Audus, 1994,<br>Anonymous, 1995   |
| IR spectrum confirmed the structure of Ethofumesate. |  | Acceptable<br><br>New study was performed as the former was |                             |   | Y                                      | Patel, A.H. (2013c)<br>Documents |   |

| Test or Study Annex Point                    | Guideline and method          | Test material purity and specification                                       | Used methods / Results   | Comments (Acceptable / Non acceptable)  | GLP        | Reference  |
|--|-------------------------------|--|--|---|------------|--|
|  |                               |  |  | not according to GLP  |            | provided in the confidential part Volume 4 since information on purity of batches is contained as well.  |
| Nuclear magnetic resonance (NMR)<br>B.2.4/03 | OECD 101<br>OPPTS<br>830.7050 | Ethofumesate pure<br>Batch n°<br>AE B049913 00<br>1B99 0002<br>purity 99.9 % | <sup>1</sup> H-NMR<br><sup>13</sup> C-NMR<br>The spectra confirmed the structure   | <b>Acceptable</b><br>New study was performed as the former was not according to GLP.                                      | Y          | <b>Taskforce:</b><br>Wiche, A.<br>Bogdoll, B<br>2012<br>M-435863-01-1  |
|  |                               | Ethofumesate pure<br>purity 99.9 %   | <sup>1</sup> H-NMR and <sup>13</sup> C-NMR spectra confirmed the structure<br><br><sup>1</sup> H-NMR and <sup>13</sup> C-NMR spectra confirmed the structure | EU agreed endpoint<br>DAR 1998<br><br><b>Acceptable</b><br>New study was performed as the former was not according to GLP | N<br><br>Y | <b>UPL:</b><br>Audus, 1994,<br>Anonymous, 1995<br>Patel, A.H. (2013c)<br>Documents provided in the confidential part Volume 4 since information on purity of batches is contained as well. |
| Mass spectra (MS)<br>B.2.4/04                | OECD 101<br>OPPTS<br>830.7050 | Ethofumesate pure<br>Batch n°<br>AE B049913 00<br>1B99 0002<br>purity 99.9 % | Mass spectrum (LC-MS/ESI <sup>+</sup> -spectrum)<br>The spectrum confirmed the structure   | <b>Acceptable</b><br>New study was performed as the former was not according to GLP.                                      | Y          | <b>Taskforce:</b><br>Wiche, A.<br>Bogdoll, B<br>2012<br>M-435863-01-1  |
|  |                               | Ethofumesate pure<br>purity 99.9 %   | Mass spectrum (EI-spectrum)<br>The spectrum confirmed the structure<br><br>Mass spectrum (EI-spectrum)<br>The spectrum confirmed the structure               | EU agreed endpoint<br>DAR 1998<br><br><b>Acceptable</b><br>New study was performed as the former was not according to GLP | N<br><br>Y | <b>UPL:</b><br>Audus, 1994,<br>Anonymous, 1995<br>Patel, A.H. (2013c)<br>Documents provided in the confidential part Volume 4 since information on purity of batches is contained as well. |



| Test or Study Annex Point  | Guideline and method          | Test material purity and specification  | Used methods / Results   | Comments (Acceptable / Non acceptable)  | GLP        | Reference  |
|--|-------------------------------|---|--|---|------------|--|
| Spectra for impurities<br>EMS (ethyl methane sulfonate)<br>B.2.4/05a | OECD 101<br>OPPTS<br>830.7050 | Ethyl methanesulfonate (EMS ; AE C639174)<br>Batch n° AE C639174-PU-01 / 1292222<br>purity 97.8 % | <b>EMS (AE C639174)</b><br>UV/VIS-, IR-, <sup>1</sup> H-NMR-, <sup>13</sup> C-NMR and MS-spectra are provided to confirm the chemical structure.<br>UV/VIS: Measurements at 1 g/L were performed in neutral medium but no meaningful spectra could be achieved. Therefore the molar extinction coefficients are ultimately not calculable but extinction/absorption coefficient can be anticipated to be < 10 L/mol x cm at wavelength > 290 nm.<br>Furthermore, no measurements were performed at even higher concentrations and in acidic and alkaline medium. | <b>Acceptable</b><br>This impurity was not considered to be relevant for the first Annex I inclusion. However, according to the FAO specification for ethofumesate (2007) a remark that ethyl methane sulfonate can occur as a result of certain manufacturing processes and if it occurs at ≥0.1 mg/kg (relative to ethofumesate) it would be designated as relevant impurity. | Y          | <b>Taskforce:</b><br>Selzer, J.<br>2013<br>M-465124-01-1   |
|  |                               | Ethyl methanesulfonate (EMS)<br>purity 99.99 %  | It is demonstrated that there is no UV/VIS absorption even not at higher concentration.<br><br>MS-EI-, IR- and NMR-spectra are included in study Patel, A.H. (2013c)   | <b>Acceptable</b>   | Y<br><br>Y | <b>UPL:</b><br>Bhandari, N.M. (2013)<br>Patel, A.H. (2013c)<br>Documents provided in the confidential part Volume 4 since information on purity of batches is contained as well. |

| Test or Study Annex Point  | Guideline and method          | Test material purity and specification   | Used methods / Results   |   | Comments (Acceptable / Non acceptable)   | GLP               | Reference  |  |
|--|-------------------------------|--|--|---|--|-------------------|--|--|
| Spectra for impurities<br><b>iBMS (isobutyl-methane sulfonate)</b><br><b>B.2.4/05b</b> | OECD 101<br>OPPTS<br>830.7050 | Isobutyl-methane sulfonate (iBMS ; AE C639170)<br>Batch n° AE C639170 00 1B99 0002 / MD2082<br>purity 98.7 % | <b>iBMS (AE C639170)</b><br>UV/VIS-, IR-, <sup>1</sup> HNMR-, <sup>13</sup> C-NMR and MS-spectra are provided to confirm the chemical structure.<br>UV/VIS: neutral medium (water) |   | <b>Acceptable</b><br>This impurity was not considered to be relevant for the first Annex I inclusion. However, according to the FAO specification for ethofumesate (2007) a remark that isobutyl-methane sulfonate can occur as a result of certain manufacturing processes and if it occurs at ≥0.1 mg/kg (relative to ethofumesate) it would be designated as relevant impurity. | Y                 | <b>Taskforce:</b><br>Selzer, J.<br>2013<br>M-465124-01-1 |  |
|  |                               |  | Wavelength [nm]  | Molar extinction coefficient [L/mol x cm]   |  |                   |  |  |
|  |                               |  | 200  | 6   |  |                   |  |  |
|  |                               |  | 291  | 0   |  |                   |  |  |
|  |                               |  | acidic medium (HCl)  |   |  |                   |  |  |
|  |                               |  | Wavelength [nm]  | Molar extinction coefficient [L/mol x cm]   |  |                   |  |  |
|  |                               |  | 203  | 6   |  |                   |  |  |
|  |                               |  | 291  | 0   |  |                   |  |  |
|  |                               |  | basic medium (NaOH)  |   |  |                   |  |  |
|  |                               |  | Wavelength [nm]  | Molar extinction coefficient [L/mol x cm]   |  |                   |  |  |
|  |                               |  | 220  | 3   |  |                   |  |  |
|  |                               |  | 291  | 0   |  |                   |  |  |
|  |                               |  | Isobutyl-methane sulfonate (iBMS)<br>purity 99.32 %  | It is demonstrated that there is no UV/VIS absorption even not at higher concentration. |  | <b>Acceptable</b> | Y<br><br>Y   | <b>UPL:</b><br>Bhandari, N.M. (2013)<br>Patel, A.H. (2013c)<br>Documents provided in the confidential part Volume 4 since information on purity of batches is contained as well. |
|  |                               |  |  | MS-EI-, IR- and NMR-spectra are included in study Patel, A.H. (2013c)                   |  |                   |  |  |
|  |                               |  |  |   |  |                   |  |  |
|  |                               |  |  |   |  |                   |  |  |

