

# ***European Commission***



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

## **BAS 750F (Mefentrifluconazole) Volume 2**

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

**Version History**

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**A. LIST OF THE TESTS, STUDIES AND INFORMATION SUBMITTED****A.1. IDENTITY**

<b>Data Point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCA 1.8/1	Guentner A.	2014 a	Validation of an analytical method for the determination of [REDACTED] in Reg. No 5834378  2013/1222534  BASF SE - GMC Competence Center Analytics, Ludwigshafen, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 1.11/1	Harsch M.	2015 a	Chemical analysis of five batches BAS 750 F - Technical Grade Active Ingredient (TGAI)  2015/1111987  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 1.11/2	Harsch M.	2015 a	Report Amendment No. 1: Chemical analysis of five batches BAS 750 F - Technical Grade Active Ingredient (TGAI)  2016/1227821  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 1.11/3	Harsch M.	2016 b	Chemical analysis of five batches BAS 750 F - Technical grade active ingredient (TGAI)  2016/1138208  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 1.11/4	Harsch M.	2015 b	Determination of the enantiomeric ratio of BAS 750 F in TGAI and formulations  2015/1180118  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 1.11/5	Fries J	2015 a	BAS 750 F TGAI - Analytical profiles of three batches of BAS 750 F TGAI  2015/1164015  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCA 1.11/6	Fries J.	2015 a	BAS 750 F TGAI - Stability of BAS 750 F TGAI  2015/1164013  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	Yes	Data for first approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 1.11/7	Fries J.	2015 b	BAS 750 F TGAI - Stability of BAS 750 F TGAI  2015/1164014  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	Yes	Data for first approval	BASF
KCA 1.11/8	Harsch M.	2014	Reanalysis of Reg.No. 5834378, batch COD-001662  2014/1330594  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first approval	BASF
KCA 1.11/9	Deissroth S.	2012	BAS 750 F, certificate of analysis  2012/1370382  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	Yes	Data for first approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 1.11/10	Hundsbuchler D.	2015 a	BAS 750 F: Analysis of five representative batches - determination of [REDACTED]  2015/1229493  Intertek Schweiz AG, Basel, Switzerland  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 1.11/11	Anonymous	2016 a	[REDACTED] - [REDACTED] [REDACTED]  2016/1232653  <none>, <none>, <none>  no  Unpublished	No	Yes	Data for first approval	BASF
KCA 1.11/12	Rahn R.-T.	2016 b	BAS 750 F (Mefentrifluconazole, ISO proposed) - request for additional data: Information on the analytics of [REDACTED]  2016/1233625  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	Yes	Data for first approval	BASF

## BAS 750 01 F

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 1.4.3/1	Anonymous	2015 a	Safety data sheet - [REDACTED] 2015/1103801 [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/2	Anonymous	2015 b	Safety data sheet - [REDACTED] 2015/1238011 [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/3	Anonymous	2015 c	Safety data sheet - [REDACTED] 2015/1254480 [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 1.4.3/4	Anonmyous	2015 a	Safety data sheet - [REDACTED] 2015/1241760 [REDACTED] [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/5	Anonymous	2014 a	Safety data sheet - [REDACTED] 2015/1241762 [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/6	Anonymous	2016 a	Safety data sheet - [REDACTED] 2016/1043189 [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 1.4.3/7	Anonymous	2014 b	Safety data sheet - [REDACTED] 2014/1326693 [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/8	Anonymous	2015 d	Correspondence: MSDS for [REDACTED] [REDACTED] 2015/1198704 [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/9	Anonymous	2015 e	Correspondence: MSDS for [REDACTED] [REDACTED] 2015/1198705 [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 1.4.3/11	Anonymous	2016 b	Safety data sheet - [REDACTED] 2016/1231544 [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/12	Schwarz H.	2015 a	BAS 358 00 S - Determination of the ready biodegradability in the CO2-evolution test 2015/1041950 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data for first Approval	BASF
KCP 1.4.3/13	Anonymous	2015 g	Safety data sheet - [REDACTED] 2015/1254482 [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 1.4.3/14	Anonymous	2015 h	Safety data sheet - [REDACTED] 2015/1256301 [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/15	Anonymous	2015 i	Safety data sheet - [REDACTED] 2015/1193864 [REDACTED] [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/16	Anonymous	2015 j	Safety data sheet - [REDACTED] [REDACTED] 2015/1022683 [REDACTED] [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 1.4.3/17	Anonymous	2015 k	Safety data sheet - [REDACTED] 2013/1418920 [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/18	[REDACTED]	2015 a	Correspondence: MSDS for [REDACTED] [REDACTED] 2015/1088011 [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/19	Anonymous	2016 c	Safety data sheet - [REDACTED] 2016/1043188 [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 1.4.3/20	Anonymous	2015 l	Safety data sheet - [REDACTED] 2015/1254478 [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/21	Anonymous	2015 m	Safety data sheet - [REDACTED] 2015/1256324 [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/22	Anonymous	2015 n	Safety data sheet - [REDACTED] [REDACTED] 2015/1254481 [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 1.4.3/23	Anonymous	2015 o	Safety data sheet - [REDACTED] 2015/1215513 [REDACTED] [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]
KCP 1.4.3/24	Anonymous	2015 p	Safety data sheet - [REDACTED] 2015/1256375 [REDACTED] [REDACTED] no Unpublished	No	No	Not applicable	[REDACTED]

## A.2. PHYSICAL AND CHEMICAL PROPERTIES

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.1/1	Kroehl T.	2014 a	Physical properties of Reg.No. 5834378 - Pure active ingredient (PAI)  2014/1117052  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.1/2	Kroehl T.	2014 b	Physical and chemical properties of BAS 750 F (Reg.No. 5834378) technical active ingredient TC - Accelerated storage stability up to 2 weeks at 54°C  2014/1117053  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.2/1	Kroehl T.	2014 a	Physical properties of Reg.No. 5834378 - Pure active ingredient (PAI)  2014/1117052  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.2/2	Kroehl T.	2014 c	Henry s law constant for BAS 750 F (Reg.No. 5834378)  2014/1173597  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCA 2.3/1	Kroehl T.	2014 a	Physical properties of Reg.No. 5834378 - Pure active ingredient (PAI)  2014/1117052  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.3/2	Kroehl T.	2014 b	Physical and chemical properties of BAS 750 F (Reg.No. 5834378) technical active ingredient TC - Accelerated storage stability up to 2 weeks at 54°C  2014/1117053  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.4/1	Kroehl T. Behnken H.	2014 a	Mass, NMR, IR and UV/Vis spectra of BASF 750 F (Reg.No. 5834378)  2014/1173598  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.4/2	Kroehl T.	2015 a	Supplement to study 432182_1 - Mass, NMR, IR and UV/Vis spectra of BAS 750 F (Reg.No. 5834378)  2015/1183750  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.4/3	Kroehl T.	2016 a	Supplement No. 2 to study 432182_1 - Mass, NMR, IR and UV/Vis spectra of BAS 750 F (Reg.No. 5834378)  BASF SE, Limburgerhof, Germany Fed.Rep.  2016/1203119  no  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.5/1	Wilbrand S.	2013 a	Determination of the solubility in distilled water and in buffer solutions at pH 4 and pH 7 (Column Elution Method) of Reg.No. 5834378  2013/1397136  Allessa GmbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.5/2	Kroehl T.	2016 b	Supplement to study 432184_1 - Determination of the solubility in distilled water and in buffer solutions at pH 4 and pH 7 (Column Elution Method) of Reg.No.: 5834378  BASF SE, Limburgerhof, Germany Fed.Rep.  2016/1203120  no  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.5/3	Sonnenschein L.	2016 a	Physical and chemical properties of BAS 750 F (Reg.No. 5834378): Additional validation of analytical method applied for determination of solubility in water and organic solvents  Allessa GmbH, Frankfurt/Main, Germany Fed.Rep.  2016/1234174  yes	No	Yes	Data for first Approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 2.6/1	Wilbrand S.	2013 b	Determination of the solubility in organic solvents of Reg.No. 5834378  2013/1391669  Allessa GmbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.7/1	Wilbrand S.	2013 c	Determination of the partition coefficient 1-octanol/water (HPLC method) of Reg.No. 5834378  2013/1382370  Allessa GmbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.8/1	Wilbrand S.	2013 d	Determination of the dissociation constant of Reg.No. 5834378 in water according to OECD guideline 112  2013/1397719  Allessa GmbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.9/1	Moeller M.	2014 a	BAS 750 F - Determination of physico-chemical properties according to Directive 94/37/EC (Regulation (EC) No. 440/2008)  2014/1109962  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.10/1	Moeller M.	2014 a	BAS 750 F - Determination of physico-chemical properties according to Directive 94/37/EC (Regulation (EC) No. 440/2008)  2014/1109962  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.11/1	Moeller M.	2014 a	BAS 750 F - Determination of physico-chemical properties according to Directive 94/37/EC (Regulation (EC) No. 440/2008)  2014/1109962  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.13/1	Moeller M.	2014 a	BAS 750 F - Determination of physico-chemical properties according to Directive 94/37/EC (Regulation (EC) No. 440/2008)  2014/1109962  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.14/1	Daum A.	2015 a	Vapour pressure of Reg.No. 5924326 (M750F003)  2015/1205970  BASF SE, Limburgerhof, Germany Fed.Rep.  yes	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 2.14/2	Daum A.	2015 b	Vapour pressure of Reg.No. 6003433 (M750F005)  2015/1205971  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.14/3	Daum A.	2015 c	Vapour pressure of Reg.No. 5863469 (M750F006)  2015/1205972  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.14/4	Daum A.	2015 d	Vapour pressure of Reg.No. 6003432 (M750F007)  2015/1205973  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.14/5	Daum A.	2015 e	Vapour pressure of Reg.No. 6010286 (M750F008)  2015/1205976  BASF SE,	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Limburgerhof, Germany Fed.Rep.  yes  Unpublished				
KCA 2.14/6	Wilbrand S.	2015 a	Reg.No. 5924326: Solubility in water (Flask method) (double distilled water, pH 4, pH 9), partition coefficient 1-octanol/water (distilled water, pH 4, pH 9) and dissociation constant in water  2015/1139989  Allessa GmbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.14/7	Wilbrand S.	2016 a	Amendment No. 1 - Reg.No. 5924326: Solubility in water (Flask method) (double distilled water, pH 4, pH 9), partition coefficient 1-octanol/water (distilled water, pH 4, pH 9) and dissociation constant in water  2015/1252305  Allessa GmbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.14/8	Wilbrand S.	2016 b	Report amendment No. 2 to final report - Reg.No. 5924326: Solubility in water (Flask method) (double distilled water, pH 4, pH 9), partition coefficient 1-octanol/water (distilled water, pH 4, pH 9) and dissociation constant in water (Original No. 2 of 2)  2016/1030230  Allessa GmbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.14/9	Wilbrand S.	2015 b	Reg.No. 6003433: Solubility in water (Column Elution Method) (double distilled water, pH 4, pH 9), partition coefficient 1-Octanol/Water (distilled water, pH 4, pH 9) and dissociation constant in water (original No. 1 of 2)  2015/1139993  Allessa GmbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.14/10	Wilbrand S.	2015 c	Solubility in water (column elution method) ( double distilled water, pH 4, pH 9), partition coefficient 1-octanol/water (distilled water, pH 4, pH 9) and dissociation constant in water (original no. 2 of 2)  2015/1139994  Allessa GmbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 2.14/11	Wilbrand S.	2015 d	Solubility in water (flask method) ( double distilled water, pH 4, pH 9), partition coefficient 1-octanol/water (distilled water, pH 4, pH 9) and dissociation constant in water (original no. 2 of 2)  2015/1139997  Allessa GmbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 2.14/12	Wilbrand S.	2015 e	Reg.No. 6010286: Solubility in water (column elution method) (double distilled water, pH 4, pH 9), partition coefficient 1-octanol/water (distilled water, pH 4, pH 9) and dissociation constant in water (Original No. 2 of 2)  2015/1139998  Allessa GmbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

