SPIROXAMINE

List of **Annex II studies** which were considered as relied upon for the evaluation with a view to renew the Annex I inclusion and for which the main submitter has claimed data protection

Version 2.0 - (17.11.2011)

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[1] on previous use in granting national authorizations
KIIA 1.8.1 (OECD)	Schneider, K.	2005	Manufacturing process - Technical material - Spiroxamine M-300475-01-1 GLP: N, published: N, confidential 1797840 /	
KIIA 1.9.2 (OECD)	Schneider, K.	2008	Composition statement technical material - Spiroxamine - Other name: Spiroxamine techn., KWG 4168 D techn. M-115935-03-1 GLP: N, published: N, confidential 1797843 /	
KIIA 1.10.2 (OECD)	Schneider, K.	2006	Discussion of the formation of impurities for spiroxamine technical M-269936-01-1 GLP: N, published: N, confidential 1797845 /	
KIIA 1.10.2 (OECD)	Schneider, K.	2008	Composition statement technical material - Spiroxamine - Other name: Spiroxamine techn., KWG 4168 D techn. M-115935-03-1 GLP: N, published: N, confidential 1797847 /	
KIIA 1.11.2 (OECD)	Beeck, S.	2008	Analytical profile of different batches of spiroxamine used in toxicological and eco-toxicological studies 15-820-2403 ! M-304135-02-1 GLP: N, published: N, confidential 1797856 /	

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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[1] on previous use in granting national authorizations
KIIA 2.15 (OECD)	Smeykal, H.	2007	Spiroxamine (KWG 4168), technical substance Oxidising properties of liquids A.21. 20071135.01 ! M-295525-01-1 GLP: Y, published: N 1797884 /	
KIIA 2.4.1 (OECD)	Schneider, K.	2008	Appearance and odour - Spiroxamine technical M-299444-01-1 GLP: N, published: N 1797864 /	
KIIA 2.4.2 (OECD)	Schneider, K.	2008	Appearance and odour - Spiroxamine technical M-299444-01-1 GLP: N, published: N 1797868 /	
KIIA 2.5.1.1 (OECD)	Ruengeler, W.	2007	Spectral data set of Spiroxamine (KWG 4168) 15-600-2344 ! M-291731-01-1 GLP: Y, published: N 1797870 /	
KIIA 2.5.1.2 (OECD)	Ruengeler, W.	2007	Spectral data set of Spiroxamine (KWG 4168) 15-600-2344 ! M-291731-01-1 GLP: Y, published: N 1797872 /	
KIIA 2.5.1.3 (OECD)	Ruengeler, W.	2007	Spectral data set of Spiroxamine (KWG 4168) 15-600-2344 ! M-291731-01-1 GLP: Y, published: N 1797874 /	
KIIA 2.5.1.4 (OECD)	Ruengeler, W.	2007	Spectral data set of Spiroxamine (KWG 4168) 15-600-2344 ! M-291731-01-1 GLP: Y, published: N 1797876 /	
KIIA 2.5.1.5 (OECD)	Ruengeler, W.	2007	Spectral data set of Spiroxamine (KWG 4168) 15-600-2344 ! M-291731-01-1 GLP: Y, published: N 1797878 /	
KIIA 2.9.5 (OECD)	Schneider, K.	2006	Dissociation product of Spiroxamine M-269364-01-1 GLP: N, published: N 1797882 /	

