

PORTUGAL

MINISTÉRIO DA AGRICULTURA DO DESENVOLVIMENTO RURAL E DAS PESCAS
DIRECÇÃO-GERAL DE PROTECÇÃO DAS CULTURAS

**Report prepared in the context of the application for first inclusion of
dodine in Annex I of the Council Directive 91/414/EEC**

Dodine

Volume 2 rev.1

Annex A

**List of the tests and studies submitted and
of information available**

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Section A.1 Identity (Annex IIA 1, 3.1 to 3.4; Annex IIIA 1, 3.1 to 3.7, 3.9 and 12.1)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

Cousin, J.	IIA, 1.10 + 1.11/01	1998	Technical dodine: Analysis of product ingredients Rhône-Poulenc, France Chimac-Agriphar, Report No. 96-59 GLP, Unpublished CONFIDENTIAL INFORMATION	Y	CAG
Corman, C.	IIA, 1.8 + 1.9/02	2003	Product identity, composition and certified limits. Chimac-Agriphar, Report No. DOD 111203 GLP, Unpublished CONFIDENTIAL INFORMATION	Y	CAG
Corman, C.	IIA, 1.8 + 1.9/03	2006	History of dodine production: origin of batches used in the dossier. Chimac-Agriphar Not GLP, Unpublished CONFIDENTIAL INFORMATION	Y	CAG
Duff, S.	IIA, 1.10 + 1.11/03	2002	Analytical profile of Technical Dodine LIFESCIENTIFIC Laboratory, Ireland Chimac-Agriphar, Report No. CHI-020709 GLP, Unpublished CONFIDENTIAL INFORMATION	Y	CAG
Emeric, G.T.	IIA, 1.9/01	1999	Technical dodine: Certification of Ingredient Limits. Rhône-Poulenc, France Chimac-Agriphar, Report No. 99-08 GLP, Unpublished CONFIDENTIAL INFORMATION	Y	CAG
Fox, O.	IIA, 1.10 + 1.11/02	2003	CONFIDENTIAL INFORMATION – see volume 4	Y	CAG
O'Reilly, C.	IIA, 1.10 + 1.11/04	2006	Analysis of Dodine technical [REDACTED] [REDACTED] LIFESCIENTIFIC Laboratory, Ireland Chimac-Agriphar, Report No. CHI-020709 GLP, Unpublished CONFIDENTIAL INFORMATION	Y	CAG
Ryckel, de B.	IIA, 1.10 + 1.11/05	2006	Validation of specificity of HPLC method of determination of impurities in Dodine technical (quality analysis by LC/MS/MS) Walloon Agricultural Research Centre, Belgium Chimac-Agriphar, Report no. FO 21257/Ch.3196/2006A Not GLP, unpublished CONFIDENTIAL INFORMATION	Y	CAG
Stephan, D.	IIA, 1.8/01	1998	Dodine: Product identity and composition. Series 61. Rhône-Poulenc, France Chimac-Agriphar, Report No. 98-03 GLP, Unpublished CONFIDENTIAL INFORMATION	Y	CAG

Annex A

List of data and information submitted

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Section A.1 Identity (Annex IIA 1, 3.1 to 3.4; Annex IIIA 1, 3.1 to 3.7, 3.9 and 12.1)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIIA (SYLLIT 400 SC)

Chimac-Agriphar	IIIA, 1.4	2004	Composition of formulation "SYLLIT 400 SC" Chimac-Agriphar Unpublished CONFIDENTIAL INFORMATION	Y	CAG
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Section A.2 Physical and chemical properties (Annex IIA 2; Annex IIIA 2)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