## BAS 750 01 F

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1/1	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)  2014/1219235  BASF SE, Limburgerhof, Germany Fed.Rep.	No	Yes	Data for first Approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			yes  Unpublished				
KCP 2.2/1	Dreisch S.	2014 a	Determination of physico-chemical properties according to Directive 94/37/EC (Regulation (EC) No. 440/2008)  2014/1133852  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 2.3/1	Dreisch S.	2014 a	Determination of physico-chemical properties according to Directive 94/37/EC (Regulation (EC) No. 440/2008)  2014/1133852  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.4/1	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)  2014/1219235  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 2.5/1	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)  2014/1219235  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 2.6/1	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)  2014/1219235  BASF SE, Limburgerhof,	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Germany Fed.Rep.  yes  Unpublished				
KCP 2.7/1	Kroehl T.	2015 a	Chemical and physical stability of formula BAS 750 01 F when stored for up to 3 years in PA/PE-coextruded packs - 52 week report  2015/1112122  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
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  BASF SE, Limburgerhof, Germany Fed.Rep.  2016/1296130  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 2.7/3	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)  2014/1219235  BASF SE, Limburgerhof, Germany Fed.Rep.	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			yes  Unpublished				
KCP 2.8.2/1	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)  2014/1219235  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
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)  2014/1219235  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 2.9/1	Wegkamp H.-G.	2015 a	Physical and chemical compatibility in aqueous tank mixtures of BAS 750 01 F  2015/1240031  BASF SE, Limburgerhof,	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Germany Fed.Rep.  no  Unpublished				

**A.3. DATA ON APPLICATION AND EFFICACY**

<b>Data Point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCA 3.8/1	Anonymous	2016 b	Safety data sheet - BAS 750 F  2016/1052696  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCA 3.9/1	Collet K.	2014 a	Adsorption of BAS 750 F onto activated charcoal  2015/1001401  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCA 3.10/1	Anonymous	2016 b	Safety data sheet - BAS 750 F  2016/1052696  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF

## BAS 750 01 F

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3	Kienle M. Strobel D.	2016 a	Uptake of Revysol® (Mefentrifluconazole) with BAS 750 01 F in wheat  BASF SE, Limburgerhof, Germany Fed.Rep.  2016/1270660  no  Unpublished	No	Yes	Not applicable	BASF
KCP 3.8/1	Lefrancois C.,McKeown B.	2015 a	Efficacy Data and Information for Approval of new active Substance BAS 750 F - Confidential  2015/1260812  BASF Agro B.V. Arnhem (NL) - Zuerich Branch, Zuerich, Switzerland  no  Unpublished	No	No	Not applicable	BASF

## A.4. FURTHER INFORMATION

## BAS 750 01 F

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 4.2/1	Wegkamp H.-G.	2015 a	Effectiveness of procedures for cleaning application equipment and protective clothing - BAS 750 01 F  2015/1173502  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCP 4.3/1	Anonymous	2016 b	Safety data sheet - BAS 750 01 F  2016/1052608  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCP 4.4/1	Maurer B.	2014 a	EU performance test of BAS 750 01 F, AGRO-packaging made of Coex-materials (HDPE with barrier layer)  2014/1132865  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no	No	No	Not applicable	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 4.4/2	Maurer B.	2014 b	EU performance test of BAS 750 01 F, AGRO-packaging made of HDPE with flourinated barrier  2014/1132864  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCP 4.4/3	Kroehl T.	2015 a	Chemical and physical stability of formula BAS 750 01 F when stored for up to 3 years in PA/PE-coextruded packs - 52 week report  2015/1112122  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

## A.5. METHODS OF ANALYSIS

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.1/1	Bentz A.	2013 a	Analytical method APL0669/01 - Determination of the active ingredient Reg.No.5834378 in Reg.No. 5834378 TGAI  2013/1140545  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCA 4.1.1/2	Bentz A. Harsch M.	2013 a	Validation of the analytical method APL0669/01: Determination of the active ingredient Reg.No. 5834378 in Reg.No. 5834378 TGAI  2013/1140546  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.1/3	Harsch M.	2015 d	Analytical method APL0711/01 - Determination of the impurities Reg.No. [REDACTED], Reg.No. [REDACTED] and Reg.No. [REDACTED] in Reg.No. 5834378 TGAI by HPLC  2015/1001369  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCA 4.1.1/4	Harsch M.	2015 e	Validation of the analytical method APL0711/01: Determination of the impurities Reg.No. [REDACTED], Reg.No. [REDACTED] and Reg.No. [REDACTED] in Reg.No. 5834378 TGAI by HPLC  2015/1001370  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.1/5	Harsch M.	2015 c	Validation of the analytical method APL0706/01: Determination of the	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			<p>impurity Reg.No. [REDACTED] in Reg.No. 5834378 TGAI by HPLC</p> <p>2014/1273312</p> <p>BASF SE, Limburgerhof, Germany Fed.Rep.</p> <p>yes</p> <p>Unpublished</p>				
KCA 4.1.1/6	Harsch M.	2014 g	<p>Analytical method APL0706/01 - Determination of the impurity Reg.No. [REDACTED] in Reg.No. 5834378 TGAI by HPLC</p> <p>2014/1273313</p> <p>BASF SE, Limburgerhof, Germany Fed.Rep.</p> <p>no</p> <p>Unpublished</p>	No	No	Not applicable	BASF
KCA 4.1.1/7	Harsch M.	2013 a	<p>Analytical method APL0680/01: Determination of the impurity Reg.No. [REDACTED] in Reg.No. 5834378 TGAI</p> <p>2013/1256227</p> <p>BASF SE, Limburgerhof, Germany Fed.Rep.</p>	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			no Unpublished				
KCA 4.1.1/8	Harsch M.	2013 b	Validation of the analytical method APL0680/01: Determination of the impurity Reg.No. [REDACTED] in Reg.No. 5834378 TGAI  2013/1256228  BASF SE, Limburgerhof, Germany Fed.Rep.  yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.1/9	Harsch M.	2014 b	Analytical method APL0685/01 - Determination of [REDACTED] [REDACTED] in Reg.No. 5834378 TGAI (Technical Grade Active Ingredient) by GC  2014/1010801  BASF SE, Limburgerhof, Germany Fed.Rep.  no Unpublished	No	No	Not applicable	BASF
KCA 4.1.1/10	Harsch M.	2014 c	Validation of the analytical method APL0685/01:	No	Yes	Data for first	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Determination of in Reg.No. 5834378 TGAI (Technical Grade Active Ingredient) by GC  2014/1010802  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished			Approval	
KCA 4.1.1/11	Harsch M.	2015 a	Validation of the analytical method APL0705/01 - Determination of and in BAS 750 F TGAI and formulation by GC/MS headspace  2014/1271746  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.1/12	Harsch M.	2016 a	Amendment No. 1 - Validation of the analytical method APL0705/01: Determination of [REDACTED] and [REDACTED] in BAS 750 F TGAI and formulation by GC/MS headspace  2016/1010767  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.1/13	Harsch M.	2014 e	Analytical method APL0705/01 - Determination of [REDACTED] and [REDACTED] in BAS 750 F TGAI and formulation by GC/MS headspace  2014/1271748  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCA 4.1.1/14	Behnken H. Kalyon B.	2015 a	Confirmation of identity of active substance and technical impurities in Technical Grade BAS 750 F	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2015/1027724  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished				
KCA 2.5/3 (4.1.1)	Sonnenschein L.	2016 a	Physical and chemical properties of BAS 750 F (Reg.No. 5834378): Additional validation of analytical method applied for determination of solubility in water and organic solvents		KCA 2.5/3	Sonnenschein L.	2016 a
KCA 4.1.2/1	Studenroth S. Lueer D.	2015 a	Validation of analytical method L0214/01 for the determination of BAS No. 750 F (Reg.No. 5834378) and metabolites of Reg.No. 5924326 and 1,2,4-Triazole (Reg.No. 87084) in soil by LC-MS/MS  2015/1039006  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.2/2	Lueer D.	2016 a	Report Amendment No. 1: Validation of analytical method L0214/01 for the determination of BAS No. 750 F (Reg.No. 5834378) and its metabolites Reg.No. 5924326 and 1,2,4-Triazole (Reg.No. 87084) in soil by LC-MS/MS  BASF SE, Limburgerhof, Germany Fed.Rep.  2016/1030227  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/3	Obermann M.	2016 a	Report Amendment No. 2: Validation of analytical method L0214/01 for the determination of BAS No. 750 F (Reg.No. 5834378) and its metabolites Reg.No. 5924326 and 1,2,4-Triazole (Reg.No. 87084) in soil by LC-MS/MS  BASF SE, Limburgerhof, Germany Fed.Rep.  2016/1215646  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/4	Geschke S.	2014 a	Validation of an analytical method for determination of BAS 555 F (Metconazole) and its metabolite 1,2,4-(1H)-Triazole in	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			soil  2013/1377001  Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Fed.Rep.  yes  Unpublished				
KCA 4.1.2/5	Malinsky D.S.	2016 a	Validation of analytical method D1506/01: Method for the determination of Mefentrifluconazole (BAS 750 F, Reg. No.5834378) and its metabolites M750F003 (Reg. No.5924326), M750F005 (Reg. No.6003433), M750006 (Reg. No.5863469), M750F007 (Reg. No.6003432) and M750F008 (Reg. No.6010286) in surface and drinking water by LC-MS/MS  2015/7001125  BASF Crop Protection, Research Triangle Park NC, United States of America  yes	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 4.1.2/6	Malinsky D.S.	2016 a	Amended Report: Validation of analytical method D1506/01: Determination of Mefentrifluconazole (BAS 750 F, Reg. No.5834378) and its metabolites M750F003 (Reg. No.5924326), M750F005 (Reg. No.6003433), M750006 (Reg. No.5863469), M750F007 (Reg. No.6003432) and M750F008 (Reg. No.6010286) in surface and drinking water by LC-MS/MS  2016/7010048  BASF Crop Protection, Research Triangle Park NC, United States of America  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/7	Penning H. et al.	2013 a	Validation of analytical method L0199/01 for the determination of 1,2,4-Triazole (Reg.No. 87084) in water by LC-MS/MS	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2012/1297158  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished				
KCA 4.1.2/8	Obermann M. Studenroth S.	2015 a	Validation of analytical method L0327/01, for the determination of BAS 750 F in air by LC-MS/MS  2015/1111330  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/9	Baltussen E.	2013 a	Development and validation of an analytical method for the analysis of BAS 750 F in diet  2015/1189151  WIL Research Europe BV, s-Hertogenbosch, Netherlands  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.2/10	Baltussen E.	2016 a	Report Amendment Number 1: Development and validation of an analytical method for the analysis of BAS 750 F in diet  2016/1041496  WIL Research BV, s-Hertogenbosch, Netherlands  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/11	Becker M Kamp H.	2015 i	BAS 750 F - Validation of an analytical method for the analysis of BAS 750 F in diet using HPLC-UV  2015/1174512  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/12	Becker M. Kamp H.	2015 j	BAS 750 F - Validation of an analytical method for the analysis of BAS 750 F in diet using HPLC-UV  2015/1175541  BASF SE, Ludwigshafen/Rhein,	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Germany Fed.Rep.  yes  Unpublished				
KCA 4.1.2/13	Becker M. Kamp H.	2015 a	BAS 750 F - Validation of an analytical method for the analysis of BAS 750 F in diet using LC-MS/MS  2015/1175542  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/14	Becker M. Kamp H.	2015 b	BAS 750 F - Validation of an analytical method for the analysis of BAS 750 F in aqueous Carboxymethylcellulose (CMC) using HPLC-UV  2015/1177605  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/15	Becker M. Kamp H.	2015 c	BAS 750 F - Validation of an analytical method for the analysis of BAS	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			750 F in a mixture of Dimethyl Sulfoxide and corn oil using HPLC-UV  2015/1185311  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished				
KCA 4.1.2/16	Becker M. Kamp H.	2015 d	BAS 750 F - Validation of an analytical method for the analysis of BAS 750 F in corn oil using HPLC-UV  2015/1184812  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/17	Becker M. Kamp H.	2015 e	BAS 750 F - Validation of an analytical method for the analysis of BAS 750 F in Dimethyl sulfoxide using HPLC-UV  2015/1184813  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			yes  Unpublished				
KCA 4.1.2/18	Becker M. Kamp H.	2015 f	BAS 750 F - Validation of an analytical method for the analysis of BAS 750 F in plasma using LC-MS/MS  2015/1186912  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/19	Becker M. Kamp H.	2015 g	BAS 750 F - Validation of an analytical method for the analysis of BAS 750 F in Paraffinum subliquidum using HPLC-UV  2015/1186913  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF PS
KCA 4.1.2/20	Becker M. Kamp H.	2015 k	Reg.No. 6011210 - Validation of an analytical method for the analysis of Reg.No. 6011210 in diet using HPLC-UV	No	Yes	Data for first Approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2015/1188594  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished				
KCA 4.1.2/21	Hedrich R.	2015 a	Validation of an analytical method for the analysis of Reg.No. 6011210 in corn oil using HPLC  2015/1189154  Institut Kuhlmann GmbH Analytik-Zentrum Ludwigshafen, Ludwigshafen, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/22	Becker M. Kamp H.	2015 l	Reg.No. 6011210 - Validation of an analytical method for the analysis of Reg.No. 6011210 in Dimethyl sulfoxide using HPLC-UV  2015/1188599  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 4.1.2/23	Mallat E.	2015 a	<p>The validation of the determination of Reg.No. 6011210 in mouse EDTA plasma samples using LC-MS/MS</p> <p>2015/1186930</p> <p>ABL - Analytical Biochemical Laboratory B.V., AJ Assen, Netherlands</p> <p>yes</p> <p>Unpublished</p>	No	Yes	Data for first Approval	BASF
KCA 4.1.2/24	Becker M. Kamp H.	2015 h	<p>BAS 750 01 F - Validation of an analytical method for the analysis of BAS 750 01 F in a mixture of acetone and olive oil using HPLC-UV</p> <p>2015/1188600</p> <p>BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.</p> <p>yes</p> <p>Unpublished</p>	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.2/25	Paula Jose W.F. de	2015 a	Validation of BASF Method Number L0076/09 for the determination of BAS 750 F in citrus (whole fruit), coffee (grain), dry beans (seed), soybeans (grain), tomato (whole fruit), wheat (grain) and wheat (straw) using LC-MS/MS  2015/3001681  BASF SA, Guaratingueta, Brazil  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/26	Class T.	2011 a	Modification M004 of BCS residue analytical method 01062 for the determination of 1,2,4-Triazole, Triazolylalanine, Triazole acetic acid and Triazole lactic acid by LC/DMS/MS/MS in plant materials  2012/1294644  PTRL Europe GmbH, Ulm, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	TDMG