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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[1] on previous use in granting national authorizations
KIIA 3.6 (OECD)	Mehl, A.	2008	Spiroxamine - Sensitivity monitoring and anti-resistance strategy MHA SPX-01/2008 GLP: O, published: N 1797890 /	
KIIA 3.7 (OECD)	Anonymous	2008	Spiroxamine technical fungicide M-303899-01-1 GLP: N, published: N 1797892 /	
KIIA 3.8.1 (OECD)	Schneider, K.	2008	Spiroxamine - Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions M-299432-01-1 GLP: N, published: N 1797894 /	
KIIA 5.6 KIIA 5.9.2 KII 5.9.3 KIIA 5.9.5 KIIA 5.9.6 KIIA 9 (OECD)	Henninger, K.	2009	Response of BCS to requests raised by BfR after submission of the dossier for Annex I Renewal - Reference: e-mail from the BVL, Herbert Koepp, 2009-02-11, 0914_GB_4_SPX - Kenn-Nr. WN1 024656-00/00 M-344272-01-2 BCS GLP: N, published: N 1849761 /	
KIIA 4.3 (OECD)	Nuesslein, F.	2004	Residue data of KWG 4168 in wheat and barley after comparative extraction with acetonitrile/water and acetone/water according to method 00709 MR-025/04 ! M-002917-01-1 GLP: Y, published: N 1797924 / ASB2008-6470	
KIIA 4.3 (OECD)	Schoening, R.	2008	Modification M001 of the analytical method 01013 for the simultaneous determination of residues of the active items BYF 00587, prothioconazole, tebuconazole, trifloxystrobin, spiroxamine (KWG4168) and the metabolites BYF00587-desmethyl,.... 01013/M001 ! M-297777-02-1 GLP: Y, published: N 1797938 / ASB2008-6475	
KIIA 4.3 (OECD)	Kuppels, U.; Schmeer, K.	2008	Analytical method 01089 for the determination of spiroxamine (KWG 4168) and of the total residue of spiroxamine (as aminodiol) in/on grapes by HPLC-MS/MS 01089 ! M-304677-01-1 GLP: Y, published: N 1797940 / ASB2008-6476	

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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[1] on previous use in granting national authorizations
KIIA 4.3 (OECD)	Thomas, J.	2009	Spiroxamine - Annex I renewal - Further information requested by the BfR to permit a decision to be made, or to support a review of the conditions and restrictions associated with the proposed inclusion in Annex I M-344349-01-1 GLP: N, published: N 1849706 /	
KIIA 4.3 (OECD)	Thomas, J.	2009	Spiroxamine - Annex I renewal - Further information requested by the BfR to permit a decision to be made, or to support a review of the conditions and restrictions associated with the proposed inclusion in Annex I (Word Version) M-344349-01-1 GLP: N, published: N 1849707 /	
KIIA 4.3 (OECD)	Class, Th.; Merdian, H.	2009	Independent laboratory validation of method 00395 and 00395/M001 for the determination of residues of the spiroxamine carboxylic acid metabolite in egg and fat,using GC/MS P/B 1693 G ! M-344343-01-1 GLP: Y, published: N 1849709 / ASB2009-3194	
KIIA 4.4 (OECD)	Freitag, T.; Daniels, M.	2008	Analytical method 01088 for the determination of residues of KWG 4168 (Spiroxamine) in soil and sediment by HPLC-MS/MS 01088!MR-08/028!M-298750-01-1 GLP: Y, published: N 1797946 / ASB2008-2238	
KIIA 4.6 (OECD)	Freitag, T.; Daniels, M.	2008	Analytical method 01088 for the determination of residues of KWG 4168 (Spiroxamine) in soil and sediment by HPLC-MS/MS 01088!M-298750-01-1!MR-08/028 GLP: Y, published: N 1797954 / ASB2008-2238	