Bascou, J.P.	IIA, 2.1.1/01	1998	Dodine: physical characteristics Rhône-Poulenc, France Chimac-Agriphar, Report No. 97-57- part A GLP, Unpublished	Y	CAG
Bascou, J.P.	IIA, 2.3.1/01	1999a	Dodine: vapour pressure Rhône-Poulenc, France Chimac-Agriphar, Report No. 97-57- part F GLP, Unpublished	Y	CAG
Bascou, J.P.	IIA, 2.3.2/01	1999b	Dodine: Henry's law constant Rhône-Poulenc, France Chimac-Agriphar, Report No. R&D/CRLD/AN/9916653 GLP, Unpublished	Y	CAG
Bascou, J.P.	IIA, 2.6/01	1999c	Dodine: water and solvent solubility Rhône-Poulenc, France Chimac-Agriphar, Report No. 97-57-part C GLP, Unpublished	Y	CAG
Bascou, J.P.	IIA, 2.8/01	1999	Dodine: n-octanol/water partition coefficient Rhône-Poulenc, France Chimac-Agriphar, Report No. 97-57-part D GLP, Unpublished	Y	CAG
Bascou, J.P.	IIA, 2.9.4/01	1999d	Dodine : pH and dissociation constant Rhône-Poulenc, France Chimac-Agriphar, Report No. 97-57-part B GLP, Unpublished	Y	CAG
Brekelmans, M.J.C.	IIA, 2.5.1/04	2002	Determination of the mass spectrum of dodine technical Notox, NL Chimac-Agriphar, Report No. 343215 GLP, Unpublished	Y	CAG
Brekelmans, M.J.C.	IIA, 2.8/02	2006	Determination of the partition coefficient (n-octanol / water) of dodine Rhône-Poulenc, France Chimac-Agriphar, Report No. 450045 (2006) GLP, Unpublished	Y	CAG
Daly, D.; Kabler, K. Williamson, K.	IIA, 2.9.1/01	1991	Dodine: Hydrolysis of dodecylguanidine HCl as function of pH at 25°C ABC Laboratories, USA Chimac-Agriphar, Report No. 38680 GLP, Unpublished	Y	CAG
Francois, J.M.	IIA, 2.15/01	2000	Dodine: determination of the oxidising properties Rhône-Poulenc, France Chimac-Agriphar, Report no. 00-330-SEC GLP, Unpublished	Y	CAG

Section A.2 Physical and chemical properties (Annex IIA 2; Annex IIIA 2)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Krips, H.J.	IIA, 2.5.1/05	2002	Determination of the ¹³ C-NMR spectrum of dodine technical Notox, NL Chimac-Agriphar, Report No. 348874 GLP, Unpublished	Y	CAG
Krips, H.J.	IIA, 2.11.1/02	2001	Determination of the flammability of technical dodine Notox, NL Chimac-Agriphar, Report no. 327083 GLP, Unpublished	Y	CAG
Maestracci, M.P.	IIA, 2.5.1/01	1994	Dodine – UV-visible characteristics Rhône-Poulenc, France Chimac-Agriphar, Report No. 94-140 GLP, Unpublished	Y	CAG
Phong, J.T.T.	IIA, 2.11.1/01	1998	Determination of the explosion properties, flammability, ability for self heating of technical dodine Rhône-Poulenc, France Chimac-Agriphar, Report no. 98-131 GLP, Unpublished	Y	CAG
Slagen, P.J.	IIA, 2.9.2/01	2004	Photodegradation of dodine in water Notox, NL Chimac-Agriphar, Report no. 327061 GLP, Unpublished	Y	CAG
Slagen, P.J.	IIA, 2.10/01	2001	Estimation of the degradation rate in air of dodine (Atkinson calculation) Notox, NL Chimac-Agriphar, Report no. 327072 GLP, Unpublished	Y	CAG
Van Rijsbergen, L.M.	IIA, 2.5.1/02	2002	Determination of the IR absorption spectrum of dodine technical Notox, NL Chimac-Agriphar, Report No. 343193 GLP, Unpublished	Y	CAG
Van Rijsbergen, L.M.	IIA, 2.5.1/03	2002	Determination of the H-NMR spectrum of dodine technical Notox, NL Chimac-Agriphar, Report No. 343204 GLP, Unpublished	Y	CAG

Annex IIIA (SYLLIT 400 SC)

Lamproye, J.L.	IIIA, 2.9.1	2002	Evaluation of physical compatability of tank-mixes with Syllit 400 SC Chimac-Agriphar, Report No. 2002-10-28 No GLP, Unpublished.	Y	CAG
Le Gren, I. Uceda, L.	IIIA, 2.1/01	1997	EXP 10343A: Determination of physical-chemical characteristics and storage stability Rhône-Poulenc Agro, France Chimac-Agriphar, Report No. 97-99 GLP, Unpublished.	Y	CAG