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.2/27	Devine C.	2015 a	Validation of the BASF analytical method L0272/01 for BAS 750 F in animal matrices  2015/1106707  CEMAS - CEM Analytical Services Ltd., Wokingham Berkshire RG41 2FD, United Kingdom  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/28	Heger N. Taraschewski I.	2016 b	Validation of the BASF analytical method L0309/01: For the determination of M750F022 (Reg.No. 6011210) in animal matrices  2015/1106706  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/29	Guedez Orozco A.A. Heger N.	2016 a	Determination of the fatty conjugates metabolites of M750F022 (Reg. No. 6011210) in animal matrices  2016/1001326  BASF SE,	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Limburgerhof, Germany Fed.Rep.  yes  Unpublished				
KCA 4.1.2/30	Billian P. Druskus M.	2009 a	Residue analytical method 01132 for the determination of 1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid and Triazole Lactic Acid in/on milk, egg, muscle, fat, liver and kidney by HPLC-MS/MS (including amendment No. 1)  2010/1230632  Bayer CropScience AG, Monheim, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	TF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.1.2/31	Wiesner F., Breyer N.	2016 a	Validation of BASF Analytical Method No. L0339/01 for the determination of BAS 750 F in body fluids  2016/1148911  Eurofins Agroscience Services Chem GmbH, Hamburg, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.1.2/32	Heger N.	2017 a	Revalidation of the BASF analytical method L0309/01: for the determination of M750F022 (Reg.No.6011210) in cow fat and milk  2017/1002385  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF PS
KCA 4.2/1	Klimmek S. et al.	2015 a	Validation of the multi-residue method QuEChERS, BASF method number L0295/01, for the determination of BAS 750 F in different matrices of plant origin	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2015/1106708  Eurofins Agrosience Services Chem GmbH, Hamburg, Germany Fed.Rep.  yes  Unpublished				
KCA 4.2/2	Richter S. Schmiedt S.	2015 a	Independent method validation (ILV) of the QuEChERS method for the determination of BAS 750 F in 5 plant matrices, using LC/MS/MS (BASF Method No. L0295/01)  2015/1240004  PTRL Europe, Ulm, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.2/3	Devine C.	2015 a	Validation of the BASF analytical method L0272/01 for BAS 750 F in animal matrices  2015/1106707  CEMAS - CEM Analytical Services Ltd., Wokingham Berkshire RG41 2FD, United Kingdom	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			yes  Unpublished				
KCA 4.2/4	Richter S. Djedovic S.	2015 b	Independent method validation (ILV) of a method for the determination of BAS 750 F in various foodstuffs of animal origin, using LC/MS/MS - (BASF Method No. L0272/01)  2015/1240005  PTRL Europe, Ulm, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.2/5	Heger N. Taraschewski I.	2016 b	Validation of the BASF analytical method L0309/01: For the determination of M750F022 (Reg.No. 6011210) in animal matrices  2015/1106706  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.2/6	Bendig P. Wabbel C.	2015 a	Independent method validation (ILV) of BASF method no. L0309/01 for the	No	Yes	Data for first Approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			determination of the BAS 750 F diol metabolite in various foodstuffs of animal origin, using GC/MS  2015/1240006  PTRL Europe, Ulm, Germany Fed.Rep.  yes  Unpublished				
KCA 4.2/7	Wiesner F., Breyer N.	2016 a	Validation of BASF Analytical Method No. L0339/01 for the determination of BAS 750 F in body fluids  2016/1148911  Eurofins Agrosience Services Chem GmbH, Hamburg, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.2/8	Studenroth S. Lueer D.	2015 b	Validation of analytical method L0214/01 for the determination of BAS No. 750 F (Reg.No. 5834378) and metabolites of Reg.No. 5924326 and 1,2,4-Triazole (Reg.No. 87084) in soil by LC-MS/MS  2015/1039006	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished				

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.2/9	Lueer D.	2016 a	Report Amendment No. 1: Validation of analytical method L0214/01 for the determination of BAS No. 750 F (Reg.No. 5834378) and its metabolites Reg.No. 5924326 and 1,2,4-Triazole (Reg.No. 87084) in soil by LC-MS/MS  BASF SE, Limburgerhof, Germany Fed.Rep.  2016/1030227  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.2/10	Obermann M.	2016 a	Report Amendment No. 2: Validation of analytical method L0214/01 for the determination of BAS No. 750 F (Reg.No. 5834378) and its metabolites Reg.No. 5924326 and 1,2,4-Triazole (Reg.No. 87084) in soil by LC-MS/MS  BASF SE, Limburgerhof, Germany Fed.Rep.  2016/1215646  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.2/11	Malinsky D.S.	2016 a	Validation of analytical method D1506/01: Method for the determination of Mefentrifluconazole (BAS 750 F, Reg. No.5834378) and its metabolites M750F003 (Reg. No.5924326), M750F005 (Reg. No.6003433), M750006 (Reg. No.5863469), M750F007 (Reg. No.6003432) and M750F008 (Reg. No.6010286) in surface and drinking water by LC-MS/MS  2015/7001125  BASF Crop Protection, Research Triangle Park NC, United States of America  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 4.2/12	Malinsky D.S.	2016 a	Amended Report: Validation of analytical method D1506/01: Determination of Mefentrifluconazole (BAS 750 F, Reg. No.5834378) and its metabolites M750F003 (Reg. No.5924326),	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			M750F005 (Reg. No.6003433), M750006 (Reg. No.5863469), M750F007 (Reg. No.6003432) and M750F008 (Reg. No.6010286) in surface and drinking water by LC-MS/MS  2016/7010048  BASF Crop Protection, Research Triangle Park NC, United States of America  yes  Unpublished				
KCA 4.2/13	Gu G. et al.	2016 a	Independent laboratory validation of BASF analytical method D1506/01: Method for the determination of BAS 750 F (Reg. No. 5834378) and its metabolites M750F003 (Reg. No. 5924326), M750F005 (Reg. No. 6003433), M750F006 (Reg. No. 5863469), M750F007 (Reg. No. 6003432) and M750F008 (Reg. No. 6010286) in surface and drinking water by LC-MS/MS  2015/7006199	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Alliance Pharma Inc., Malvern PA, United States of America  yes  Unpublished				
KCA 4.2/14	Obermann M. Studenroth S.	2015 b	Validation of analytical method L0327/01, for the determination of BAS 750 F in air by LC-MS/MS  2015/1111330  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

## BAS 750 01 F

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1/1	Harsch M.	2014 a	Determination of the active ingredient Reg.No. 5834378 in EC-Formulation  2014/1097912  BASF SE, Limburgerhof, Germany Fed.Rep.  no	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 5.1.1/2	Harsch M.	2014 b	Validation of the analytical method AFL0909/01: Determination of the Active Ingredient Reg.No. 5834378 in EC-Formulation  2014/1097921  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 5.1.1/3	Harsch M.,Rilinger D.	2016 b	Analytical method AFL0928/02 - Determination of [REDACTED] in BAS 750 01 F by GC  2016/1008398  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCP 5.1.1/4	Harsch M.	2015 c	Validation of the analytical method AFL0928/01: Determination of [REDACTED] in BAS 750 01 F by GC  2015/1180116  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 5.1.1/5	Rilinger D.	2016 b	Additional validation to analytical method AFL0928/01  2016/1008397	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished				