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B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
KIIA 5.1, KIIA 5.8 KIIA 6.2 KIIA 6.6.2 (OECD)	Reiner, H.; Thomas, J.	2009	Spiroxamine: Annex I Renewal Further information requested by the BfR to permit a decision to be made, or to support a review of the conditions and restrictions associated with the proposed inclusion in Annex I M-344146-01-2 ! LII/Sec.3 GLP: N, published: N ASB2009-3192	
KIIA 5.2 (OECD)	Shelanski, Y. M.	2001	A patch test procedure to facilitate the expression and detection of the irritating and sensitising propensities of KWG 4168 107791 ! M-086474-02-1 GLP: Y, published: N 1797957 / ASB2008-2231	
KIIA 5.6.11 KIIA 5.9.2 KIIA 5.9.3 KIIA 5.9.5 KIIA 5.9.6 KIIA 9 (OECD)	Henninger, K.	2009	Spiroxamine. Regulatory toxicology – Response of BCS to requests raised by BfR after submission of the dossier for Annex I Renewal, Renewal 2009, M-344272-01-2, ASB2009-2108 GLP: N, published: N	
KIIA 5.6 (OECD)	Milius, A. D.; Stuart, B. P.	2008	Technical grade Spiroxamine (BAY KWG 4168): A two generation reproductive toxicity study in the Wistar rat 201823 ! M-304231-01-1 BCS GLP: Y, published: N 1797963 / ASB2008-2232	
KIIA 5.8 (OECD)	Freyberger, A.	2008	Spiroxamine - Investigation on potential in vitro aromatase (CYP19) inhibition AT04594 ! M-301971-01-1 BCS GLP: N, published: N 1797973 / ASB2008-2235	
KIIA 5.8 (OECD)	Freyberger, A.	2008	Spiroxamine - Investigation on potential in vitro steroidgenesis inhibition AT04646 ! M-303122-01-1 BCS GLP: N, published: N 1797975 / ASB2008-2236	
KIIA 5.8 (OECD)	Kroetlinger, F.; Schilde, B.	2000	KWG 4168 N-Oxide - Study for subacute oral toxicology in rats (feeding study over 4 weeks) - 1st revised version of report no. 28161 from Nov. 17, 1998 - 28161A ! M-006504-02-1 GLP: N, published: N 1797969 / ASB2008-2233	

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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
KIIA 5.9 (OECD)	Steffens, W.	2008	Occupational medical experiences with spiroxamine M-300761-01-1 BCS GLP: N, published: N 1797971 / ASB2008-2234	

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B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
KIIA 6.3.1/08 (OECD)	Freitag, T.; Wolters, A.	2006	Determination of the residues of JAU 6476, tebuconazole and KWG 4168 in/on winter wheat after spraying of JAU 6476 & HWG 1608 & KWG 4168 (450 EC) in the field in Northern France, Germany, United Kingdom and Sweden RA-2573/05 ! M-271973-01-1 BCS GLP: Y, published: N 1797997 / ASB2008-6381	
KIIA 6.3.1 (OECD)	Freitag, T.; Wolters, A.	2006	Attachment: M-271973-01-1 RA-2573/05 BCS GLP: Y, published: N 1797995 / ASB2008-6381	
KIIA 6.3.1/09 (OECD)	Freitag, T.; Wolters, A.	2006	Determination of the residues of JAU 6476, tebuconazole and KWG 4168 in/on winter wheat after spraying of JAU 6476 & HWG 1608 & KWG 4168 (450 EC) in the field in Southern France and Greece GLP: Y, published: N RA-2574/05 ! M-271989-01-1 ! M-271989-02-1, ASB2008-6484	
KIIA 6.3.1/10 (OECD)	Schoening, R.; Erler, S.	2008	Determination of the residues of BYF 00587, JAU 6476 and KWG 4168 in/on winter wheat and spring wheat after spraying of BYF 00587 & JAU 6476 & KWG 4168 (400 EC) in the field in Northern France, the Netherlands, the United Kingdom and German RA-2040/07 ! M- 298182-01-1, 298182-02-1, BCS GLP: Y, published: N 1797999 / ASB2008-6485	
KIIA 6.3.1/11 (OECD)	Schoening, R.; Erler, S.	2008	Determination of the residues of BYF 00587, JAU 6476 and KWG 4168 in/on winter wheat and wheat, durum after spraying of BYF 00587 & JAU 6476 & KWG 4168 (400 EC) in the field in Southern France, Italy, Spain and Greece RA-2041/07 ! M-298650-02-1 BCS GLP: Y, published: N 1798001 / ASB2008-6486	