| Test or Study Annex Point                  | Guideline and method                    | Test material purity and specification                                | Used methods / Results   |                           | Comments (Acceptable / Non acceptable)  | GLP | Reference   |
|--|---|---|--|---------------------------|---|-----|---|
| B.2.5. SOLUBILITY IN WATER                 |   |   |  |                           |   |     |   |
| Solubility in water<br>B.2.5/01            | EC A.6<br>OECD 105<br>OPPTS<br>830.7840 | Ethofumesate pure<br>Batch n° C66/87<br>purity 99.9 %                 | No pH effect because the active substance is not ionisable.<br><br>Solubility = 50 mg/L at 25 °C and pH 7.7  |                           | EU agreed endpoint<br>DAR 1998  | Y   | <b>Taskforce:</b><br>Bright, A.A.S.<br>1988<br>M-155193-02-1          |
|  | EC A.6<br>OECD 105                      | Ethofumesate lot<br>no.: 234-57A<br>Content: 99%                      | At 20°C:<br>Milli RO Water 59.59 mg/L<br>pH 7 buffer 57.83 mg/L<br>pH 4 buffer 58.22 mg/L<br>pH 9 buffer 61.92 mg/L  |                           | Acceptable  | Y   | <b>UPL:</b><br>Macdonald & Craig,<br>2002                             |
|  | EC A.6<br>OECD 105                      | Ethofumesate technical<br>Content: 98.59%                             | At pH 4: 8°C 26.3 mg/L, 20°C 41.1 mg/L, 30°C 66.0 mg/L<br>At pH 6.5: 8°C 27.1 mg/L, 20°C 40.0 mg/L, 30°C 68.8 mg/L<br>At pH 9: 8°C 27.0 mg/L, 20°C 43.5 mg/L, 30°C 65.7 mg/L |                           | Acceptable<br>Although technical Ethofumesate was used the purity is > 98%.                         | Y   | Walter, D., 2003<br>(KCA 2.5/01)                                      |
| B.2.6. SOLUBILITY IN ORGANIC SOLVENTS      |   |   |  |                           |   |     |   |
| Solubility in organic solvents<br>B.2.6/01 | EC A.6<br>OECD 105                      | Ethofumesate<br>TGAI<br>Batch n°<br>AE B049913-01-08<br>purity 98.3 % | solvent  | solubility [g/L] at 20 °C | Acceptable<br>The notifier justified the new study that the old study was not sufficiently precise. | Y   | <b>Taskforce:</b><br>Eyrich, U<br>Ziemer, F.<br>2012<br>M-430903-01-1 |
|  |   |   | methanol   | 119                       |   |     |   |
|  |   |   | n-heptane  | 3.4                       |   |     |   |
|  |   |   | xylene   | > 260                     |   |     |   |
|  |   |   | 1,2 dichloroethane   | > 260                     |   |     |   |
|  |   |   | acetone  | > 260                     |   |     |   |
|  |   |   | ethyl acetate  | > 260                     |   |     |   |
|  |   |   | dimethyl sulfoxide   | > 260                     |   |     |   |
|  | CIPAC MT<br>181<br>OECD 105             | Ethofumesate lot<br>no.: 234-57A<br>Content: 99%                      | solvent  | solubility [g/L] at 20 °C | Acceptable  | Y   | <b>UPL:</b><br>Macdonald & Craig,<br>2002                             |
|  |   |   | xylene   | 250 - 500                 |   |     |   |
|  |   |   | acetone  | 1250 - 1429               |   |     |   |
|  |   |   | dichloroethane   | 1429 - 1667               |   |     |   |
|  |   |   | ethyl acetate  | 714 - 1000                |   |     |   |

| Test or Study Annex Point                              | Guideline and method                        | Test material purity and specification                             | Used methods / Results   |           | Comments (Acceptable / Non acceptable)  | GLP | Reference  |
|--|---|--|--|-----------|---|-----|--|
|  |   |  | methanol   | 114 - 133 |   |     |  |
|  |   |  | heptane  | 3.042     |   |     |  |
| B.2.7. PARTITION COEFFICIENT N-OCTANOL/WATER           |   |  |  |           |   |     |  |
| Partition coefficient n-octanol/water B.2.7/01         | EC A.8<br>OECD 117<br>(shake flask method)  | Ethofumesate pure<br>Batch n° C66/87<br>purity 99.9 %              | At 25 °C<br><br>Pow log Pow<br>pH 6.44 486 2.7<br><br>No pH effect because the active substance ethofumesate is not ionisable. |           | EU agreed endpoint<br>DAR 1998  | Y   | Taskforce and UPL:<br>Bright, A.A.S.<br>Stalker, A.M.<br>1990<br>M-155196-01-1 |
| of metabolite : Ethofumesate-NC20645 (BCS-CU88901)     | EC A.8<br>OECD 117<br>(shake flask method)  | Ethofumesate-NC20645 sodium salt<br>(BCS-CU88901)<br>purity 69.2 % | Pow log Pow<br>pH 5 2.4 0.4<br>pH 7 0.042 -1.4<br>pH 9 0.0038 -2.4<br>at room temperature (mean: 22 °C)                        |           | Acceptable<br>No surface tension is provided for this compound. However, a centrifuge (15 min at 3000 rpm) is used for phase separation.<br>This study is evaluated and considered as information for other sections. | Y   | Taskforce:<br>Ziemer, F<br>Kloeckner, C.<br>2012<br>M-428034-01-1              |
| of metabolite : Ethofumesate-acetic acid (BCS-CW35117) | EC A.8,<br>OECD 117<br>(shake flask method) | Ethofumesate-acetic acid<br>(BCS-CW35117)<br>purity 91 %           | Pow log Pow<br>pH 5 1.5 0.2<br>pH 7 0.049 -1.3<br>pH 9 0.025 -1.6<br>at room temperature (mean: 23 °C)                         |           | Acceptable<br>No surface tension is provided for this compound. However, a centrifuge (15 min at 3000 rpm) is used for phase separation.<br>This study is evaluated and considered as information for other sections. | Y   | Taskforce:<br>Eyrich, U.<br>Ziemer, F<br>2013<br>M-451360-01-1                 |
| of metabolite : Ethofumesate-NC9607 (AE C509607)       | EC A.8,<br>OECD 117<br>(HPLC-method)        | Ethofumesate-NC9607<br>(AE C509607)<br>purity 99.8 %               | Pow log Pow<br>pH 5 158 2.2<br>pH 7 158 2.2<br>pH 9 158 2.2<br>at 25 °C  |           | Acceptable<br>This study is evaluated and considered as information for other sections.   | Y   | Taskforce:<br>Bogdoll, B<br>Peschke, C.<br>2012<br>M-427346-01-1               |
| of metabolite : Ethofumesate-NC8493 (AE C508493)       | EC A.8,<br>OECD 117<br>(HPLC-method)        | Ethofumesate-NC8493<br>(AE C508493)<br>purity 99.8 %               | Pow log Pow<br>pH 5 32 1.5<br>pH 7 32 1.5<br>pH 9 32 1.5<br>at 25 °C   |           | Acceptable<br>This study is evaluated and considered as information for other sections.   | Y   | Taskforce:<br>Bogdoll, B<br>Peschke, C.<br>2012<br>M-427348-01-1               |

| Test or Study Annex Point                                 | Guideline and method | Test material purity and specification                                      | Used methods / Results  | Comments (Acceptable / Non acceptable)  | GLP | Reference  |
|---|----------------------|---|---|---|-----|--|
| <b>B.2.8. DISSOCIATION IN WATER</b>                       |                      |   |   |   |     |  |
| <b>Dissociation constant B.2.8/01</b>                     | OECD 112 (statement) | Ethofumesate  | Dissociation constant is not applicable to ethofumesate in consideration of the molecular structure.                                    | EU agreed endpoint<br>DAR 1998  | Y   | <b>Taskforce and UPL:</b><br>Ward, J.C.<br>Stalker, A.M.<br>1990<br>M-155681 |
| <b>of metabolite : Ethofumesate-NC20645 (BCS-CU88901)</b> | OECD 112             | Ethofumesate-NC20645 sodium salt (BCS-CU88901) purity 69.2 % in BCS-CU88901 | The dissociation constants of Ethofumesate-NC20645 sodium salt (BCS-CU88901) are :<br>pK <sub>a1</sub> = 4.8<br>pK <sub>a2</sub> = 11.7 | <b>Acceptable</b><br>This study for the metabolite is evaluated and considered as information for other sections. | Y   | <b>Taskforce:</b><br>Wiche, A.<br>Bogdoll, B<br>2012<br>M-436335-01-1        |
| <b>B.2.9. FLAMMABILITY AND SHELF-HEATING</b>              |                      |   |   |   |     |  |
| <b>Flammability B.2.9/01</b>                              | EC A.10              | Ethofumesate TGAI Batch n° AE B049913-01-08 purity 98.3 %                   | Ethofumesate is not a highly flammable solid in the sense of EC guideline A.10.   | <b>Acceptable</b>   | Y   | <b>Taskforce:</b><br>Winkler, S.<br>2012<br>M-425937-01-1                    |
|   |                      | Ethofumesate technical concentrate Content: 96.3%                           | Ethofumesate is not flammable,  | EU agreed endpoint<br>DAR 1998  | N   | <b>UPL:</b><br>Barker, 1991  |
| <b>Self heating B.2.9/02</b>                              | EC A.16              | Ethofumesate TTGAI Batch n° AE B049913-01-08 purity 98.3                    | No self-ignition temperature of ethofumesate was observed up to the maximum test temperature of 401°C.                                  | <b>Acceptable</b>   | Y   | <b>Taskforce:</b><br>Winkler, S.<br>2012<br>M-425939-01-1                    |
|   |                      | Ethofumesate technical concentrate Content: 96.3%                           | Ethofumesate is not autoflammable.  | EU agreed endpoint<br>DAR 1998  | N   | <b>UPL:</b><br>Barker, 1991  |