## A.6. TOXICOLOGY AND METABOLISM DATA

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.1.1/1	██████ ██████	2015 a	14C-BAS 750 F (14C-Chlorophenyl and Trifluoromethylring-U-14C labels): Study on kinetics and excretion in Wistar rats after single and repeated oral administration  2015/1208128  ████████████████████ ████████████████████ ████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.1.1/2	██████ ██████	2016 a	14C-BAS 750 F (triazole-3(5)-C14) - Study on the biokinetics in rats  2015/1078847  ████████ ████████████████████ ████████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.1.1/3	████████	2016 a	Excretion and metabolism of 14C-BAS 750 F (Reg.No. 5834378) after oral administration in rats  2015/1107610	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection n claimed Y/N	Justification if data protection is claimed	Owner
			<p>██████████ ██████████ ██████████.</p> <p>yes</p> <p>Unpublished</p>				
KCA 5.1.1/4	██████████ ██████████	2014 a	<p>14C-BAS 750 F - Study on plasma kinetics in C57BL/6 J Rj mice</p> <p>2014/1018105</p> <p>██████████ ██████████ ██████████.</p> <p>yes</p> <p>Unpublished</p>	Yes	Yes	Data for first Approval	BASF
KCA 5.1.2/1	Funk D. et al.	2016 a	<p>Comparative in-vitro-metabolism with 14C-BAS 750 F</p> <p>2015/1020123</p> <p>BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.</p> <p>yes</p> <p>Unpublished</p>	No	Yes	Data for first Approval	BASF
KCA 5.2.1/1	██████████	2013 c	<p>BAS 750 F - Acute oral toxicity study in rats</p> <p>2013/1149656</p> <p>██████████ ██████████ ██████████</p>	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			<p>yes</p> <p>Unpublished</p>				
KCA 5.2.1/2	Becker M. Kamp H.	2013 a	<p>BAS 750 F - Homogeneity and concentration control analyses in corn oil</p> <p>2013/1395622</p> <p>BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.</p> <p>yes</p> <p>Unpublished</p>	No	Yes	Data for first Approval	BASF
KCA 5.2.2/1		2013 b	<p>BAS 750 F - Acute dermal toxicity study in rats</p> <p>2013/1149657</p> <p>yes</p> <p>Unpublished</p>	Yes	Yes	Data for first Approval	BASF
KCA 5.2.2/2	Becker M. Kamp K.	2013 a	<p>Analytical report - BAS 750 F - Homogeneity and concentration control analyses in corn oil</p> <p>2013/1395620</p> <p>BASF SE, Ludwigshafen/Rhein,</p>	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Germany Fed.Rep.  yes  Unpublished				
KCA 5.2.3/1	██████████ ██████████	2014 a	BAS 750 F - Acute inhalation toxicity study in Wistar rats - 4-hour dust exposure (head-nose only)  2014/1127433  ██████████ ████████████████████ ████████████████████.  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.2.4/1	Remmele M.	2012 a	Reg.No. 5834378 - EpiDerm skin corrosion / irritation test  2012/1367952  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCA 5.2.4/2	██████████	2013 a	BAS 750 F - Acute dermal irritation / corrosion in rabbits  2013/1150122  ████████████████████ ████████████████████ ████████████████████,	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			<p>yes</p> <p>Unpublished</p>				
KCA 5.2.5/1	Remmele M.	2012 b	<p>Reg.No. 5834378 - EpiOcular eye irritation test</p> <p>2012/1367953</p> <p>BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.</p> <p>no</p> <p>Unpublished</p>	No	No	Not applicable	BASF
KCA 5.2.5/2	Remmele M.	2012 c	<p>Reg.No. 5834378 - Bovine corneal opacity and permeability test (BCOP test)</p> <p>2012/1367954</p> <p>BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.</p> <p>no</p> <p>Unpublished</p>	No	No	Not applicable	BASF
KCA 5.2.5/3	<p>■■■■■</p> <p>■■■■■</p> <p>■</p>	2013 a	<p>BAS 750 F - Acute eye irritation in rabbits</p> <p>2013/1150121</p> <p>■■■■■</p> <p>■■■■■</p> <p>■■■■■</p> <p>■■■■■</p>	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			yes  Unpublished				
KCA 5.2.6/1	████████	2013 a	BAS 750 F - Test for skin sensitization using the guinea pig maximization test (GPMT)  2013/1150123  ████████████████████ ████████████████ ████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.2.6/2	Grauert E. Kamp H.	2014 a	Analytical report - BAS 750 F - Homogeneity and concentration control analyses in paraffinum subliquidum  2014/1116448  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 5.2.6/3	Stinchcombe S.	2016 a	Assessment of the skin sensitization potential of BAS 750 F - Consideration of the appropriate sub-category for GHS classification as skin sensitizer	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection n claimed Y/N	Justification if data protection is claimed	Owner
			2016/1028946  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished				
KCA 5.2.7/1	Cetto V. Landsiedel R.	2015 a	BAS 750 F - In vitro 3T3 NRU phototoxicity test  2015/1117503  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 5.3.1/1	██████████ ████	2015 a	BAS 750 F - Repeated dose 28-day toxicity study in Wistar rats - Administration via the diet  2014/1170747  ██████████ ████████████████████ ████████████████████.  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.3.1/2	██████████ ██████████	2015 a	Amendment No. 1 to the report - BAS 750 F - Repeated dose 28-day toxicity study in Wistar rats - Administration via the	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			diet  2015/1249664  [REDACTED] [REDACTED] [REDACTED]  yes  Unpublished				
KCA 5.3.1/3	[REDACTED]	2014 a	BAS 750 F - Repeated-dose 28-day toxicity study in C57BL/6 Rj mice - Administration via the diet  2013/1110704  [REDACTED] [REDACTED] [REDACTED]  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.3.1/4	[REDACTED]	2015 a	BAS 750 F - Repeated-dose 28-day oral toxicity study in beagle dogs - Oral administration (capsule)  2014/1170748  [REDACTED] [REDACTED] [REDACTED]  yes  Unpublished	Yes	Yes	Data for first Approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.3.2/1	██████████ ████	2015 b	Final amended report - BAS 750 F - Repeated dose 90-day oral toxicity study in Wistar rats - Administration via the diet  2015/1198721  ██████████ ██████████████████ ██████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.3.2/2	██████████ ██████████	2015 a	90-day oral dietary toxicity study with BAS 750 F in C57BL/6JRj mice  2014/1046542  ██████████████████ ██████████████ ██████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.3.2/3	Becker M. Kamp H.	2014 a	BAS 750 F - Plasma analysis for external studies  2014/1177165  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.3.2/4	Becker M.	2015 a	Amendment No. 1 to the report: BAS 750 F - Plasma analysis for external studies  2015/1240217  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 5.3.2/5	██████████	2015 a	BAS 750 F - Repeated-dose 90-day oral toxicity study in beagle dogs - Oral administration (capsule)  2015/1000530  ██████████ ████████████████████ ████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.3.2/6	██████████	2016 b	BAS 750 F - Repeated-dose 12-month toxicity study in Beagle dogs - Oral administration (capsule)  ██████████ ████████████████████ ████████████████  2016/1273716  yes  Unpublished	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.3.3/1	██████████ ████	2015 b	BAS 750 F - Repeated dose 28-day dermal toxicity study in Wistar rats  2014/1170751  ██████████ ██████████████████ ██████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.4.1/1	Woitkowiak C.	2014 a	BAS 750 F - Salmonella typhimurium / Escherichia coli reverse mutation assay  2014/1128030  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 5.4.1/2	Becker M.,Kamp H.	2013 b	BAS 750 F - Stability analysis in Dimethyl sulfoxide  2015/1040886  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA	Woitkowiak	2015	BAS 750 F - Salmonella	No	Yes	Data for first	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
5.4.1/3	C.	a	typhimurium / Escherichia coli - Reverse mutation assay  2015/1116956  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished			Approval	
KCA 5.4.1/4	Wollny H.-E.	2015 a	BAS 750 F: In vitro cell mutation assay at the thymidine kinase locus (TK+/-) in mouse lymphoma L5178Y cells  2015/1112683  Harlan Cytotest Cell Research GmbH, Rossdorf, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 5.4.1/5	Wollny H.-E.	2015 b	BAS 750 F: In vitro cell mutation assay at the thymidine kinase locus (TK+/-) in mouse lymphoma L5178Y cells  2015/1101908  Envigo CRS GmbH, Rossdorf, Germany Fed.Rep.	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection n claimed Y/N	Justification if data protection is claimed	Owner
			yes  Unpublished				
KCA 5.4.1/6	Schulz M.,Landsiedel R.	2014 a	BAS 750 F - In vitro micronucleus assay in V79 cells (Cytokinesis Block Method)  2013/1375108  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 5.4.1/7	Sokolowski A.	2015 a	BAS 750 F: Micronucleus test in human lymphocytes in vitro  2015/1101907  Envigo CRS GmbH, Rossdorf, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 5.4.2/1	■■■■■ ■	2014 a	BAS 750 F - Micronucleus test in bone marrow cells of the mouse  2014/1043159  ■■■■■ ■■■■■■■■■■■■■■■■■■■■ ■■■■■■■■■■■■■■■■■■■■  yes	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 5.5/1	██████████ ████	2016 b	BAS 750 F - Combined chronic toxicity/carcinogenicity study in Wistar rats - Administration via the diet up to 24 months  2015/1000531  ██████████ ████████████████████ ██████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.5/2	██████████	2015 a	Historical control data - Compilation from 24-month studies in Wistar rats (CrI:WI (Han)) - Performed at BASF SE Experimental Toxicology and Ecology, Ludwigshafen, Germany  2015/1261375  ██████████ ████████████████████ ██████████████████  no  Unpublished	No	No	Not applicable	BASF
KCA 5.5/3	██████████ ██████████	2015 b	18-month carcinogenicity study with BAS 750 F in male and female	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			C57BL/6JRJ mice  2015/1000532  [REDACTED] [REDACTED] [REDACTED]  yes  Unpublished				
KCA 5.5/4	[REDACTED]	2015 a	Historical control data mouse study - Compilation from 18-month studies in male and female C57BL/6JRj mice - Performed at BASF SE, Experimental Toxicology and Ecology, Ludwigshafen, Germany  2015/1261376  [REDACTED] [REDACTED] [REDACTED]  no  Unpublished	No	No	Not applicable	BASF
KCA 5.5/5	Becker M. Kamp H.	2015 a	BAS 750 F - Plasma analysis for external studies  2015/1186254  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection n claimed Y/N	Justification if data protection is claimed	Owner
			yes  Unpublished				
KCA 5.6.1/1	██████████ ██████	2015 c	BAS 750 F - Two-generation reproduction toxicity study in Wistar rats - Administration via the diet  2014/1170754  ██████████ ██████████████████ ██████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.6.2/1	██████████ ██████	2015 a	BAS 750 F - Prenatal developmental toxicity study in Wistar rats - Oral administration (gavage)  2014/1170755  ██████████ ██████████████████ ██████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.6.2/2	██████████ ██████	2015 b	BAS 750 F - Prenatal developmental toxicity study in New Zealand white rabbits - Oral administration (gavage)	Yes	Yes	Data for first Approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2014/1170757 [REDACTED] [REDACTED] [REDACTED] yes Unpublished				
KCA 5.6.2/3	[REDACTED]	2016	Report Amendment: BAS 750 F - Prenatal developmental toxicity study in New Zealand white rabbits - Oral administration (gavage)  2016/1321110 [REDACTED] [REDACTED] [REDACTED] yes Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.6.2/4	[REDACTED] [REDACTED] [REDACTED]	2017	Relevance of the skeletal finding “fused sternebra” in the prenatal developmental toxicity study in NZW rabbits with BAS 750 F  2017/1042996 [REDACTED] [REDACTED] [REDACTED] no	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 5.7.1/1	██████████ ████	2015 c	BAS 750 F - Acute oral neurotoxicity study in Wistar rats - Administration by gavage  2014/1170759  ██████████ ██████████████████ ██████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.1/1	██████ ██████ ██	2015 a	Reg.No. 6011210 - Acute oral toxicity study in rats  2015/1175551  ██████████████████ ██████████████████ ██████████████████ yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.8.1/2	Schmitt D.	2015 a	Concentration control analysis and homogeneity control analysis of Reg.No. 6011210 in vehicle corn oil  2015/1186900  Institut Kuhlmann GmbH Analytik-Zentrum Ludwigshafen, Ludwigshafen, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 5.8.1/3	Lawson S.	2015 a	Toxicological analysis of BAS 750 F and a metabolite using Derek Nexus  2015/1112684  ForthTox Ltd., Linlithgow West Lothian EH49 7YU,	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection n claimed Y/N	Justification if data protection is claimed	Owner
			United Kingdom  no  Unpublished				
KCA 5.8.1/4	Woitkowiak C.	2015 b	Reg.No. 6011210 - Salmonella typhimurium / Escherichia coli - Reverse mutation assay  2015/1174564  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 5.8.1/5	Becker M. Kamp M.	2015 a	Reg.No. 6011210 - Stability analysis in dimethyl sulfoxide  2015/1186975  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 5.8.1/6	Schulz M. Landsiedel R.	2015 a	Reg.No. 6011210 - In vitro gene mutation test in L5178Y mouse lymphoma cells (TK+/- Locus assay, microwell version)  2015/1174532  BASF SE,	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished				
KCA 5.8.1/7	Sokolowski A.	2015 b	Reg.No. 6011210: Micronucleus test in human lymphocytes in vitro  2015/1038964  Envigo CRS GmbH, Rossdorf, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 5.8.1/8	██████████ ████	2016 a	Reg.No. 6011210: Repeated-dose 28-day toxicity study in C57BL/6 J Rj mice - Administration via the diet  2016/1000646  ██████████ ████████████████████ ████████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.8.1/9	Anonymus	2016 a	OASIS/TIMES QSAR analysis of BAS 750 F impurities -Prediction for chromosomal aberration in vitro  2016/1008387	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			<none>  no  Unpublished				
KCA 5.8.1/10	Anonymous	2016 d	OASIS/TIMES QSAR analysis of BAS 750 F impurities - Prediction for AMES mutagenicity  2016/1008388  <none>  no  Unpublished	No	No	Not applicable	BASF
KCA 5.8.1/11	Anonymous	2016 e	Prediction and applicability domain analysis for models: Mutagenicity model (CAESAR) - Mutagenicity SarPy model - Benigni-Bossa Mutagenicity ToxTree - VEGA QSAR analysis of BAS 750 F impurities  2016/1008389  <none>  no  Unpublished	No	No	Not applicable	BASF
KCA 5.8.1/12	██████	2015 a	██████ ██████ - Acute toxicity study in rats  2015/1017686  ██████	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			<p> ██████████  ██████████  ██████████    yes    Unpublished </p>				
KCA 5.8.1/13	██████████	2015 a	<p> Amendment No 1:  ██████████ ██████████  ██████████ - Acute  toxicity study in rats    2015/1253713    ██████████  ██████████  ██████████  ██████████    yes    Unpublished </p>	Yes	Yes	Data for first Approval	BASF
KCA 5.8.1/14	Hedrich R.	2015 a	<p> Concentration control  analysis of ██████████  ██████████ in  vehicle corn oil    2015/1128720    Institut Kuhlmann  GmbH Analytik-  Zentrum  Ludwigshafen,  Ludwigshafen,  Germany Fed.Rep.    yes    Unpublished </p>	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.1/15	Remmele M.	2015 a	<p>██████████ - In vitro skin irritation and corrosion turnkey testing strategy</p> <p>2015/1244420</p> <p>BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.</p> <p>no</p> <p>Unpublished</p>	No	No	Not applicable	BASF
KCA 5.8.1/16	Remmele M.	2015 b	<p>██████████ - In vitro eye irritation turnkey testing strategy</p> <p>2015/1244419</p> <p>BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.</p> <p>no</p> <p>Unpublished</p>	No	No	Not applicable	BASF
KCA 5.8.1/17	██████████	2015 a	<p>██████████ - Skin sensitization: Local lymph node assay</p> <p>2015/1017694</p> <p>████████████████████</p> <p>██████████████████</p> <p>██████████████████</p> <p>yes</p> <p>Unpublished</p>	Yes	Yes	Data for first Approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.1/18	Grauert E. Kamp H.	2015 a	<p>Concentration control analysis in methyl ethyl ketone</p> <p>2015/1237989</p> <p>BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.</p> <p>yes</p> <p>Unpublished</p>	No	Yes	Data for first Approval	BASF
KCA 5.8.1/19	Woitkowiak C.	2015 c	<p>- Salmonella typhimurium/ Escherichia coli reverse mutation assay</p> <p>2015/1244416</p> <p>BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.</p> <p>yes</p> <p>Unpublished</p>	No	Yes	Data for first Approval	BASF
KCA 5.8.1/20		2015 c	<p>- Acute oral toxicity study in rats</p> <p>2015/1005956</p> <p>yes</p> <p>Unpublished</p>	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.1/21	Uhlschmied C.	2015 b	Concentration analysis of [REDACTED] [REDACTED] [REDACTED] in vehicle corn oil  2015/1089789  Institut Kuhlmann GmbH Analytik-Zentrum Ludwigshafen, Ludwigshafen, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 5.8.1/22	Hedrich R.	2015 c	Amendment No. 1 to study report: Concentration analysis of [REDACTED] [REDACTED] [REDACTED] in vehicle corn oil  2015/1096113  Institut Kuhlmann GmbH Analytik-Zentrum Ludwigshafen, Ludwigshafen, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 5.8.1/23	Remmele M.	2015 c	[REDACTED] [REDACTED] - In vitro skin irritation and corrosion turnkey testing strategy	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2015/1254180  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished				