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KIIA 6.3.2/09 (OECD)	Freitag, T.; Wolters, A.	2006	Determination of the residues of JAU 6476, tebuconazole and KWG 4168 in/on spring barley after spraying of JAU 6476 & HWG 1608 & KWG 4168 (450 EC) in the field in Northern France, United Kingdom, Germany and Sweden RA-2571/05 ! M-272012-01-1 BCS GLP: Y, published: N 1798011 / ASB2008-6489	
KIIA 6.3.2/10 (OECD)	Freitag, T.; Wolters, A.	2006	Determination of the residues of JAU 6476, Tebuconazole and KWG 4168 in/on winter barley after spraying of JAU 6476 & HWG 1608 & KWG 4168 (450 EC) in the field in Southern France and Spain RA-2572/05 ! M-272115-01-1 BCS GLP: Y, published: N 1798013 / ASB2008-6490	
KIIA 6.3.2/11 (OECD)	Schoening, R.; Erler, S.	2008	Determination of the residues of BYF 00587, JAU 6476 and KWG 4168 in/on spring barley and winter barley after spraying of BYF 00587 & JAU 6476 & KWG 4168 (400 EC) in the field in Northern France, Germany, the United Kingdom and the Netherla RA-2042/07 ! M-298147-01-1 BCS GLP: Y, published: N 1798015 / ASB2008-6491	
KIIA 6.3.2/12 (OECD)	Schoening, R.; Erler, S.	2008	Determination of the residues of BYF 00587, JAU 6476 and KWG 4168 in/on winter barley and spring barley after spraying of BYF 00587 & JAU 6476 & KWG 4168 (400 EC) in the field in Southern France, Spain, Italy and Portugal RA-2043/07 ! M-298412-01-1 BCS GLP: Y, published: N 1798017 / ASB2008-6492	
KIIA 6.3.3/06 (OECD)	Kuppels, U.; Schmeer, K.	2008	Determination of the residues of KWG 4168 in/on grape after low-volume spraying and spraying of KWG 4168 (500 EC) in the field in Northern France and Germany RA-2649/07 ! M-301984-01-1 BCS GLP: Y, published: N 1798033 / ASB2008-6495	

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KIIA 6.3.3/11 (OECD)	Kuppels, U.; Schmeer, K.	2008	Determination of the residues of KWG 4168 in/on grape after low-volume spraying and spraying of KWG 4168 (500 EC) in the field in Southern France, Italy, Spain and Greece RA-2650/07 ! M-301988-01-1 BCS GLP: Y, published: N 1798043 / ASB2008-6498	
KIIA 6.3/12 (OECD)	Thomas, J.	2008	Statistical evaluation of a metric response: Total residues of spiroxamine in grapes M-304376-01-1 BCS GLP: Y, published: N 1798045 / ASB2008-6499	
KIIA 6.3/13 (OECD)	Thomas, J.	2008	Statistical evaluation of a metric response: Spiroxamine (parent) residues in grapes M-304379-01-1 BCS GLP: Y, published: N 1798047 / ASB2008-6500	
KIIA 6.6.2/02 (OECD)	Miebach, D.; Bongartz, R.	2008	Metabolism of [1,3-dioxolane-4-14C] KWG 4168 in confined rotational crops - First part: 1st rotation MEF-08/120 ! M-303904-01-1 BCS GLP: Y, published: N 1798060 / ASB2008-6502	
KIIA 6.6.2 (OECD)	Bongartz, R.; Miebach, D	2009	Metabolism of [1,3-dioxolane-4-14C] KWG 4168 in confined rotational crops - Second Part: 2nd and 3rd Rotation MEF-09/131; M1301752-9 BCS GLP: Y, published: N ASB2009-3193	