| Test or Study Annex Point         | Guideline and method | Test material purity and specification                                | Used methods / Results  | Comments (Acceptable / Non acceptable)   | GLP | Reference  |
|-----------------------------------|----------------------|---|---|--|-----|--|
| B.2.10. FLASH POINT               |                      |   |   |  |     |  |
| Flash point<br>B.2.10/01          |                      |   | Not applicable. The active substance is a solid; its melting point is > 40 °C |  |     |  |
| B.2.11. EXPLOSIVE PROPERTIES      |                      |   |   |  |     |  |
| Explosive properties<br>B.2.11/01 | EC A.14              | Ethofumesate<br>TGAI<br>Batch n°<br>AE B049913-01-08<br>purity 98.3 % | Ethofumesate has no explosive properties in the sense of EC guideline A.14.   | Acceptable<br><br>A statement based on the chemical structure was given in the DAR 1998.   | Y   | Taskforce:<br>Winkler, S.<br>2012<br>M-425938-01-1 |
|                                   |                      | Ethofumesate<br>technical<br>concentrate<br>Content: 96.3%            | Ethofumesate is not explosive.  | EU agreed endpoint<br>DAR 1998   | N   | UPL:<br>Barker, 1991                               |
| B.2.12. SURFACE TENSION           |                      |   |   |  |     |  |
| Surface tension<br>B.2.12/01      | EC A.5<br>OECD 115   | Ethofumesate<br>TGAI<br>Batch n°<br>9728<br>purity 98.5 %             | 68.3 mN/m at 20 °C (saturated aqueous solution)                               | EU agreed endpoint<br>DAR 1998<br><br>Active substance is classified to be non-surface active according to EC Guideline A.5.<br><br>Acceptable<br>According to the new requirement the study has to be performed with the analytical standard but can be accepted, since the purity is > 98 %. | Y   | Taskforce:<br>Walter, D.<br>1999<br>M-249651-01-1  |
|                                   |                      | Ethofumesate<br>TGAI<br>Batch n°1997/1<br>purity 98.5 9%              | 63.9 mN/m at 20 °C (saturated aqueous solution)                               | Acceptable<br>According to the new requirement the study has to be performed with the analytical standard but can be accepted, since the purity is > 98 %.   | Y   | UPL:<br>Walter, D., 2002                           |

| Test or Study Annex Point                            | Guideline and method                    | Test material purity and specification                                | Used methods / Results  | Comments (Acceptable / Non acceptable)   | GLP | Reference   |
|--|---|---|---|--|-----|---|
| <b>B.2.10. FLASH POINT</b>                           |   |   |   |  |     |   |
| <b>B.2.13. OXIDISING PROPERTIES</b>                  |   |   |   |  |     |   |
| <b>Oxidizing properties<br/>B.2.13/01</b>            | EC A.17                                 | Ethofumesate<br>TGAI<br>Batch n°<br>AE B049913-01-08<br>purity 98.3 % | Ethofumesate has no oxidizing properties in the sense of EC guideline A.17. | <b>Acceptable</b><br>In the DAR 1998 a statement based on the chemical structure was given which was acceptable as well. | Y   | <b>Taskforce:</b><br>Winkler, S.<br>2012<br>M-425948-01-1                 |
|  | statement                               |   | Not oxidative based on chemical structure                                   | EU agreed endpoint<br>DAR 1998   | N   | <b>UPL:</b><br>Barker, 1991<br>Schnell, 1993<br>(see DAR)                 |
| <b>B.2.14. OTHER STUDIES</b>                         |   |   |   |  |     |   |
| <b>Relative density of purified active substance</b> | EC A.3<br>OECD 109<br>OPPTS<br>830.7300 | Ethofumesate pure<br>Batch n° R000047<br>purity 99.9 %                | $D_4^{20} = 1.29$   | EU agreed endpoint<br>DAR 1998   | Y   | <b>Taskforce:</b><br>Stalker, A.M.<br>Ward, J.C.<br>1990<br>M-155675-01-1 |

**Taskforce:**

Technical grade ethofumesate are beige platelets with intensive not characteristic odor with low water solubility and low vapor pressure. The melting point of ethofumesate at atmosphere pressure is 70°C. It boiled under decomposition under atmospheric pressure and its boiling range is 305-320°C. It shows an endothermic effect in the temperature range of 65 to 90°C (melting point) and an exothermal decomposition in the temperature range 290-405°C with a mean energy of 375 J/g. The calculated Henry's law constant of ethofumesate is low, which indicates that the substance is not expected to evaporate from water to the atmosphere. The substance is not expected to dissociate in water in consideration of the molecular structure. The solubility in water is 50 mg/L at 25°C without pH effect. The partition coefficient, n-octanol/water is 2.7, which indicates that the substance will be slightly moderately absorbed to organic matter in soil and sediment. Ethofumesate is not a highly flammable solid in the sense of EC guideline A.10. No self-ignition temperature of ethofumesate was observed up to the maximum test temperature of 401°C. Ethofumesate has no explosive properties in the sense of EC guideline A.14 and no oxidizing properties in the sense of EC guideline A.17.

**UPL:**

Ethofumesate technical is a white crystalline powder which melts at about 70°C and decomposes above 220°C before reaching the boiling point. Additionally, it does not dissociate in water, has a limited to fair solubility in organic solvents and – most importantly – does not pose physical-chemical hazards, because Ethofumesate is neither flammable, nor auto-flammable, oxidising and explosive.



## B.2.15. 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  | Vertebra<br>te study<br>Y/N | Data<br>protection<br>claimed<br>Y/N | Justificat<br>ion if<br>data<br>protectio<br>n is<br>claimed | Owner   | Previous<br>evaluatio<br>n |
|-------------------------|---|------|--|-----------------------------|--------------------------------------|--|---|----------------------------|
| KCA<br>Section 2<br>/01 | Brehm, M.   | 1992 | ESTIMATION OF THE<br>PHOTOCHEMICAL- OXIDATIVE<br>DEGRADATION OF ETHOFUMESATE<br>(SCHERING CODE NO ZK 49 913) IN<br>THE ATMOSPHERE<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A83382,<br>Report includes Trial Nos.:<br>92/076<br>Edition Number: M-155650-01-1<br>Date: 1992-06-04<br>GLP/GEP: no, unpublished<br>...also filed: KCA 2.14 /02<br>...also filed: KCA 7.3.1 /01  | N                           | N                                    | -  | Bayer<br>CropScience                          | In DAR<br>(1998)           |
| KCA<br>Section 2<br>/02 | Schneider, E.   | 1994 | Abschaetzung des photochemischen<br>oxidativen Abbaus von Ethofumesat in der<br>Troposphaere<br>Dr.Krebs Analytik, Koeln, Germany<br>Feinchemie Schwebda ,<br>Report No.: M-351846-01-1,<br>Edition Number: M-351846-01-1<br>GLP/GEP: n.a., unpublished  | N                           | N                                    | -  | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)           |
| KCA 2.1<br>/01          | Ward, J. C.;<br>Stalker, A. M.                        | 1990 | DETERMINATION OF THE MELTING<br>RANGE OF: i) ETHOFUMESATE<br>REFERENCE STANDARD R000047. ii)<br>ETHOFUMESATE TECHNICAL GRADE<br>ACTIVE INGREDIENT CR 19291/1<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A83412,<br>Edition Number: M-155680-01-1<br>EPA MRID No.: 41752102<br>Date: 1990-08-21<br>GLP/GEP: yes, unpublished  | N                           | N                                    | -  | Bayer<br>CropScience                          | In DAR<br>(1998)           |
| KCA 2.1<br>/02          | Howarth, R.;<br>Tremain, S.<br>P.; Bartlett, A.<br>J. | 1991 | TECHNICAL ETHOFUMESATE:<br>DETERMINATION OF PHYSICO-<br>CHEMICAL PROPERTIES<br>Safepharm Lab. Ltd., Derby, United<br>Kingdom<br>Bayer CropScience,<br>Report No.: A87526,<br>Report includes Trial Nos.:<br>245/25<br>Edition Number: M-161417-01-1<br>Date: 1991-01-07<br>GLP/GEP: yes, unpublished<br>...also filed: KCA 2.2 /02<br>...also filed: KCA 2.5 /03<br>...also filed: KCA 2.7 /02<br>...also filed: KCA 2.8 /03<br>...also filed: KCA 7.2.1.2 /03 | N                           | N                                    | -  | Bayer<br>CropScience                          | In DAR<br>(1998)           |
| KCA 2.1<br>/03          | Johnson, M.<br>K.                                     | 1990 | ETHOFUMESATE PRODUCT<br>CHEMISTRY ADDITIONAL PHYSICAL<br>AND CHEMICAL CHARACTERISTICS<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A83416,<br>Edition Number: M-155684-01-1<br>EPA MRID No.: 41997203<br>GLP/GEP: no, unpublished<br>...also filed: KCA 2.3 /01  | N                           | N                                    | -  | Bayer<br>CropScience                          | In DAR<br>(1998)           |
| KCA 2.1<br>/04          | Werle, H.   | 1997 | Determination of the thermal stability /<br>Stability in air of ethofumesate technical -<br>Differential scanning calorimetry (DSC) and  | N                           | N                                    | -  | Adama<br>(formerly<br>Feinchemie              | In DAR<br>(1998)           |