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.1/24	Remmele M.	2015 d	<p>██████████ - In vitro eye irritation turnkey testing strategy</p> <p>2015/1254181</p> <p>BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.</p> <p>no</p> <p>Unpublished</p>	No	No	Not applicable	BASF
KCA 5.8.1/25	██████████	2015 c	<p>██████████ - Skin sensitization: Local lymph node assay</p> <p>2015/1036006</p> <p>██████████ ██████████ ██████████ ██████████</p> <p>yes</p> <p>Unpublished</p>	Yes	Yes	Data for first Approval	BASF
KCA 5.8.1/26	Grauert E. Kamp H.	2015 c	<p>Analytical report - ██████████ ██████████ Concentration control analysis in Methyl ethyl ketone</p> <p>2015/1099662</p> <p>BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.</p> <p>yes</p>	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection n claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 5.8.1/27	Woitkowiak C.	2015 d	<p>██████████ - Salmonella typhimurium / Escherichia coli - Reverse mutation assay</p> <p>2015/1254182</p> <p>BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.</p> <p>yes</p> <p>Unpublished</p>	No	Yes	Data for first Approval	BASF
KCA 5.8.2/1	██████████ ██████████	2015 a	<p>A 28 day dietary study with BAS 750 F in male and female C57BL mice: Elucidation of hepatic mode of action and time course</p> <p>2014/1170760</p> <p>██████████ ██████████ ██████████</p> <p>no</p> <p>Unpublished</p>	Yes	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.2/2	██████████ ██████████ ██	2016 a	BAS 750 F - S-phase response study in livers (histopathological examination) of mice for the study: A 28 day dietary study with BAS 750 F in male and female C57BL mice: Elucidation of hepatic mode of action and time course  2014/1170771  ██████████ ██████████████████ ██████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.8.2/3	██████████ ██████	2015 c	A 7 day dietary study with BAS 750 F in male and female C57BL/6 wild-type and Pxr KO/Car KO mice  2015/1037704  ██████████████████ ██████████████████ ██████████████████  no  Unpublished	Yes	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection n claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.2/4	██████████ ██████████ ████	2016 b	BAS 750 F - S-phase response study in livers (histopathological examination) of mice for the study: A 7 day dietary study with BAS 750 F in male and female C57BL/6 wild-type and Pxr KO/Car KO mice  2015/1040901  ██████████ ██████████████████ ██████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.8.2/5	██████████ ████	2015 d	BAS 750 F- S-Phase response study in Wistar rats - Administration via the diet for 3, 7, 14 and 28 days  2014/1170772  ██████████ ██████████████████ ██████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 5.8.2/6	██████████ ██████	2015 b	Ex vivo analysis of liver samples taken at termination of a 3, 7, 14 and 28 day dietary study administering BAS 750 F in the diet	Yes	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection n claimed Y/N	Justification if data protection is claimed	Owner
			to male and female Wistar rats  2014/1170773  [REDACTED] [REDACTED] [REDACTED]  no  Unpublished				
KCA 5.8.2/7	Elcombe B. et al.	2016 a	BAS 750 F - Enzyme and DNA-Synthesis induction in cultured male and female wild-type and Pxr KO/Car KO mouse hepatocytes  2015/1037705  CXR Biosciences, Dundee DD1 5JJ, United Kingdom  no  Unpublished	No	No	Not applicable	BASF
KCA 5.8.2/8	Elcombe B.	2016 a	BAS 750 F - Enzyme and DNA-Synthesis induction in cultured male and female human hepatocytes  2015/1037703  CXR Biosciences, Dundee DD1 5JJ, United Kingdom  no  Unpublished	No	No	Not applicable	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection n claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.3/1	Mentzel T.	2016 c	Reg.No. 5834378 (BAS 750 F, R,S-racemate), Reg.No. 5934588 (S-enantiomer), Reg.No. 5934591 (R-enantiomer), Reg.No. 6011210 (metabolite) - Human recombinant aromatase assay  2015/1261377  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection n claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.3/2	Mentzel T.	2016 d	Letrozole – Econazole nitrate – 4-OH ASDN – Fenarimol – Epoxiconazole – Nitrofen – Atrazine – Bis(2-ethylhexyl)phthalate – Human recombinant aromatase assay  2016/1001905  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCA 5.8.3/3	Mentzel T.	2017 a	Reg.No. 5834378 (BAS 750 F, R,S-racemate) - Reg.No. 5934588 (S-enantiomer) - Reg.No. 5934591 (R-enantiomer) - Epoxiconazole - Rat recombinant aromatase assay		KCA 5.8.3/3	Mentzel T.	2017 a
KCA 5.8.3/4	Mentzel T.	2017 b	Letrozole - Econazole nitrate - Fenarimol - Nitrofen - Atrazine - Bis(2-ethylhexyl)phthalate - Rat recombinant aromatase assay		KCA 5.8.3/4	Mentzel T.	2017 b

## BAS 750 01 F

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.1/1	██████	2015 a	BAS 750 01 F - Acute oral toxicity study in rats  2014/1170774  ████████████████████ ████████████████████ ████████████████████ yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCP 7.1.2/1	██████	2015 b	BAS 750 01 F - Acute dermal toxicity study in rats  2014/1170776  ████████████████████ ████████████████████ ████████████████████ yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCP 7.1.3/1	██████	2014 a	BAS 750 01 F: 4-hour acute inhalation toxicity study in the rat  2014/1170778  ████████████████████ ████████████████████ yes  Unpublished	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.4/1	Wareing B.	2014 a	Summary report - BAS 750 01 F - EpiDerm skin corrosion test  2014/1127439  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCP 7.1.4/2	Wareing B.	2014 b	Summary report - BAS 750 01 F - EpiDerm skin irritation test  2014/1127441  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCP 7.1.4/3	████████	2015 c	BAS 750 01 F - Acute dermal irritation / corrosion in rabbits  2014/1170779  ████████████████████ ████████████████████ ████████████████████ ████████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.5/1	Wareing B.	2014 c	Summary report - BAS 750 01 F - Bovine corneal opacity and permeability test (BCOP test)  2014/1127440  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCP 7.1.5/2	Remmele M.	2014 a	Summary report - BAS 750 01 F - EpiOcular eye irritation test  2014/1083341  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCP 7.1.5/3	████████	2015 d	BAS 750 01 F - Acute eye irritation in rabbits  2014/1170780  ████████████████████ ████████████████████ ████████████████████ ████████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.5/4	██████	2015 e	Amendment No.1 - BAS 750 01 F - Acute eye irritation in rabbits  2015/1216058  ████████████████████ ████████████████████ ████████████████████ yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCP 7.1.6/1	██████	2014 a	BAS 750 01 F - Skin sensitisation: Local lymph node assay  2014/1170756  ████████████████████ ████████████████████ ████████████████████ yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCP 7.1.6/2	Becker M. Kamp H.	2015 a	Analytical report - BAS 750 01 F - Concentration control analyses in a mixture of acetone and olive oil 4+1 (V/V)  2014/1278739  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 7.3/1	Fabian E. Landsiedel R.	2014 a	14C-BAS 750 F in BAS 750 01 F - Study of penetration through human skin in vitro  2014/1147839  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 7.3/2	Fabian E.	2015 a	Amendment No. 1 to the report: 14C-BAS 750 F in BAS 750 01 F - Study of penetration through human skin in vitro  2015/1005063  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