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B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
KIIA 7.1.1 (OECD)	Telscher, M.	2008	[1,3-Dioxolane-4-14C]spiroxamine: Metabolic screening for degradation pathways under aerobic conditions in soil MEF-08/214 GLP: Y, published: N 1798063 /	
KIIA 7.3.1 (OECD)	Hardy, I.; Patel, M.	2007	Kinetic modelling analysis of spiroxamine and its metabolites KWG 4557 and KWG 4669 from field soil residue studies conducted in Europe VC/07/007A GLP: N, published: N 1798079 /	
KIIA 7.3.1 (OECD)	Hardy, I.; Patel, M.	2008	Kinetic modelling analysis of spiroxamine and its metabolites KWG 4557 and KWG 4669 from field soil residue studies conducted in Europe normalised to 20ÂºC and pF2 VC/08/019 GLP: N, published: N 1798081 /	
KIIA 7.8.3 (OECD)	Dehner, D.; Heinemann, O.	2008	[1,3-Dioxolane-4-14C]spiroxamine: Aerobic aquatic metabolism MEF-07/483 GLP: Y, published: N 1798095 /	
KIIA 7.8.3 (OECD)	Hardy, I.; Patel, M.	2008	Kinetic modelling evaluations of data from water sediment studies to derive modelling endpoints VC/08/029 GLP: N, published: N 1798097 /	
KIIA 7.13 (OECD)	Krohn, J.	2004	Partition cofficients of soil metabolites of spiroxamine MEF 04/370 k.A. GLP: Y, published: N 1798103 /	

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B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
KIIA 8.1.3 (OECD)	Hancock, G. A.	1998	Results from the KWG 4168 northern bobwhite pilot reproduction study 108264 k.A. GLP: Y, published: N 1798125 /	
KIIA 8.1.4 (OECD)	Barfknecht, R.; Ebeling, M.	2008	Evaluation of historical control data on bobwhite quail 14-d chick body weights to establish the NOAEL in the study SXR/REP 04 with spiroxamine M-304591-01-1 BCS GLP: Y, published: N 1798121 /	
KIIA 8.2.1.2 (OECD)	Teigeler, M.	2008	Acute toxicity of spiroxamine to zebra fish (Danio rerio) over 96 hours BAY-033/4-11 BCS GLP: Y, published: N 1798127 /	
KIIA 8.2.2 (OECD)	Bomke, C.	2008	Spiroxamine - Fish screening assay (FSA) with fathead minnow EBKWX094 BCS GLP: Y, published: N 1798129 /	
KIIA 8.2.4 (OECD)	Matlock, D.; Lam, C. V.	2008	Effects of spiroxamine technical on selected early life stages of rainbow trout (Oncorhynchus mykiss) in a static water/sediment system EBKWX092 BCS GLP: Y, published: N 1798133 /	
KIIA 8.2.5 (OECD)	Teigeler, M.	2009	Final report: Zebra fish, life cycle test, flow through conditions BAY-033/4-60/A BCS GLP: Y, published: N 1849758/	