| 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   | Vertebra<br>te study<br>Y/N | Data<br>protection<br>claimed<br>Y/N | Justificat<br>ion if<br>data<br>protectio<br>n is<br>claimed | Owner                                | Previous<br>evaluatio<br>n                  |
|-------------|--|------|---|-----------------------------|--------------------------------------|--|--------------------------------------|---|
|             |  |      | thermogravimetric analysis (TGA)<br>BioChem GmbH, Karlsruhe, Germany<br>Feinchemie Schwebda ,<br>Report No.: 97 50 40 168,<br>Edition Number: M-351791-01-1<br>Date: 1997-04-17<br>GLP/GEP: yes, unpublished  |                             |                                      |  | Schwebda)                            |   |
| KCA 2.1 /05 | Schnell, R.                                  | 1993 | Ethofumesate determination of melting point<br>Feinchemie Schwebda GmbH, Eschwege, Germany<br>Feinchemie Schwebda,<br>Report No.: M-468320-01-1,<br>Edition Number: M-468320-01-1<br>Date: 1993-02-17<br>GLP/GEP: no, unpublished   | N                           | N                                    | -  | Adama (formerly Feinchemie Schwebda) | In DAR (1998)                               |
| KCA 2.1 /06 | Schnell, R.                                  | 1993 | Ethofumesate determination of temperature of decomposition or sublimation<br>Feinchemie Schwebda GmbH, Eschwege, Germany<br>Feinchemie Schwebda,<br>Report No.: M-468332-01-1,<br>Edition Number: M-468332-01-1<br>Date: 1993-02-17<br>GLP/GEP: yes, unpublished  | N                           | N                                    | -  | Adama (formerly Feinchemie Schwebda) | In DAR (1998)                               |
| KCA 2.1 /07 | Smeykal, H.                                  | 2008 | Ethofumesate (AE B049913): Melting point - Boiling point - Thermal stability<br>Siemens AG, Frankfurt am Main, Germany<br>Bayer CropScience,<br>Report No.: 20080157.01,<br>Edition Number: M-299734-01-1<br>Date: 2008-03-31<br>GLP/GEP: yes, unpublished  | N                           | Y                                    | Former study was not according to GLP                        | Bayer CropScience                    | Submitted for the purpose of renewal (2014) |
| KCA 2.2 /01 | Bright, A. A. S.                             | 1988 | DETERMINATION OF THE VAPOUR PRESSURE OF ETHOFUMESATE<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A82705,<br>Edition Number: M-155198-01-1<br>EPA MRID No.: 41752102<br>Date: 1988-05-04<br>GLP/GEP: yes, unpublished   | N                           | N                                    | -  | Bayer CropScience                    | In DAR (1998)                               |
| KCA 2.2 /02 | Howarth, R.; Tremain, S. P.; Bartlett, A. J. | 1991 | TECHNICAL ETHOFUMESATE: DETERMINATION OF PHYSICO-CHEMICAL PROPERTIES<br>Safepharm Lab. Ltd., Derby, United Kingdom<br>Bayer CropScience,<br>Report No.: A87526,<br>Report includes Trial Nos.: 245/25<br>Edition Number: M-161417-01-1<br>Date: 1991-01-07<br>GLP/GEP: yes, unpublished<br>...also filed: KCA 2.1 /02<br>...also filed: KCA 2.5 /03<br>...also filed: KCA 2.7 /02<br>...also filed: KCA 2.8 /03<br>...also filed: KCA 7.2.1.2 /03 | N                           | N                                    | -  | Bayer CropScience                    | In DAR (1998)                               |
| KCA 2.2 /03 | Bright, A. A. S.; Stalker, A. M.             | 1994 | ETHOFUMESATE: HENRY'S CONSTANT CALCULATION<br>Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany<br>Bayer CropScience,<br>Report No.: A85670,<br>Edition Number: M-158022-01-1<br>Date: 1994-04-19  | N                           | N                                    | -  | Bayer CropScience                    | In DAR (1998)                               |

| 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   | Vertebra<br>te study<br>Y/N | Data<br>protection<br>claimed<br>Y/N | Justificat<br>ion if<br>data<br>protectio<br>n is<br>claimed | Owner   | Previous<br>evaluatio<br>n                  |
|-------------|-----------------------------|------|---|-----------------------------|--------------------------------------|--|---|---|
|             |                             |      | GLP/GEP: no, unpublished  |                             |                                      |  |   |   |
| KCA 2.2 /04 | Krebs, G.                   | 1992 | Analysenbericht des Dampfdruckes von ethofumesate<br>Dr. Krebs Analytik, Koeln, Germany<br>Feinchemie Schwebda ,<br>Report No.: OFC00004809,<br>Edition Number: M-351794-01-1<br>Date: 1992-10-02<br>GLP/GEP: no, unpublished   | N                           | N                                    | -  | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)                            |
| KCA 2.2 /05 | Krebs, G.;<br>Schneider, E. | 1991 | Bestimmung des Dampfdruckes von ethofumesat<br>Dr. G. Krebs Analytik, Köln, Germany<br>Feinchemie Schwebda,<br>Report No.: M-468361-01-1,<br>Edition Number: M-468361-01-1<br>Date: 1991-06-10<br>GLP/GEP: yes, unpublished   | N                           | N                                    | -  | Feinchemie<br>Schwebda                        | In DAR<br>(1998)                            |
| KCA 2.2 /06 | Schnell, R.                 | 1993 | Ethofumesate determination of bulk density<br>Feinchemie Schwebda GmbH, Eschwege,<br>Germany<br>Feinchemie Schwebda,<br>Report No.: M-468355-01-1,<br>Edition Number: M-468355-01-1<br>Date: 1993-02-17<br>GLP/GEP: no, unpublished   | N                           | N                                    | -  | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)                            |
| KCA 2.2 /07 | Schnell, R.                 | 1993 | Ethofumesate determination of relative density<br>Feinchemie Schwebda GmbH, Eschwege,<br>Germany<br>Feinchemie Schwebda,<br>Report No.: M-468359-01-1,<br>Edition Number: M-468359-01-1<br>Date: 1993-02-17<br>GLP/GEP: no, unpublished   | N                           | N                                    | -  | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)                            |
| KCA 2.3 /01 | Johnson, M.<br>K.           | 1990 | ETHOFUMESATE PRODUCT<br>CHEMISTRY ADDITIONAL PHYSICAL<br>AND CHEMICAL CHARACTERISTICS<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A83416,<br>Edition Number: M-155684-01-1<br>EPA MRID No.: 41997203<br>GLP/GEP: no, unpublished<br>...also filed: KCA 2.1 /03 | N                           | N                                    | -  | Bayer<br>CropScience                          | In DAR<br>(1998)                            |
| KCA 2.3 /02 | Zierner, F.;<br>Strunk, B.  | 2012 | Ethofumesate (AE B049913), pure substance: Physical characteristics colour, physical state and odour<br>Bayer CropScience,<br>Report No.: PA12/010,<br>Edition Number: M-431327-01-1<br>Date: 2012-05-09<br>GLP/GEP: yes, unpublished   | N                           | Y                                    | Former study was not according to GLP                        | Task Force<br>Ethofumesate                    | Submitted for the purpose of renewal (2014) |
| KCA 2.3 /03 | Zierner, F.;<br>Strunk, B.  | 2012 | Ethofumesate (AE B049913), technical substance: Physical characteristics colour, physical state and odour<br>Bayer CropScience,<br>Report No.: PA12/009,<br>Edition Number: M-431325-01-1<br>Date: 2012-05-09<br>GLP/GEP: yes, unpublished  | N                           | Y                                    | Former study was not according to GLP                        | Task Force<br>Ethofumesate                    | Submitted for the purpose of renewal (2014) |
| KCA 2.3/01  | Diepenhorst, PC.            | 2011 | ETHOFUMESATE<br>TECHNICAL EX UNITED<br>PHOSPHORUS LTD.<br>SELECTED PHYSICO-<br>CHEMICAL PROPERTIES<br>United Phosphorus Ltd., DL 11-073   | N                           | Y                                    | New data for active ingredient, not previous                 | UPL   | Submitted for the purpose of renewal (2014) |