## A.7. RESIDUE DATA

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.1/1	Guedez-Orozco A.-A. Eilers B.	2015 a	Storage stability of BAS 750 F in plant matrices  2015/1106709  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 6.1/2	Guedez Orozco A.-A.	2016 a	Storage Stability of BAS 750 F in plant matrices  BASF SE, Limburgerhof, Germany Fed.Rep. 2016/1112644  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 6.1/3	Heger N. Taraschewski I.	2015 a	Storage stability of Reg.No. 6011210 in animal matrices  2015/1106710  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 6.1/4	Heger N. Guedez-Orozco A.-A.	2015 b	Storage stability of BAS 750 F in animal matrices  2015/1106711	No	Yes	Data for first Approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished				
KCA 6.1/5	Perez R.	2015 a	Freezer storage stability of Triazolyl lactic acid in plant samples  2015/7005764  ADPEN Laboratories Inc., Jacksonville FL, United States of America  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 6.2.1/1	Rabe U. Bogen C.	2015 a	Metabolism of 14C LS 5834378 in wheat  2015/1001872  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 6.2.1/2	Thiaener J. Bogen C.	2015 a	Metabolism of 14C-BAS 750 F in soybean  2014/1224012  BASF SE, Limburgerhof, Germany Fed.Rep.	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			yes  Unpublished				
KCA 6.2.1/3	Birk B., Bogen C.	2015 a	Metabolism of 14C-BAS 750 F in grape  2015/1073822  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 6.2.1/4	Birk B. et al.	2015 b	Investigation of the extractability of BAS 750 F in samples from 14C plant metabolism studies  2014/1261057  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 6.2.2/1	■■■■■ ■	2015 a	The metabolism of 14C-Reg. No 5834378 (BAS 750 F) in laying hens  2015/1001001  ■■■■■ ■■■■■ ■■■■■  yes	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 6.2.2/2	Thiaener J. Glaessgen W.E.	2015 b	Investigation of the extractability of BAS 750 F and M750F022 in samples from 14C animal metabolism studies  2015/1161960  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 6.2.3/1	██████████ ████	2015 a	The metabolism of 14C-Reg. No. 5834378 (BAS 750 F) in lactating goats  2015/1078841  ██████████ ██████████ ██████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 6.2.3/2	Thiaener J. Glaessgen W.E.	2015 b	Investigation of the extractability of BAS 750 F and M750F022 in samples from 14C animal metabolism studies  2015/1161960  BASF SE, Limburgerhof,	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Germany Fed.Rep.  yes  Unpublished				
KCA 6.2.5/1	██████ ██████	2015 a	The metabolism of 14C-BAS 750 F in rainbow trout (Oncorhynchus mykiss)  2015/1106141  ████████████████████ ████████████████ ████████████████████ ████████ ████████████████ ████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 6.3.1/1	Erdmann H.- P.	2015 a	Study on the residue behaviour of Reg.No. 5834378 (BAS 750 F) in wheat after application of EXP 5834378 F-AV (BAS 750 00 F) under field condition in Germany, The Netherlands, United Kingdom, Southern France, Greece, Italy and Spain, 2013  2014/1010809  Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep.	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			yes  Unpublished				
KCA 6.3.1/2	Ale E.	2015 a	Residue study (Decline) with BAS 750 01 F, BAS 750 00 F and BAS 750 BU F applied to wheat in Northern and Southern Europe in 2014  2015/1099704  Envigo CRS Limited Sucursal en Espana, Valencia, Spain  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 6.3.2/1	Erdmann H.- P.	2015 b	Study on the residue behaviour of Reg.No. 5834378 (BAS 750 F) in barley after application of EXP 5834378 F-AV (BAS 750 00 F) under field condition in Germany, The Netherlands, United Kingdom, Southern France, Greece, Italy and Spain, 2013  2014/1010808  Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep.  yes	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 6.3.2/2	Ale E.	2015 b	Residue study (Decline) with BAS 750 01 F, BAS 750 00 F and BAS 750 BU F applied to barley in Northern and Southern Europe in 2014  2015/1099703  Envigo CRS Limited Sucursal en Espana, Valencia, Spain  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 6.4.1/1	██████	2015 a	Magnitude of residues in tissues and eggs of laying hens following multiple oral administrations of BAS 750 F  2015/1106667  ██████ ██████████ ██████ ██████████.  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 6.4.2/1	██████ ██████	2015 a	Magnitude of residues in milk and tissues of dairy cows following multiple oral administration of BAS 750 F	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2015/1107649  [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]  yes  Unpublished				
KCA 6.4.2/2	Guedez Orozco A.A. Heger N.	2016 a	Determination of the fatty conjugates metabolites of M750F022 (Reg. No. 6011210) in animal matrices  2016/1001326  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 6.5.1/1	Hassink J. Bartmann S.	2014 a	BAS 750 F: Hydrolysis at 90°C, 100°C and 120°C  2014/1170665  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 6.5.3/1	Plier S.,Elze M.	2015 a	Determination of residues of BAS 750 F (Reg.No. 5834378)	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			<p>in wheat and its processed products after two applications of BAS 750 01 F in Germany, 2014</p> <p>2014/1315283</p> <p>BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.</p> <p>yes</p> <p>Unpublished</p>				
KCA 6.5.3/2	Plier S., Elze M.	2015 b	<p>Determination of residues of BAS 750 F (Reg.No. 5834378) in barley and its processed products after two applications of BAS 750 01 F in Germany, 2014</p> <p>2014/1315282</p> <p>BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.</p> <p>yes</p> <p>Unpublished</p>	No	Yes	Data for first Approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.6.1/1	Rabe U. Glaessgen W.	2015 a	Confined rotational crop study with 14C LS 5834378  2015/1001871  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 6.6.2/1	Martin T.	2015 a	Study on the residue behavior of BAS 750 F on the rotational crops: wheat, carrots or radish, broccoli or cauliflower and spinach or lettuce after one application of BAS 750 01 F to bare soil under field conditions, 2014-2015  2015/1106682  Agrologia SLU, Utrera, Spain  yes  Unpublished	No	Yes	Data for first Approval	BASF

## A.8. ENVIRONMENTAL FATE AND BEHAVIOUR

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 7.1.1.1/1	Staudenmaier H. Dalkmann P.	2015 a	Aerobic soil metabolism of BAS 750 F  2014/1275177  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.1.1/2	Staudenmaier H. Dalkmann P.	2015 a	Aerobic soil metabolism of Trifluoromethylphenyl-labeled BAS 750 F  2015/1003306  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.1.2/1	Leed M.G.	2015 a	Anaerobic soil metabolism of 14C-BAS 750 F  2014/7003496  BASF Crop Protection, Research Triangle Park NC, United States of America  yes	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 7.1.1.3/1	Hassink J. Delgado M.	2014 a	Soil photolysis of BAS 750 F  2014/1181666  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.2.1.1/1	Staudenmaier H. Dalkmann P.	2015 b	Degradation of BAS 750 F in soil under aerobic conditions  2014/1275178  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.2.1.1/2	Platz K.	2015 a	Normalized modelling DegT50 endpoints of BAS 750 F derived from laboratory soil degradation experiments  2015/1239053  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 7.1.2.1.2/1	Szegedi K.	2015 a	Estimation of the formation fraction of 1,2,4-triazole from BAS 750F  BASF SE, Limburgerhof, Germany Fed.Rep. 2015/1260802  no Unpublished	No	Yes	Not applicable	BASF
KCA 7.1.2.1.2/2	Szegedi K.	2016 c	Estimation of the formation fraction of 1,2,4-triazole (M750F001) from BAS 750F using modelling endpoints  BASF SE, Limburgerhof, Germany Fed.Rep. 2016/1234478  no Unpublished	No	Yes	Not applicable	BASF
KCA 7.1.2.2.1/1	Schaeufele M.	2015 d	Field soil dissipation study of Reg.No. 5834378 in the formulation EXP 5834378 F-AV on bare soil at six sites in Europe, 2013  2015/1046920  Envigo CRS Limited, Suffolk IP23 7PX, United Kingdom  yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.2.2.1/2	Schaeufele M.	2015 e	Final report amendment No. 1: Field soil dissipation	No	Yes	Data for first	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			study of Reg.No. 5834378 in the formulation EXP 5834378 F-AV on bare soil at six sites in Europe, 2013  2015/1242234  Envigo CRS Limited, Suffolk IP23 7PX, United Kingdom  yes  Unpublished			Approval	
KCA 7.1.2.2.1/3	Jacobson B. et al.	2016 a	Terrestrial field dissipation of the fungicide BAS 750 F following broadcast applications of BAS 750 01 F (EC) or BAS 750 UA F (SC)  2015/7006396  Waterborne Environmental Inc., Leesburg VA, United States of America  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.2.2.1/4	Studenroth S. Pape L.	2015 a	Kinetic evaluation of a field dissipation study with BAS 750 F conducted in 2013 to 2015: Determination of best-fit and modeling endpoints according to FOCUS	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2015/1249176  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished				
KCA 7.1.2.2.1/5	Staudenmaier H. Dalkmann P.	2015 b	Investigation of the extractability of BAS 750 F in samples from 14C soil degradation studies  2015/1182724  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.2.2.1/6	Brewin S.	2015 a	Storage stability of residues of BAS 750 F- Reg.No. 5834378 and its metabolite Reg.No. 5924326 in soil when stored at approximately -20°C for 540 days - Interim Report  2015/1050221  Envigo CRS Limited, Suffolk IP23 7PX, United Kingdom  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 7.1.2.2.1/7	Brewin S.	2015 b	Interim report Amendment No. 1: Storage stability of residues of BAS 750 F- Reg.No. 5834378 and its metabolite Reg.No. 5924326 in soil when stored at approximately -20°C for 540 days - Interim Report  2015/1249072  Envigo CRS Limited, Suffolk IP23 7PX, United Kingdom  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.2.2.1/8	Brewin S.	2016 a	Storage stability of residues of BAS 750 – Reg.No. 5834378 and its metabolite Reg.No.5924326 in soil when stored at approximately -20°C for 650 days  2015/1106725  Envigo CRS Limited, Suffolk IP23 7PX, United Kingdom  yes  Unpublished	No	Yes	New data for AIR3 renewal	BASF
KCA 7.1.2.2.1/9	Geschke S.	2015 a	Determination of storage stability of BAS 555 F (Metconazole) and	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			its metabolite 1,2,4-Triazole in soil  2015/1204922  Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Fed.Rep.  yes  Unpublished				
KCA 7.1.2.2.2/1	Schaeufele M.	2015 b	Final Interim report No.1 - Accumulation behaviour of BAS 750 F in soil under field conditions in the United Kingdom following repeated application onto winter wheat over several years  2015/1076325  Envigo CRS Limited, Suffolk IP23 7PX, United Kingdom  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.2.2.2/2	Schaeufele M.	2015 c	Final Interim report No.1 - Accumulation behaviour of BAS 750 F in soil under field conditions in Germany following repeated application onto winter barley over several years	No	Yes	Data for first Approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2015/1076326  Envigo CRS Limited, Suffolk IP23 7PX, United Kingdom  yes  Unpublished				
KCA 7.1.3.1.1/1	Vasques A.C.	2015 a	Adsorption / desorption behavior of 14C-BAS 750 F on different US, Japanese and European soils  2014/3017870  BASF SA, Guaratingueta, Brazil  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.3.1.1/2	Vasques A.C.	2016 a	AMENDET FINAL REPORT Adsorption / desorption behavior of 14C-BAS 750 F on different US, Japanese and European soils  2016/3003661  BASF SA, Guaratingueta, Brazil  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.3.1.2/1	Szegedi K.	2015 b	Estimation of adsorption coefficients of	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			metabolites of BAS 750F with QSAR  2015/1260816  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished				
KCA 7.1.4/1	Sandt H.J. van de	2015 a	Determination of foliar DT50 of Triazole (BAS 750 F) after application of BAS 750 01 F to wheat surfaces  2015/1130156  De Bredelaar BV, Elst, Netherlands  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.2.1.1/1	Hassink J.	2015 b	BAS 750 F: Aqueous hydrolysis at four different pH values  2015/1046919  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.2.1.2/1	Zhixing Y.	2015 a	Aqueous Photolysis of 14C-BAS 750 F	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2015/7000233  BASF Crop Protection, Research Triangle Park NC, United States of America  yes  Unpublished				
KCA 7.2.2.1/1	Schwarz H.	2014 a	BAS 750 F - Determination of the ready biodegradability in the CO2-evolution test  2014/1239574  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.2.2.2/1	Michel A.	2015 a	14C-BAS 750F: aerobic mineralization in surface water  2015/1186902  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.2.2.3/1	Ebert D. Dalkmann P.	2015 a	Aerobic aquatic metabolism of BAS	No	Yes	Data for first	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			750 F (Reg.No. 5834378)  2015/1000941  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished			Approval	
KCA 7.3.1/1	Hassink J.	2015 a	Photochemical oxidative degradation of BAS 750 F (QSAR estimates)  2015/1005046  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF