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KIIA 8.2.5 (OECD)	Bruns, E.; Bomke, C.	2009	Statement concerning questions related to the Fish Full Life Cycle test listed in the Draft Re-assessment Report on Spiroxamine GLP: N, published: N 1879829/	
KIIA 8.3.3 (OECD)	Bruns, E.; Arnold, M.; Krebber, R.; Brumhard, B.; Schoening, R.; Strauss, T.	2008	Biological effects and fate of Spiroxamine EC 500 in outdoor mesocosm ponds simulating actual exposure conditions in agricultural use EBKWX091 BCS GLP: Y, published: N 1798149 /	
KIIA 8.4 (OECD)	Dorgerloh, M.	2006	Desmodesmus subspicatus growth inhibition test with Spiroxamine EBKWX077 BCS GLP: Y, published: N 1798153 /	
KIIA 8.4 (OECD)	Dorgerloh, M.	2006	Non-GLP recalculation report Navicula pelliculosa growth inhibition test with 14 C - KWG 4168 DOM 26021 BCS GLP: N, published: N 1798159 /	
KIIA 8.4 (OECD)	Dorgerloh, M.	2007	Desmodesmus subspicatus growth inhibition test with spiroxamine - desethyl EBKWX080 BCS GLP: Y, published: N 1798161 /	
KIIA 8.4 (OECD)	Dorgerloh, M.	2007	Desmodesmus subspicatus growth inhibition test with spiroxamine - N - oxid EBKWX081 BCS GLP: Y, published: N 1798163 /	
KIIA 8.4 (OECD)	Pross, S.	2008	Evaluations in aquatic risk assessments under 91/414/EEC based on studies with algae: Choice of biomass or growth rate M-296921-01-3 BCS GLP: N, published: N 1798165 /	
KIIA 8.6 (OECD)	Dorgerloh, M.	2008	Non-GLP recalculation report: KWG 4168 - toxicity (14 days) to Lemna gibba G3 DOM 28002 BCS GLP: N, published: N 1798171 /	

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KIIA 8.6 (OECD)	Dorgerloh, M.	2008	Non-GLP recalculation report: 14C-KWG 4168- toxicity (14 days) to Lemna gibba G3 DOM 28003 BCS GLP: N, published: N 1798173 /	
KIIA 8.8.2.1 (OECD)	Jans, D.	2007	Toxicity to the parasitoid wasp Aphidius rhopalosiphi (DESTEPHANI-PEREZ) (Hymenoptera: Braconidae) using an extended laboratory test Spiroxamine EC 500 g/L CW07/012 BCS GLP: Y, published: N 1798183 /	
KIIA 8.8.2.3 (OECD)	Schmitzer, S.	2006	Determination of Spiroxamine residues in the carabid beetle Poecilus cupreus L. - Extended laboratory study - 31861007 BCS GLP: Y, published: N 1798217 /	
KIIA 8.8.2.5 (OECD) DAR: KIIA 8.16.1/02	Frommholz, U.	2007	KWG 4168 tech.: Influence on the reproduction of the collembola species Folsomia candida tested in artificial soil with 5 % peat FRM-COLL-52/07 BCS GLP: Y, published: N 1798211 /	
KIIA 8.8.2.5 (OECD) DAR: KIIA 8.16.1/02	Frommholz, U.	2007	KWG 4168-desethyl (Metabolite of KWG 4168): Influence on the reproduction of the collembola species Folsomia candida tested in artificial soil with 5 % peat FRM-COLL-53/07 BCS GLP: Y, published: N 1798213 /	
KIIA 8.8.2.5 (OECD) DAR: KIIA 8.16.1/03	Frommholz, U.	2007	KWG 4168-despropyl (Metabolite of KWG 4168): Influence on the reproduction of the collembola species Folsomia candida tested in artificial soil with 5 % peat FRM-COLL-54/07 BCS GLP: Y, published: N 1798215 /	
KIIA 8.9.2 (OECD)	Leicher, T.	2007	KWG 4168-Desethyl (technical): Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5 % peat LRT-RG-R-26/06 BCS GLP: Y, published: N 1798189 /	

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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
KIIA 8.14.1 (OECD) DAR: KIIA 8.12/05 Bayer: KIIIA1 10.8.1.2/02	Bach, F.	2008	Spiroxamine EC 500 G: Effect on the vegetative vigour of two non crop species of non-target terrestrial plants (Tier 2) VV 08/002 BCS GLP: Y, published: N 1798205 /	
KIIA 8.9.2 (OECD)	Leicher, T.	2007	KWG 4168-N-Oxid (technical): Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5 % peat LRT-RG-R-27/06 BCS GLP: Y, published: N 1798191 /	
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[1] Entries are based on information received from the main data submitter and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
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