| 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   | Vertebra<br>te study<br>Y/N | Data<br>protection<br>claimed<br>Y/N | Justificat<br>ion if<br>data<br>protectio<br>n is<br>claimed                                | Owner   | Previous<br>evaluatio<br>n                                  |
|--|-------------------|------|---|-----------------------------|--------------------------------------|---|---|---|
|  |                   |      | Cerexagri B.V., Rotterdam, NL<br>GLP/GEP: no<br>Published: no   |                             |                                      | sly<br>submitt<br>ed nor<br>evalu<br>ed   |   |   |
| KCA 2.4<br>/01                                 | Johnson, M.<br>K. | 1990 | IDENTIFYING SPECTRAL DATA FOR<br>ETHOFUMESATE<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A85624,<br>Edition Number: M-157941-01-1<br>Date: 1990-11-16<br>GLP/GEP: yes, unpublished  | N                           | N                                    | -   | Bayer<br>CropScience                          | In DAR<br>(1998)  |
| KCA 2.4/01<br>KCA<br>2.4/05a<br>KCA<br>2.4/05b | Bhandari,<br>N.M. | 2013 | UV-visible analysis of Ethofumesate<br>technical and its associated impurities<br>United Phosphorus Ltd., 216-2-11-6925<br>Jai Research Foundation; Valvada 396 108;<br>Gujarat; India<br>GLP: yes<br>Published: no   | N                           | Y                                    | New data<br>for active<br>ingredient,<br>not<br>previously<br>submitted<br>nor<br>evaluated | UPL   | Submitte<br>d for the<br>purpose<br>of<br>renewal<br>(2014) |
| KCA 2.4<br>/02                                 | Anon.             | 1995 | ETHOFUMESATE ANAL. GRADE, MS-<br>SPECTRUM AND ETHOFUMESATE<br>TECH., MS-SPECTRUM<br>Kemira Agro Oy, Helsinki, FIN;<br>Bayer CropScience,<br>Report No.: A87535,<br>Edition Number: M-161430-01-1<br>Date: 1995-02-15<br>GLP/GEP: no, unpublished  | N                           | N                                    | -   | Bayer<br>CropScience                          | In DAR<br>(1998)  |
| KCA 2.4<br>/03                                 | Anon.             | 1995 | 1H NMR AND 13C NMR SPECTRUM -<br>TECH. ETHOFUMESATE 112.3 MG/0.5<br>ML CDCL3 FROM KEMIRA AGRO OY'S<br>PRODUCTION (BATCH) AND 1H NMR<br>SPECTRUM - ANALYTICAL GRADE<br>ETHOFUMESATE 101.1 MG/0.5 ML<br>CDCL3 PURITY MIN 99% (W/W).<br>Kemira Agro Oy, Helsinki, FIN;<br>Bayer CropScience,<br>Report No.: A87542,<br>Edition Number: M-161440-01-1<br>Date: 1995-11-27<br>GLP/GEP: no, unpublished | N                           | N                                    | -   | Bayer<br>CropScience                          | In DAR<br>(1998)  |
| KCA 2.4<br>/04                                 | Anon.             | 1995 | UV/VIS-SPECTRUM OF<br>ETHOFUMESATE, TECHNICAL AND<br>ANALYTICAL GRADE<br>Kemira Agro Oy, Helsinki, FIN;<br>Bayer CropScience,<br>Report No.: A87548,<br>Edition Number: M-161448-01-1<br>Date: 1995-02-01<br>GLP/GEP: no, unpublished   | N                           | N                                    | -   | Bayer<br>CropScience                          | In DAR<br>(1998)  |
| KCA 2.4<br>/05                                 | Anon.             | 1995 | IR-SPECTRUM OF ETHOFUMESATE,<br>TECHNICAL AND ANALYTICAL<br>GRADE<br>Kemira Agro Oy, Helsinki, FIN;<br>Bayer CropScience,<br>Report No.: A87549,<br>Edition Number: M-161450-01-1<br>Date: 1995-02-01<br>GLP/GEP: no, unpublished   | N                           | N                                    | -   | Bayer<br>CropScience                          | In DAR<br>(1998)  |
| KCA 2.4<br>/06                                 | Anon.             | 1990 | Ethofuemsat - UV-Spektrum<br>Frings Pharma GmbH, Frechen, Germany<br>Feinchemie Schwebda ,<br>Report No.: OFC00004810,<br>Edition Number: M-351798-01-1<br>Date: 1990-06-03   | N                           | N                                    | -   | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)  |

| 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  | Vertebra<br>te study<br>Y/N | Data<br>protection<br>claimed<br>Y/N | Justificat<br>ion if<br>data<br>protectio<br>n is<br>claimed                                  | Owner   | Previous<br>evaluatio<br>n                                  |
|-------------|---------------------------|------|--|-----------------------------|--------------------------------------|---|---|---|
| KCA 2.4 /07 | Anon.                     | 1990 | GLP/GEP: no, unpublished<br>IR spectra of ethofumesate tec.<br>Feinchemie Schwebda GmbH, Eschwege, Germany<br>Feinchemie Schwebda,<br>Report No.: M-468366-01-1,<br>Edition Number: M-468366-01-1<br>Date: 1990-03-06<br>GLP/GEP: no, unpublished                              | N                           | N                                    | -   | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)  |
| KCA 2.4 /08 | Anon.                     | 1990 | Mass spectra of ethofumesate tec.<br>Feinchemie Schwebda GmbH, Eschwege, Germany<br>Feinchemie Schwebda,<br>Report No.: M-468371-01-1,<br>Edition Number: M-468371-01-1<br>Date: 1990-03-06<br>GLP/GEP: no, unpublished  | N                           | N                                    | -   | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)  |
| KCA 2.4 /09 | Anon.                     | 1990 | NMR spectra of ethofumesate tec.<br>Feinchemie Schwebda GmbH, Eschwege, Germany<br>Feinchemie Schwebda,<br>Report No.: M-468373-01-1,<br>Edition Number: M-468373-01-1<br>Date: 1990-03-06<br>GLP/GEP: no, unpublished   | N                           | N                                    | -   | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)  |
| KCA 2.4 /10 | Wiche, A.;<br>Bogdoll, B. | 2012 | Spectral data (UV / VIS, IR, 1H-NMR, 13C-NMR, MS) and molar extinction coefficients of ethofumesate (AE B049913), pure substance<br>Bayer CropScience,<br>Report No.: PA11/046,<br>Edition Number: M-435863-01-1<br>Date: 2012-07-30<br>GLP/GEP: yes, unpublished              | N                           | Y                                    | Former study was not according to GLP   | Task Force<br>Ethofumesate                    | Submitte<br>d for the<br>purpose<br>of<br>renewal<br>(2014) |
| KCA 2.4 /11 | Hellpointner, E.          | 2013 | Ethofumesate: Assessment of the environmental half-life of the direct photo-degradation in water<br>Bayer CropScience,<br>Report No.: EnSa-13-0355,<br>Edition Number: M-461408-01-1<br>Date: 2013-08-06<br>GLP/GEP: yes, unpublished<br><b>...also filed: KCA 7.2.1.2 /07</b> | N                           | Y                                    | New regulatory requirement, extinction coefficient in water required for phototoxicity topic. | Task Force<br>Ethofumesate                    | Submitte<br>d for the<br>purpose<br>of<br>renewal<br>(2014) |
| KCA 2.4 /12 | Selzer, J.                | 2013 | Spectral data (UV / VIS, IR, 1H-NMR, 13C-NMR, MS) and molar extinction coefficients of AE C639174 and AE C639170<br>Bayer CropScience,<br>Report No.: PA13/045,<br>Edition Number: M-465124-01-1<br>Date: 2013-09-20<br>GLP/GEP: yes, unpublished                              | N                           | Y                                    | New regulatory requirement  | Task Force<br>Ethofumesate                    | Submitte<br>d for the<br>purpose<br>of<br>renewal<br>(2014) |
| KCA 2.5 /01 | Bright, A. A. S.          | 1987 | ETHOFUMESATE: SOLUBILITY IN WATER AT 25C<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A82700,<br>Edition Number: M-155193-02-1<br>EPA MRID No.: 41752102<br>Date: 1987-06-29<br><b>...Amended: 1988-05-04</b><br>GLP/GEP: yes, unpublished             | N                           | N                                    | -   | Bayer<br>CropScience                          | In DAR<br>(1998)  |
| KCA 2.5 /02 | De Vries, R.              | 1993 | DETERMINATION OF THE WATER SOLUBILITY OF ETHOFUMESATE AT PH3, 4 AND 5  | N                           | N                                    | -   | Bayer<br>CropScience                          | In DAR<br>(1998)  |