## BAS 750 01 F

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.1.3/1	Pape L.	2016 a	Predicted environmental concentrations of BAS 750 F and its metabolite 1,2,4-Triazole in soil	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			following application to cereals  2015/1260841  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished				
KCP 9.2.4.1/1	Pape L. Imukova K.	2016 a	Predicted environmental concentrations of BAS 750 F and its metabolites in groundwater following application to cereals  2015/1260842  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.4.1/2	Pape L.	2016 a	Predicted environmental concentrations of BAS 750 F and its metabolites in groundwater following application to cereals  BASF SE, Limburgerhof, Germany Fed.Rep.  2016/1237568  no  Unpublished	No	Yes	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.5/1	Pape L. Imukova K.	2016 b	Predicted environmental concentrations of BAS 750 F and its metabolites in surface water and sediment following application to cereals  2015/1260843  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCP 9.2.5/2	Pape L.	2017 a	Predicted environmental concentrations of BAS 750 F and its metabolites in surface water and sediment following application to cereals – Updated Tier 2 calculations  2017/1002935  Dr. Knoell Consult GmbH, Mannheim, Germany Fed.Rep.  no  Unpublished	No	Yes	Not applicable	BASF

## A.9. ECOTOXICOLOGY DATA

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.1.1.1/1	██████	2014 a	BAS 750 F - Acute toxicity in the bobwhite quail ( <i>Colinus virginianus</i> ) after single administration (LD50)  2014/1095701  ██████ ██████████████ ██████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 8.1.1.1/2	██████	2014 b	BAS 750 F - Acute toxicity in the mallard duck ( <i>Anas platyrhynchos</i> ) after single oral administration (LD50)  2014/1095700  ██████ ██████████████ ██████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 8.1.1.1/3	██████████	2015 a	BAS 750 F - Acute toxicity in the canary ( <i>Serinus canaria</i> ) after single oral administration (LD50)  2015/1085493  ██████ ██████████████ ██████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.1.1.2/1	██████	2014 c	BAS 750 F - Avian dietary toxicity test in chicks of the bobwhite quail ( <i>Colinus virginianus</i> )  2014/1127963  ██████ ██████████████ ██████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 8.1.1.2/2	██████	2015 a	Amendment No. 1 - BAS 750 F - Avian dietary toxicity test in chicks of the bobwhite quail ( <i>Colinus virginianus</i> )  2015/1223324  ██████ ██████████████ ██████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 8.1.1.2/3	██████	2014 d	BAS 750 F - Avian dietary toxicity test in ducklings of the mallard duck ( <i>Anas platyrhynchos</i> )  2014/1117035  ██████ ██████████████ ██████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.1.1.3/1	██████████ ████	2014 a	BAS 750 F: A reproduction study with the Northern bobwhite  2013/1281276  ████████████████████ ████████████████████ ██████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 8.1.1.3/2	██████████ ████	2015 a	BAS 750 F: A reproduction study with the mallard  2015/7005819  ████████████████████ ████████████████████ ██████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 8.2.1/1	██████████	2014 a	BAS 750 F - Acute toxicity study in the rainbow trout (Oncorhynchus mykiss)  2014/1036951  ██████████ ████████████████████ ████████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.2.1/2	██████████ ████	2015 b	Reg.No. 6003432 (metabolite of BAS 750 F, M750F007) - Rainbow trout, acute toxicity test  2015/1001489  ████████████████████ ████████████████████ ████████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 8.2.1/3	██████████ ████	2016 a	Reg.No. 5863469 (metabolite of BAS 750 F, M750F006) - Rainbow trout, acute toxicity test  2016/1128152  ████████████████████ ████████████████████ ████████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 8.2.1/4	██████████ ████	2015 a	BAS 750 F (Reg.No. 5834378) - Zebrafish acute toxicity test  2015/1001581  ████████████████████ ████████████████████ ████████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.2.1/5	[REDACTED]	2014 a	BAS 750 F: Acute toxicity to the sheepshead minnow, <i>Cyprinodon variegatus</i> , determined under static-renewal test conditions  2014/7002810  [REDACTED] [REDACTED] [REDACTED]  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 8.2.1/6	[REDACTED]	2015 c	BAS 750 F - Acute toxicity study in the common carp ( <i>Cyprinus carpio</i> )  2015/1249071  [REDACTED] [REDACTED] [REDACTED]  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 8.2.2.1/1	[REDACTED]	2015 a	BAS 750 F: Early life-stage toxicity test with the sheepshead minnow, <i>Cyprinodon variegatus</i> , under flow-through conditions  2015/7000619  [REDACTED] [REDACTED] [REDACTED]  yes  Unpublished	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.2.2.1/2	██████████ ████	2015 a	BAS 750 F - Early life-stage toxicity test on the zebrafish (Danio rerio) in a flow through system  2014/1262160  ██████████ ██████████████████ ██████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 8.2.2.1/3	██████████	2015 b	BAS 750 F - Fish sexual development test on the zebrafish (Danio rerio)  2015/1099093  ██████████ ██████████████████ ██████████████████  yes  Unpublished	Yes	Yes	Data for first Approval	BASF
KCA 8.2.2.1/4	Obermann M.	2014 a	Concentration control analysis of BAS 750 F, Reg.No. 5834378 in mixing-water, GV/T Project No. 56F0741/11E177  2014/1161851  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.2.2.1/5	Obermann M.	2015 a	Report Amendment No. 1 - Concentration control analysis of BAS 750 F, Reg.No. 5834378 in mixing-water, GV/T Project No. 56F0741/11E177  2015/1117846  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.2.1/6	Obermann M.	2015 b	Report amendment no. 2 to final report: Concentration control analysis of BAS 750 F, Reg.No. 5834378 in mixing-water, GV/T Project No. 56F0741/11E177  2015/1181295  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.2.3/1	██████████ ██	2015 a	14C-BAS 750 F (label: triazole-3(5)-C14) - Bioconcentration study in the rainbow trout (Oncorhynchus mykiss)  2015/1122811  ██████████ ██████████████████ ██████████████████  yes	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 8.2.4.1/1	Brzozowska K.	2014 a	BAS 750 F (Reg.No. 5834378) - Daphnia magna, acute immobilization test  2013/1250866  Institute of Industrial Organic Chemistry, Pszczyna, Poland  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.4.1/2	Backfisch K. Haerthe N.	2015 a	Acute toxicity of Reg.No. 6003432 (M750F007; metabolite of BAS 750 F) to Daphnia magna STRAUS in a 48 hour static test  2015/1003915  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.4.1/3	Haerthe N.	2016 a	Acute toxicity of Reg.No. 5924326 /M750F003; metabolite of BAS 750 F) to Daphnia magna STRAUS in a 48 hour static test  BASF SE, Limburgerhof, Germany Fed.Rep.  2016/1289876  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.4.1/4	Rzodeczko H.	2015 c	Reg.No. 5863469 (metabolite of BAS 750 F, M750F006) - Daphnia	No	Yes	Data for first	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			magna, acute immobilization test  2015/1001492  Institute of Industrial Organic Chemistry, Pszczyna, Poland  yes  Unpublished			Approval	
KCA 8.2.4.1/5	Rzodeczko H.	2015 d	Reg.No. 6003433 (metabolite of BAS 750 F, M750F005) - Daphnia magna, acute immobilization test  2015/1001490  Institute of Industrial Organic Chemistry, Pszczyna, Poland  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.4.1/6	Rzodeczko H.	2015 e	Reg.No. 6010286 (metabolite of BAS 750 F, M750F008) - Daphnia magna, acute immobilization test  2015/1001493  Institute of Industrial Organic Chemistry, Pszczyna, Poland  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.4.2/1	VanHooser A.	2014 a	BAS 750 F: Acute toxicity test with the saltwater mysid, Americamysis bahia, determined under flow- through test conditions  2014/7002845  ABC Laboratories Inc., Columbia MO, United States	No	Yes	Data for first Approval	BASF



Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			of America  yes  Unpublished				
KCA 8.2.4.2/2	VanHooser A.	2015 a	BAS 750 F: Effect on new shell growth of the eastern oyster ( <i>Crassostrea virginica</i> )  2015/7000021  ABC Laboratories Inc., Columbia MO, United States of America  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.5.1/1	Janson G.-M.	2014 a	Chronic toxicity of the BAS 750 F (Reg.No. 5834378) to <i>Daphnia magna</i> STRAUS in a 21 day semi-static test  2014/1098028  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.5.2/1	Janson G.-M.	2015 b	Chronic toxicity of BAS 750 F (Reg.No. 5834378) to <i>Daphnia longispina</i> in a 21 day semi-static test  2015/1003912  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

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KCA 8.2.5.2/2	Janson G.-M.	2015 c	Report Amendment No.1 - Chronic toxicity of BAS 750 F (Reg.No. 5834378) to <i>Daphnia longispina</i> in a 21 day semi-static test  2015/1251197  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.5.2/3	Janson G.-M.	2015 a	Chronic toxicity of BAS 750 F (Reg.No. 5834378) to <i>Daphnia pulex</i> in a 21 day semi-static test  2015/1003913  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.5.2/4	Dinehart S.	2016 a	BAS 750 F: Life-cycle toxicity test of the saltwater mysid, <i>Americamysis bahia</i> , conducted under flow-through conditions  2016/7001293  ABC Laboratories Inc., Columbia MO, United States of America  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.2.5.3/1	Clark R.	2015 a	BAS 750 F - 10-day toxicity test exposing midge (Chironomus dilutus) to a test substance applied to sediment under static-renewal conditions  2015/7000621  Smithers Viscient LLC, Wareham MA, United States of America  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.5.3/2	Backfisch K. Weltje L.	2015 a	Chronic toxicity of Reg.No. 5924326 (M750F003; metabolite of BAS 750 F) to the non-biting midge Chironomus riparius - a spiked sediment study  2015/1003916  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.5.3/3	Backfisch K. Weltje L.	2015 a	Chronic toxicity of Reg.No. 5834378 to the non-biting midge Chironomus riparius - A spiked sediment study  2014/1243181  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.2.5.4/1	Clark R.	2015 b	BAS 750 F - 10-Day toxicity test exposing freshwater amphipods ( <i>Hyalella azteca</i> ) to a test substance applied to sediment under static-renewal conditions  2015/7000622  Smithers Viscient LLC, Wareham MA, United States of America  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.5.4/2	Clark R.	2015 c	BAS 750 F - 10-Day toxicity test exposing estuarine amphipods ( <i>Leptocheirus plumulosus</i> ) to a test substance applied to sediment under static conditions  2015/7000623  Smithers Viscient LLC, Wareham MA, United States of America  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.6.1/1	Brzozowska K.	2014 b	BAS 750 F (Reg.No. 5834378) - Pseudokirchneriella subcapitata SAG 61.81 - Growth inhibition test  2013/1250865  Institute of Industrial Organic Chemistry, Pszczyna, Poland  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.2.6.1/2	Backfisch K.	2015 a	Effect of Reg.No. 6003432 (M750F007, metabolite of BAS 750 F) on the growth of the green alga <i>Pseudokirchneriella subcapitata</i>  2015/1003914  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.6.1/3	Brzozowska-Wojczech K.	2015 a	Reg.No. 6010286 (metabolite of BAS 750 F, M750F008) - <i>Pseudokirchneriella subcapitata</i> SAG 61.81 - Growth inhibition test  2015/1001491  Institute of Industrial Organic Chemistry, Pszczyna, Poland  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.6.1/4	Rzodeczko H.	2016 a	Reg.No. 5863469 (metabolite of BAS 750 F, M750F006) - <i>Pseudokirchneriella subcapitata</i> SAG 61.81 - Growth inhibition test  2015/1184815  Institute of Industrial Organic Chemistry, Pszczyna, Poland  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.2.6.1/5	Rzodeczko H.	2016 b	Reg.No. 6003433 (metabolite of BAS 750 F, M750F005) - Pseudokirchneriella subcapitata SAG 61.81 - Growth inhibition test  2015/1184816  Institute of Industrial Organic Chemistry, Pszczyna, Poland  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.6.1/6	Backfisch K.	2016 a	Effect of Reg.No. 5924326 (M750F003, metabolite of BAS 750 F) on the growth of the green alga Pseudokirchneriella subcapitata  BASF SE, Limburgerhof, Germany Fed.Rep.  2016/1289875  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.6.2/1	Bergfield A.	2015 a	BAS 750 F: Growth inhibition test with the marine diatom, Skeletonema costatum  2015/7000620  ABC Laboratories Inc., Columbia MO, United States of America  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.2.6.2/2	Horn C.	2016 b	Recalculation of endpoints for the study Bergfield A., 2015a (BASF DocID 2015/7000620): "BAS 750 F: Growth inhibition test with marine diatom, <i>Skeletonema costatum</i> "  BASF SE, Limburgerhof, Germany Fed.Rep.  2016/1292092  no  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.6.2/3	Bergfield A.	2015 b	BAS 750 F: Growth inhibition test with the freshwater diatom, <i>Navicula pelliculosa</i>  2015/7000618  ABC Laboratories Inc., Columbia MO, United States of America  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.6.2/4	Horn C.	2016 a	Recalculation of endpoints for the study by Bergfield A., 2015b (BASF DocID 2015/7000618): BAS 750 F: Growth inhibition test with the freshwater diatom <i>Navicula pelliculosa</i>  BASF SE, Limburgerhof, Germany Fed.Rep.  2016/1292093  no  Unpublished	No	Yes	Data for first approval	BASF