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|----------------|---|------|--|-----------------------------|--------------------------------------|--|---|---|
|                |   |      | RCC Notox B.V., s'Hertogenbosch,<br>Netherlands<br>Bayer CropScience,<br>Report No.: A87527,<br>Edition Number: M-161418-01-1<br>Date: 1993-02-26<br>GLP/GEP: yes, unpublished   |                             |                                      |  |   |   |
| KCA 2.5<br>/03 | Howarth, R.;<br>Tremain, S.<br>P.; Bartlett, A.<br>J. | 1991 | TECHNICAL ETHOFUMESATE:<br>DETERMINATION OF PHYSICO-<br>CHEMICAL PROPERTIES<br>Safepharm Lab. Ltd., Derby, United<br>Kingdom<br>Bayer CropScience,<br>Report No.: A87526,<br>Report includes Trial Nos.:<br>245/25<br>Edition Number: M-161417-01-1<br>Date: 1991-01-07<br>GLP/GEP: yes, unpublished<br>...also filed: KCA 2.1 /02<br>...also filed: KCA 2.2 /02<br>...also filed: KCA 2.7 /02<br>...also filed: KCA 2.8 /03<br>...also filed: KCA 7.2.1.2 /03 | N                           | N                                    | -  | Bayer<br>CropScience                          | In DAR<br>(1998)  |
| KCA 2.5<br>/04 | De Vries, R.  | 1994 | DETERMINATION OF THE WATER<br>SOLUBILITY OF ETHOFUMESATE AT<br>PH9 AND 11<br>RCC Notox B.V., s'Hertogenbosch,<br>Netherlands<br>Bayer CropScience,<br>Report No.: A87528,<br>Edition Number: M-161420-01-1<br>Date: 1994-09-27<br>GLP/GEP: yes, unpublished  | N                           | N                                    | -  | Bayer<br>CropScience                          | In DAR<br>(1998)  |
| KCA 2.5<br>/05 | Schnell, R.   | 1993 | Ethofumesate determination of acidity /<br>alkalinity of ethofumesate<br>Feinchemie Schwebda GmbH, Eschwege,<br>Germany<br>Feinchemie Schwebda,<br>Report No.: M-468374-01-1,<br>Edition Number: M-468374-01-1<br>Date: 1993-03-10<br>GLP/GEP: no, unpublished   | N                           | N                                    | -  | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)  |
| KCA 2.5/01     | Walter, D.  | 2003 | WATER SOLUBILITY OF<br>ETHOFUMESATE<br>United Phosphorus Ltd., 20021050/01-<br>PCSB<br>GAB Biotechnologie GmbH, Niefern-<br>Öschelbronn, Germany<br>GLP: yes<br>Published: no  | N                           | Y                                    | New<br>data for<br>active<br>ingredie<br>nt, not<br>previous<br>ly<br>submitte<br>d nor<br>evaluate<br>d | UPL   | Submitte<br>d for the<br>purpose<br>of<br>renewal<br>(2014) |
| KCA 2.5/02     | Macdonald, E.<br>Craig, W.B.                          | 2002 | ETHOFUMESATE DETERMINATION<br>OF THE PHYSICO-CHEMICAL<br>PROPERTIES OF ETHOFUMESATE<br>AgriChem B.V., 21131<br>Inveresk Research International, Tranent,<br>Scotland<br>GLP: yes<br>Published: no  | N                           | Y                                    | New<br>data for<br>active<br>ingredie<br>nt, not<br>previous<br>ly<br>submitte<br>d nor<br>evaluate<br>d | ACM*  | Submitte<br>d for the<br>purpose<br>of<br>renewal<br>(2014) |
| KCA 2.6<br>/01 | Ward, J. C.;<br>Stalker, A. M.                        | 1990 | SOLUBILITY OF ETHOFUMESATE IN<br>ORGANIC SOLVENTS AT 25C   | N                           | N                                    | -  | Bayer<br>CropScience                          | In DAR<br>(1998)  |

| 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   | Vertebra<br>te study<br>Y/N | Data<br>protection<br>claimed<br>Y/N | Justificat<br>ion if<br>data<br>protectio<br>n is<br>claimed           | Owner                                | Previous<br>evaluatio<br>n                  |
|-------------|--|------|---|-----------------------------|--------------------------------------|--|--------------------------------------|---|
|             |  |      | Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A83410,<br>Edition Number: M-155678-01-1<br>EPA MRID No.: 41752102<br>Date: 1990-08-21<br>GLP/GEP: yes, unpublished   |                             |                                      |  |                                      |   |
| KCA 2.6 /02 | Bright, A. A. S.; Scott, G. H. E.            | 1988 | SOLUBILITY IN ORGANIC SOLVENTS<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A83411,<br>Edition Number: M-155679-01-1<br>Date: 1988-04-27<br>GLP/GEP: no, unpublished  | N                           | N                                    | -  | Bayer CropScience                    | In DAR (1998)                               |
| KCA 2.6 /03 | Eyrich, U.; Ziemer, F.                       | 2012 | Ethofumesate (AE B049913), technical substance: Solubility in organic solvents<br>Bayer CropScience,<br>Report No.: PA12/033,<br>Edition Number: M-430903-01-1<br>Date: 2012-05-09<br>GLP/GEP: yes, unpublished   | N                           | Y                                    | Former study not precise enough  | Task Force Ethofumesate              | Submitted for the purpose of renewal (2014) |
| KCA 2.6/01  | Macdonald, E. Craig, W.B.                    | 2002 | ETHOFUMESATE DETERMINATION OF THE PHYSICO-CHEMICAL PROPERTIES OF ETHOFUMESATE<br>AgriChem B.V., 21131 Inveresk Research International, Tranent, Scotland<br>GLP: yes<br>Published: no   | N                           | Y                                    | New data for active ingredient, not previously submitted nor evaluated | ACM*                                 | Submitted for the purpose of renewal (2014) |
| KCA 2.7 /01 | Bright, A. A. S.; Stalker, A. M.             | 1990 | ETHOFUMESATE: DETERMINATION OF THE PARTITION COEFFICIENT BETWEEN N-OCTANOL AND WATER AT 25C<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A82703,<br>Edition Number: M-155196-01-1<br>EPA MRID No.: 41752102<br>Date: 1990-05-21<br>GLP/GEP: yes, unpublished  | N                           | N                                    | -  | Bayer CropScience                    | In DAR (1998)                               |
| KCA 2.7 /02 | Howarth, R.; Tremain, S. P.; Bartlett, A. J. | 1991 | TECHNICAL ETHOFUMESATE: DETERMINATION OF PHYSICO-CHEMICAL PROPERTIES<br>Safepharm Lab. Ltd., Derby, United Kingdom<br>Bayer CropScience,<br>Report No.: A87526,<br>Report includes Trial Nos.: 245/25<br>Edition Number: M-161417-01-1<br>Date: 1991-01-07<br>GLP/GEP: yes, unpublished<br>...also filed: KCA 2.1 /02<br>...also filed: KCA 2.2 /02<br>...also filed: KCA 2.5 /03<br>...also filed: KCA 2.8 /03<br>...also filed: KCA 7.2.1.2 /03 | N                           | N                                    | -  | Bayer CropScience                    | In DAR (1998)                               |
| KCA 2.7 /03 | Mueller, J.                                  | 1990 | Determination of the partition coefficient n-octanol-water of ethofumesate<br>Fraunhofer Institut, Schmallenberg, Germany<br>Feinchemie Schwebda,<br>Report No.: OFC00004816,<br>Edition Number: M-351804-01-1  | N                           | N                                    | -  | Adama (formerly Feinchemie Schwebda) | In DAR (1998)                               |

| 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  | Vertebra<br>te study<br>Y/N | Data<br>protection<br>claimed<br>Y/N | Justificat<br>ion if<br>data<br>protectio<br>n is<br>claimed | Owner                      | Previous<br>evaluatio<br>n                                  |
|----------------|---|------|--|-----------------------------|--------------------------------------|--|----------------------------|---|
|                |   |      | Date: 1990-08-27<br>GLP/GEP: yes, unpublished  |                             |                                      |  |                            |   |
| KCA 2.7<br>/04 | Ziemer, F.;<br>Kloeckner, C.                          | 2012 | BCS-CU88901 (Ethofumesate-NC20645<br>sodium salt): Partition coefficients 1-octanol<br>/ water at pH 5, pH 7 and pH 9 (shake flask<br>method)<br>Bayer CropScience,<br>Report No.: PA12/001,<br>Edition Number: M-428034-01-1<br>Date: 2012-03-26<br>GLP/GEP: yes, unpublished   | N                           | Y                                    | New<br>regulatory<br>requireme<br>nt                         | Task Force<br>Ethofumesate | Submitte<br>d for the<br>purpose<br>of<br>renewal<br>(2014) |
| KCA 2.7<br>/05 | Eyrich, U.;<br>Ziemer, F.                             | 2013 | BCS-CW35117 (ethofumesate-acetic acid):<br>Partition coefficients 1-octanol / water at pH<br>5, pH 7 and pH 9 (shake flask method)<br>Bayer CropScience,<br>Report No.: PA13/023,<br>Edition Number: M-451360-01-1<br>Date: 2013-04-18<br>GLP/GEP: yes, unpublished  | N                           | Y                                    | New<br>regulatory<br>requireme<br>nt                         | Bayer<br>CropScience       | Submitte<br>d for the<br>purpose<br>of<br>renewal<br>(2014) |
| KCA 2.7<br>/06 | Bogdoll, B.;<br>Peschke, C.                           | 2012 | AE C509607 (Ethofumesate-NC9607):<br>Partition coefficients 1-octanol / water at pH<br>5, pH 7 and pH 9 (HPLC method)<br>Bayer CropScience,<br>Report No.: PA11/090,<br>Edition Number: M-427346-01-1<br>Date: 2012-02-29<br>GLP/GEP: yes, unpublished   | N                           | Y                                    | New<br>regulatory<br>requireme<br>nt                         | Bayer<br>CropScience       | Submitte<br>d for the<br>purpose<br>of<br>renewal<br>(2014) |
| KCA 2.7<br>/07 | Bogdoll, B.;<br>Peschke, C.                           | 2012 | AE C508493 (Ethofumesate-NC8493):<br>Partition coefficients 1-octanol / water at pH<br>5, pH 7 and pH 9 (HPLC method)<br>Bayer CropScience,<br>Report No.: PA11/088,<br>Edition Number: M-427348-01-1<br>Date: 2012-02-29<br>GLP/GEP: yes, unpublished   | N                           | Y                                    | New<br>regulatory<br>requireme<br>nt                         | Bayer<br>CropScience       | Submitte<br>d for the<br>purpose<br>of<br>renewal<br>(2014) |
| KCA 2.8<br>/01 | Keirs, D. C.  | 2000 | Aqueous photolysis (14C)-ethofumesate<br>Inveresk Research Int. Ltd., Tranent,<br>Scotland<br>Bayer CropScience,<br>Report No.: C009667,<br>Edition Number: M-199018-01-1<br>EPA MRID No.: 46157901<br>Date: 2000-09-13<br>GLP/GEP: yes, unpublished<br>...also filed: KCA 7.2.1.2 /04   | N                           | N                                    | -  | Bayer<br>CropScience       | In DAR<br>(1998)  |
| KCA 2.8<br>/02 | Brown, P. M.;<br>Reary, J. B.;<br>Whiteoak, R.<br>J.  | 1978 | THE HYDROLYSIS OF<br>ETHOFUMESATE UNDER ACIDIC,<br>NEUTRAL AND BASIC CONDITIONS<br>Fisons plc, United Kingdom<br>Bayer CropScience,<br>Report No.: A83306,<br>Edition Number: M-155575-01-1<br>Date: 1978-02-20<br>GLP/GEP: no, unpublished<br>...also filed: KCA 7.2.1.1 /01  | N                           | N                                    | -  | Bayer<br>CropScience       | In DAR<br>(1998)  |
| KCA 2.8<br>/03 | Howarth, R.;<br>Tremain, S.<br>P.; Bartlett, A.<br>J. | 1991 | TECHNICAL ETHOFUMESATE:<br>DETERMINATION OF PHYSICO-<br>CHEMICAL PROPERTIES<br>Safepharm Lab. Ltd., Derby, United<br>Kingdom<br>Bayer CropScience,<br>Report No.: A87526,<br>Report includes Trial Nos.:<br>245/25<br>Edition Number: M-161417-01-1<br>Date: 1991-01-07<br>GLP/GEP: yes, unpublished<br>...also filed: KCA 2.1 /02 | N                           | N                                    | -  | Bayer<br>CropScience       | In DAR<br>(1998)  |



| 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   | Vertebra<br>te study<br>Y/N | Data<br>protection<br>claimed<br>Y/N | Justificat<br>ion if<br>data<br>protectio<br>n is<br>claimed | Owner                                | Previous<br>evaluatio<br>n |
|-------------|--------------------------------|------|---|-----------------------------|--------------------------------------|--|--------------------------------------|----------------------------|
|             |                                |      | ...also filed: KCA 2.2 /02<br>...also filed: KCA 2.5 /03<br>...also filed: KCA 2.7 /02<br>...also filed: KCA 7.2.1.2 /03  |                             |                                      |  |                                      |                            |
| KCA 2.8 /04 | Knoch, E.                      | 1994 | DETERMINATION OF THE DIRECT PHOTOTRANSFORMATION OF 14C-ETHOFUMESATE IN A BUFFERED MEDIUM AT PH4<br>RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany<br>Bayer CropScience,<br>Report No.: A87609,<br>Edition Number: M-161541-01-1<br>Date: 1994-09-01<br>GLP/GEP: yes, unpublished<br>...also filed: KCA 7.2.1.2 /02 | N                           | N                                    | -  | Bayer CropScience                    | In DAR (1998)              |
| KCA 2.8 /05 | Brehm, M.                      | 1989 | THE PHOTOLYSIS OF ETHOFUMESATE (SCHERING CODE NO. ZK 49913) IN AQUEOUS SOLUTION<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A83339,<br>Edition Number: M-155608-01-1<br>EPA MRID No.: 42200901<br>Date: 1989-01-13<br>GLP/GEP: yes, unpublished<br>...also filed: KCA 7.2.1.2 /01            | N                           | N                                    | -  | Bayer CropScience                    | In DAR (1998)              |
| KCA 2.8 /06 | Ward, J. C.;<br>Stalker, A. M. | 1990 | ETHOFUMESATE REFERENCE STANDARD R000047:<br>DETERMINATION OF THE pka<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A83413,<br>Edition Number: M-155681-01-1<br>EPA MRID No.: 41752102<br>Date: 1990-08-21<br>GLP/GEP: yes, unpublished   | N                           | N                                    | -  | Bayer CropScience                    | In DAR (1998)              |
| KCA 2.8 /07 | Anon.                          | 1990 | Versickerungsverhalten des Pflanzenschutzmittels - Ethofumesat<br>ICD GmbH, Koeln, Germany<br>Feinchemie Schwebda ,<br>Report No.: OFC00004875,<br>Edition Number: M-351822-01-1<br>Date: 1990-02-23<br>GLP/GEP: no, unpublished  | N                           | N                                    | -  | Adama (formerly Feinchemie Schwebda) | In DAR (1998)              |
| KCA 2.8 /08 | Schneider, E.                  | 1994 | Ethofumesate - Direct phototransformation in water<br>Dr.Krebs Analytik, Koeln, Germany<br>Feinchemie Schwebda ,<br>Report No.: PR94/023,<br>Edition Number: M-351827-01-1<br>Date: 1994-09-11<br>GLP/GEP: yes, unpublished   | N                           | N                                    | -  | Adama (formerly Feinchemie Schwebda) | In DAR (1998)              |
| KCA 2.8 /09 | Kloepffer, W.                  | 1994 | Photoabbau des Wirkstoffs ethofumesat in Wasser - V-32 179-01<br>Battelle Europe, Frankfurt am Main, Germany<br>Feinchemie Schwebda ,<br>Report No.: PHY/WK22,<br>Edition Number: M-351831-01-1<br>Date: 1994-02-03<br>GLP/GEP: no, unpublished   | N                           | N                                    | -  | Adama (formerly Feinchemie Schwebda) | In DAR (1998)              |
| KCA 2.8 /10 | Schneider, E.                  | 1999 | Dissoziationskonstante Ethofumesate (Punkt AII 2.9.4)<br>UCL Umwelt Control Labor, Koeln, Germany<br>Feinchemie Schwebda ,  | N                           | N                                    | -  | Adama (formerly Feinchemie Schwebda) | In DAR (1998)              |

| 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   | Vertebra<br>te study<br>Y/N | Data<br>protection<br>claimed<br>Y/N | Justificat<br>ion if<br>data<br>protectio<br>n is<br>claimed | Owner   | Previous<br>evaluatio<br>n                                  |
|----------------|--------------|------|---|-----------------------------|--------------------------------------|--|---|---|
|                |              |      | Report No.: OFC00004823,<br>Edition Number: M-351835-01-1<br>Date: 1999-11-15<br>GLP/GEP: no, unpublished   |                             |                                      |  |   |   |
| KCA 2.9<br>/01 | Baker, G. P. | 1991 | POSSIBLE PHYSICO-CHEMICAL<br>HAZARDS OF ETHOFUMESATE AND<br>ITS FORMULATIONS<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A83422,<br>Edition Number: M-155690-01-1<br>EPA MRID No.: 41997203<br>GLP/GEP: n.a., unpublished<br><b>...also filed: KCA 2.11 /01</b>  | N                           | N                                    | -  | Bayer<br>CropScience                          | In DAR<br>(1998)  |
| KCA 2.9<br>/02 | Walter, D.   | 1999 | Flammability (solids) of ethofumesate<br>techn.<br>GAB Biotechnologie GmbH & IFU<br>Umweltanalytik GmbH, Niefern-<br>Oeschelbronn, Germany<br>Feinchemie Schwebda ,<br>Report No.: 99164/01-PCFS,<br>Edition Number: M-351844-01-1<br>Date: 1999-06-02<br>GLP/GEP: yes, unpublished       | N                           | N                                    | -  | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)  |
| KCA 2.9<br>/03 | Warncke, U.  | 1999 | Determination of the self-ignition<br>temperature of the test substance<br>ethofumesate techn.<br>Urania Agrochem GmbH, Christinenthal,<br>Germany<br>Feinchemie Schwebda ,<br>Report No.: OFC00004826,<br>Edition Number: M-351850-01-1<br>Date: 1999-07-21<br>GLP/GEP: yes, unpublished | N                           | N                                    | -  | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)  |
| KCA 2.9<br>/04 | Schnell, R.  | 1993 | Ethofumesate determination of auto -<br>flammability<br>Feinchemie Schwebda GmbH, Eschwege,<br>Germany<br>Feinchemie Schwebda,<br>Report No.: M-468379-01-1,<br>Edition Number: M-468379-01-1<br>Date: 1993-04-20<br>GLP/GEP: no, unpublished   | N                           | N                                    | -  | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)  |
| KCA 2.9<br>/05 | Schnell, R.  | 1993 | Ethofumesate determination of flammability<br>Feinchemie Schwebda GmbH, Eschwege,<br>Germany<br>Feinchemie Schwebda,<br>Report No.: M-468377-01-1,<br>Edition Number: M-468377-01-1<br>Date: 1993-04-01<br>GLP/GEP: no, unpublished   | N                           | N                                    | -  | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)  |
| KCA 2.9<br>/06 | Winkler, S.  | 2012 | Ethofumesate (AE B049913), technical<br>substance: Flammability (solids)<br>Siemens AG, Frankfurt am Main, Germany<br>Bayer CropScience,<br>Report No.: 20110430.01,<br>Edition Number: M-425937-01-1<br>Date: 2012-02-21<br>GLP/GEP: yes, unpublished                                    | N                           | Y                                    | New<br>regulatory<br>requireme<br>nt                         | Bayer<br>CropScience                          | Submitte<br>d for the<br>purpose<br>of<br>renewal<br>(2014) |
| KCA 2.9<br>/07 | Winkler, S.  | 2012 | Ethofumesate (AE B049913), technical<br>substance: Auto-flammability<br>Siemens AG, Frankfurt am Main, Germany<br>Bayer CropScience,<br>Report No.: 20110430.03,<br>Edition Number: M-425939-01-1<br>Date: 2012-02-21<br>GLP/GEP: yes, unpublished  | N                           | Y                                    | New<br>regulatory<br>requireme<br>nt                         | Bayer<br>CropScience                          | Submitte<br>d for the<br>purpose<br>of<br>renewal<br>(2014) |