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KCA 8.2.6.2/5	Bergfield A.	2015 c	BAS 750 F: Growth inhibition test with the cyanobacterium, <i>Anabaena flos-aquae</i>  2015/7000617  ABC Laboratories Inc., Columbia MO, United States of America  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.2.7/1	Swierkot A.	2014 a	BAS 750 F (Reg.No. 5834378) - <i>Lemna gibba</i> CPCC 310 growth inhibition test  2014/1001322  Institute of Industrial Organic Chemistry, Poczyna, Poland  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.3.1.1.1/1	Franke M.	2015 a	Acute toxicity of BAS 750 F to the honeybee <i>Apis mellifera</i> L. under laboratory conditions  2015/1128674  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF



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KCA 8.3.1.1.1/2	Amsel K.	2015 a	Acute toxicity of BAS 750 F to the bumblebee <i>Bombus terrestris</i> L. under laboratory conditions  2014/1275250  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.3.1.1.2/1	Franke M.	2015 b	Acute toxicity of BAS 750 F to the honeybee <i>Apis mellifera</i> L. under laboratory conditions  2015/1128674  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.3.1.1.2/2	Amsel K.	2015 a	Acute toxicity of BAS 750 F to the bumblebee <i>Bombus terrestris</i> L. under laboratory conditions  2014/1275250  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.3.1.2/1	Kleebaum K.	2015 a	Chronic toxicity of BAS 750 F (Reg.No. 5834378) to the honeybee <i>Apis mellifera</i> L. under laboratory conditions  2013/1235086  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.3.1.3/1	Kleebaum K.	2015 b	Acute toxicity of BAS 750 F to honeybee larvae ( <i>Apis mellifera</i> L.) under laboratory conditions (in vitro)  2013/1235087  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.3.1.3/2	Royer S.	2015 a	BAS 750 F (Reg.No. 5834378) - Honey bee larvae test (repeated exposure, observation 21 days) under laboratory conditions (in vitro) - Non-GLP  2014/1327676  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.4.1/1	Friedrich S.	2013 a	Sublethal toxicity of Reg.No. 5834378 (BAS 750 F) to the earthworm <i>Eisenia fetida</i> in artificial soil  2013/1235075  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.4.2.1/1	Friedrich S.	2013 b	Effects of BAS 750 F on the reproduction of the collembolan <i>Folsomia candida</i>  2013/1235081  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.4.2.1/2	Schulz L.	2014 a	Effects of BAS 750 F on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i>  2013/1235082  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

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KCA 8.4.2.1/3	Schulz L.	2014 b	1,2,4-triazole - CGA71019 - Effects on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i>  2014/1326895  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	TDMG
KCA 8.5/1	Schulz L.	2015 a	Effects of BAS 750 F (Reg.No. 5834378) on the activity of soil microflora (Nitrogen transformation test)  2015/1108623  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.7/1	Friedrich S.	2015 a	Acute toxicity of BAS 750 F to the earthworm <i>Eisenia fetida</i> in artificial soil with 10% peat  2015/1003342  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.7/2	Schulz L.	2015 b	Effects of BAS 750 F (Reg.No. 5834378) on the activity of soil microflora (Carbon transformation test)  2015/1108621  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCA 8.8/1	Hammer S.	2014 a	BAS 750 F - Determination of the inhibition of oxygen consumption in the activated sludge respiration inhibition test  2014/1049095  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

## BAS 750 01 F

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2.1/1	██████████ ██	2014 a	BAS 750 01 F - Rainbow trout, acute toxicity test  2014/1117112  ████████████████████ ████████████████████	Yes	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			<p>yes</p> <p>Unpublished</p>				
KCP 10.2.1/2		2015 a	<p>BAS 750 BS F (blank formulation of BAS 750 01 F) - Rainbow trout, acute toxicity test</p> <p>2015/1001875</p> <p>yes</p> <p>Unpublished</p>	Yes	Yes	Data for first Approval	BASF
KCP 10.2.1/3	Turek T.	2015 a	<p>BAS 750 01 F - Daphnia magna acute immobilization test</p> <p>2014/1117111</p> <p>Institute of Industrial Organic Chemistry, Pszczyna, Poland</p> <p>yes</p> <p>Unpublished</p>	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2.1/4	Brzozowska-Wojczech K.	2015 a	BAS 750 BS F (blank formulation of BAS 750 01 F) - Daphnia magna, acute immobilization test  2015/1177056  Institute of Industrial Organic Chemistry, Pszczyna, Poland  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 10.2.1/5	Turek T.	2015 b	BAS 750 01 F - Pseudokirchneriella subcapitata SAG 61.81 - Growth inhibition test  2014/1117110  Institute of Industrial Organic Chemistry, Pszczyna, Poland  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 10.3.1.1.1/1	Franke M.	2015 a	Acute toxicity of BAS 750 01 F to the honeybee Apis mellifera L. under laboratory conditions  2014/1242741  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF

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KCP 10.3.1.1.2/1	Franke M.	2015 a	Acute toxicity of BAS 750 01 F to the honeybee <i>Apis mellifera</i> L. under laboratory conditions  2014/1242741  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 10.3.2.1/1	Fallowfield L.	2015 a	A rate-response laboratory test to determine the effects of BAS 750 01 F on the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae)  2014/1242742  Mambo-Tox Ltd., Southampton SO16 7NP, United Kingdom  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 10.3.2.1/2	Stevens J.	2015 a	A rate-response laboratory test to determine the effects of BAS 750 01 F on the parasitic wasp <i>Aphidius rhopalosiphii</i> (Hymenoptera, Braconidae)  2014/1242743  Mambo-Tox Ltd., Southampton SO16 7NP, United Kingdom	No	Yes	Data for first Approval	BASF



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			yes  Unpublished				
KCP 10.3.2.2/1	Fallowfield L.	2015 b	A rate-response extended laboratory test to determine the effects of BAS 750 01 F on the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae)  2015/1020207  Mambo-Tox Ltd., Southampton SO16 7NP, United Kingdom  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 10.3.2.2/2	Stevens J.	2015 b	A rate-response extended laboratory test to determine the effects of BAS 750 01 F on the parasitic wasp <i>Aphidius rhopalosiphii</i> (Hymenoptera: Braconidae)  2014/1242744  Mambo-Tox Ltd., Southampton SO16 7NP, United Kingdom  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 10.3.2.2/3	Vaughan R.	2015 a	A rate-response extended laboratory test to evaluate the effects of fresh residues of BAS 750 01 F on the green lacewing <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae)	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2015/1020206  Mambo-Tox Ltd., Southampton SO16 7NP, United Kingdom  yes  Unpublished				
KCP 10.4.1.1/1	Ganssmann M.	2015 a	Effects of BAS 750 01 F on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil with 10% peat  2015/1000884  Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 10.4.1.2/1	Hamberger A.	2015 a	BAS 752 AM F - A field study to investigate effects on earthworm fauna in Southern Germany  2015/1000261  Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 10.4.1.2/2	Schulz L.	2015 a	Effects of BAS 750 01 F on earthworms under field conditions	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2015/1000163  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished				
KCP 10.4.2.1/1	Friedrich S.	2015 a	Effects of BAS 750 01 F on the reproduction of the collembolan Folsomia candida  2015/1000885  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 10.4.2.1/2	Ganssmann M.	2015 b	Effects of BAS 750 01 F on reproduction of the predatory mite Hypoaspis aculeifer in artificial soil with 5% peat  2014/1242737  Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP	Ganssmann	2015	1 st Final report	No	Yes	Data for	BASF

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10.4.2.1/3	M.	c	<p>amendment: Effects of BAS 750 01 F on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil with 5% peat</p> <p>2015/1035024</p> <p>Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep.</p> <p>yes</p> <p>Unpublished</p>			first Approval	
KCP 10.5/1	Persdorf M.	2014 a	<p>Effects of BAS 750 01 F on the activity of soil microflora (Nitrogen transformation test)</p> <p>2014/1242736</p> <p>BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.</p> <p>yes</p> <p>Unpublished</p>	No	Yes	Data for first Approval	BASF
KCP 10.6.2/1	Marquardt J.	2015 a	<p>BAS 750 01 F: A test to determine the effects on non-target plants</p> <p>2014/1242738</p> <p>RLP AgroScience GmbH, Neustadt/Weinstrasse, Germany Fed.Rep.</p> <p>yes</p>	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 10.6.2/2	Marquardt J.	2015 b	BAS 750 01 F: A test to determine the effects on non-target plants  2014/1242739  Rheinland Pfalz AgroScience GmbH, Neustadt/Weinstrasse, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 10.6.2/3	Siemoneit-Gast S.	2016 a	Amendment No. 1: BAS 750 01 F: A test to determine the effects on non-target plants  Rheinland Pfalz AgroScience GmbH, Neustadt/Weinstrasse, Germany Fed.Rep.  2016/1280262  yes  Unpublished	No	Yes	Data for first approval	BASF
KCP 10.7/1	Schulz L.	2015 b	Effects of BAS 750 01 F on the activity of soil microflora (carbon transformation test)  2015/1000993  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished	No	Yes	Data for first Approval	BASF
KCP 10.7/2	Straube D.	2015 a	BAS 750 01 F: Acute toxicity to the earthworm <i>Eisenia fetida</i> in artificial soil  2015/1188048	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep.  yes  Unpublished				

## A.10. LITERATURE SEARCH REPORTS

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 9/1	Zander-El-Metwally M.  Esswein U.	2015 b	Literature search report - BAS 750 F & metabolites  2016/1052687  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished	No	No	Not applicable	BASF
KCA 9/2	Welter K.	2016 a	BAS 750 F Scientific Peer Reviewed Open Literature - Regulation 1107/2009 - Ecotoxicology - Assessment of Relevance and Reliability  2016/1052028  BASF SE, Limburgerhof, Germany Fed.Rep.	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			no Unpublished				
KCA 9/3	Thornton H.	2015 a	Literature search - Triazole derivative metabolites, being common metabolites of Triazole-Fungicides  2015/1277467  Syngenta Jealott s Hill International Research Centre, Bracknell Berkshire RG42 6EY, United Kingdom  no Unpublished	No	No	Not applicable	TDMG
KCA 9/4	Zander-El-Metwally M. Esswein U.	2015 a	Literature search report - BAS 750 F impurities - BASF confidential  2015/1277150  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no Unpublished	No	No	Not applicable	BASF