| 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  | Vertebra<br>te study<br>Y/N | Data<br>protection<br>claimed<br>Y/N | Justificat<br>ion if<br>data<br>protectio<br>n is<br>claimed           | Owner                                | Previous<br>evaluatio<br>n                  |
|--------------|--------------|------|--|-----------------------------|--------------------------------------|--|--------------------------------------|---|
| KCA 2.11 /01 | Baker, G. P. | 1991 | POSSIBLE PHYSICO-CHEMICAL HAZARDS OF ETHOFUMESATE AND ITS FORMULATIONS<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A83422,<br>Edition Number: M-155690-01-1<br>EPA MRID No.: 41997203<br>GLP/GEP: n.a., unpublished<br>...also filed: KCA 2.9 /01 | N                           | N                                    | -  | Bayer CropScience                    | In DAR (1998)                               |
| KCA 2.11 /02 | Anon.        | 1999 | Dokument K, Annex II - Point: 2.13, Explosivity - Ethofumesate technical<br>EBRC Consulting GmbH, Hannover, Germany<br>Feinchemie Schwebda ,<br>Report No.: OFC00004828,<br>Edition Number: M-351858-01-1<br>Date: 1999-07-01<br>GLP/GEP: no, unpublished                  | N                           | N                                    | -  | Adama (formerly Feinchemie Schwebda) | In DAR (1998)                               |
| KCA 2.11 /03 | Schnell, R.  | 1993 | Ethofumesate detemrination of explosive properties<br>Feinchemie Schwebda GmbH, Eschwege, Germany<br>Feinchemie Schwebda,<br>Report No.: M-468381-01-1,<br>Edition Number: M-468381-01-1<br>Date: 1993-04-20<br>GLP/GEP: no, unpublished                                   | N                           | N                                    | -  | Adama (formerly Feinchemie Schwebda) | In DAR (1998)                               |
| KCA 2.11 /04 | Winkler, S.  | 2012 | Ethofumesate (AE B049913), technical substance: Explosive properties<br>Siemens AG, Frankfurt am Main, Germany<br>Bayer CropScience,<br>Report No.: 20110430.02,<br>Edition Number: M-425938-01-1<br>Date: 2012-02-21<br>GLP/GEP: yes, unpublished                         | N                           | Y                                    | New regulatory requirement   | Task Force Ethofumesate              | Submitted for the purpose of renewal (2014) |
| KCA 2.12 /01 | Walter, D.   | 1999 | Surface tension of ethofumesate tech.<br>GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Oeschelbronn, Germany<br>Bayer CropScience,<br>Report No.: C048293,<br>Edition Number: M-249651-01-1<br>Date: 1999-06-02<br>GLP/GEP: yes, unpublished                  | N                           | N                                    | -  | Bayer CropScience                    | In DAR (1998)                               |
| KCA 2.12 /02 | Walter, D.   | 1999 | Surface tension of ethofumesate techn.<br>GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Oeschelbronn, Germany<br>Feinchemie Schwebda ,<br>Report No.: OFC00004830,<br>Edition Number: M-351860-01-1<br>Date: 1999-02-06<br>GLP/GEP: yes, unpublished          | N                           | N                                    | -  | Adama (formerly Feinchemie Schwebda) | In DAR (1998)                               |
| KCA 2.12/01  | Walter, D.   | 2002 | SURFACE TENSION OF ETHOFUMESATE<br>GAB Biotechn. GmbH & IFU Umweltanalytik GmbH, Germany<br>United Phosphorus Ltd.<br>Report no. 20021050/01-PCST<br>GLP: yes<br>Published: no   | N                           | Y                                    | New data for active ingredient, not previously submitted nor evaluated | UPL                                  | Submitted for the purpose of renewal (2014) |
| KCA 2.13 /01 | Anon.        | 1999 | Dokument K, Annex II - Point: 2.15, Oxidising properties - Ethofumesate  | N                           | N                                    | -  | Adama (formerly                      | In DAR (1998)                               |

| 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  | Vertebra<br>te study<br>Y/N | Data<br>protection<br>claimed<br>Y/N | Justificat<br>ion if<br>data<br>protectio<br>n is<br>claimed | Owner   | Previous<br>evaluatio<br>n                                  |
|-----------------|--------------------------------|------|--|-----------------------------|--------------------------------------|--|---|---|
|                 |                                |      | technical<br>EBRC Consulting GmbH, Hannover,<br>Germany<br>Feinchemie Schwebda ,<br>Report No.: OFC00004831,<br>Edition Number: M-351865-01-1<br>Date: 1999-11-24<br>GLP/GEP: no, unpublished  |                             |                                      |  | Feinchemie<br>Schwebda)                       |   |
| KCA 2.13<br>/02 | Schnell, R.                    | 1993 | Ethofumesate detemrination of oxidizing<br>properties<br>Feinchemie Schwebda GmbH, Eschwege,<br>Germany<br>Feinchemie Schwebda,<br>Report No.: M-468383-01-1,<br>Edition Number: M-468383-01-1<br>Date: 1993-04-20<br>GLP/GEP: no, unpublished   | N                           | N                                    | -  | Adama<br>(formerly<br>Feinchemie<br>Schwebda) | In DAR<br>(1998)  |
| KCA 2.13<br>/03 | Winkler, S.                    | 2012 | Ethofumesate (AE B049913), technical<br>substance: Oxidizing properties<br>Siemens AG, Frankfurt am Main, Germany<br>Bayer CropScience,<br>Report No.: 20110430.04,<br>Edition Number: M-425948-01-1<br>Date: 2012-02-21<br>GLP/GEP: yes, unpublished  | N                           | Y                                    | New<br>regulatory<br>requireme<br>nt                         | Task Force<br>Ethofumesate                    | Submitte<br>d for the<br>purpose<br>of<br>renewal<br>(2014) |
| KCA 2.14<br>/01 | Ward, J. C.;<br>Stalker, A. M. | 1990 | DETERMINATION OF THE RELATIVE<br>DENSITY OF i) ETHOFUMESATE<br>REFERENCE STANDARD R000047. ii)<br>ETHOFUMESATE TECHNICAL GRADE<br>ACTIVE INGREDIENT CR 19291/1<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A83407,<br>Edition Number: M-155675-01-1<br>EPA MRID No.: 41752102<br>Date: 1990-08-21<br>GLP/GEP: yes, unpublished  | N                           | N                                    | -  | Bayer<br>CropScience                          | In DAR<br>(1998)  |
| KCA 2.14<br>/02 | Brehm, M.                      | 1992 | ESTIMATION OF THE<br>PHOTOCHEMICAL- OXIDATIVE<br>DEGRADATION OF ETHOFUMESATE<br>(SCHERING CODE NO ZK 49 913) IN<br>THE ATMOSPHERE<br>Schering AG, Berlin, Germany<br>Bayer CropScience,<br>Report No.: A83382,<br>Report includes Trial Nos.:<br>92/076<br>Edition Number: M-155650-01-1<br>Date: 1992-06-04<br>GLP/GEP: no, unpublished<br>...also filed: KCA 7.3.1 /01<br>...also filed: KCA Section 2 /01 | N                           | N                                    | -  | Bayer<br>CropScience                          | In DAR<br>(1998)  |