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Section A.2 Physical and chemical properties (Annex IIA 2; Annex IIIA 2)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Le Gren, I. Uceda, L.	IIIA, 2.7.3/01	1999	EXP 10343A: Stability after 2 years storage at ambient temperature Rhône-Poulenc Agro, France Chimac-Agriphar, Report No. 97-99/2A GLP, Unpublished.	Y	CAG
Ryckel de, B.	IIIA, 2.7.2/01	2004	Chemical and physico-chemical properties of Dodine 400 SC Agricultural Research Center, Belgium Chimac-Agriphar, Report No. FO20722/3014/2003/206 GLP, Unpublished.	Y	CAG
Treand, G.	IIIA, 2.2.1/01	1997	Determination of the flash point, the autoflamability and the explosion properties of EXP10343A Rhône-Poulenc Industrie, France Chimac-Agriphar, Report No. 97-166-SEC GLP, Unpublished.	Y	CAG

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Annex A

List of data and information submitted

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Section A.3 Further information (Annex IIA 3; Annex IIIA 3 and 4)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

Unspecified	IIA, 3.7	2004	Material safety data sheet: Dodine technical	N	CAG
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Annex IIIA (SYLLIT 400 SC)

Le Gren, I.; Uceda L.	IIIA, 4.1.3 (2.7.3/01)	1999	EXP 10343A: Stability after 2 years storage at ambient temperature Chimac-Agriphar, Report no. 97-99/2A GLP, Unpublished.	Y	CAG
Unspecified	IIIA, 4.1.1/01	2002	Description and specification of the packaging and materials used in packaging, size, capacity, size of openings, types of closures and seals – 1L bottles Chimac-Agriphar	N	CAG
Unspecified	IIIA, 4.1.1/02	2002	Description and specification of the packaging and materials used in packaging, size, capacity, size of openings, types of closures and seals – 5L containers Chimac-Agriphar	N	CAG
Unspecified	IIIA, 4.4	2004	Material safety data sheet: SYLLIT 400 SC	N	CAG

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Section A.4 Classification, packaging and labelling (Annex IIA 10; Annex IIIA 12.3 and 12.4)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

Batham P.	IIA, 5.3.1/01	1994a	A 4 week oral (gavage) toxicity study of dodecylguanidine acetate (dodine) in the albino rat Bio-Research Laboratories, Canada Report no. 84568 GLP Unpublished	Yes	CAG
Batham P.	IIA, 5.3.1/02	1994b	A 4 week oral (diet) toxicity study of dodecylguanidine acetate (dodine) in the albino rat Bio-Research Laboratories, Canada Report no. 84569 GLP Unpublished	Yes	CAG
Chimac-Agriphar	IIA, 5.9.1	2002	Report on medical surveillance of manufacturing plant personnel Chimac-Agriphar Unpublished Statement	Yes	CAG
Dange M.	IIA, 5.3.1/03	1997	Dodecylguanidine acetate (dodine) - 28-day toxicity study in the rat by dietary administration Rhône-Poulenc Agrochimie, France Report no. SA94448 GLP Unpublished	Yes	CAG
Dange M.	IIA, 5.3.1/04	1996	Dodecylguanidine acetate (dodine) - Assessment of gut motility following dietary administration of dodine in the rat Rhône-Poulenc Agrochimie, France Report no. SA94453 GLP Unpublished	Yes	CAG
Dange M.	IIA, 5.5/01	1998	Chronic toxicity and carcinogenicity study of dodecylguanidine acetate (dodine) in the Sprague-Dawley rat by dietary administration Rhône-Poulenc Agro, France Report no. SA95083 GLP Unpublished	Yes	CAG
Davis P.B.	IIA, 5.4.1/04	1985	An investigation into the possible induction of point mutation at the HGPRT locus of Chinese hamster ovary cells by dodine TNO, Netherlands Report no. R85/105 GLP Unpublished	Yes	CAG
Hazelden K.P. Wilson J.A.	IIA, 5.6.2/01	1989a	Dose range finding study in rats preliminary to teratogenicity study Inveresk Research International, Scotland Report no. 5596 GLP Unpublished	Yes	CAG

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Section A.4 Classification, packaging and labelling (Annex IIA 10; Annex IIIA 12.3 and 12.4)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Hazelden K.P., Wilson J.A.	IIA, 5.6.2/02	1989b	Dodine : teratogenicity study in rats Inveresk Research International, Scotland Report no. 5965 GLP Unpublished	Yes	CAG
Hemalatha Murli	IIA, 5.4.2/02	1992	Mutagenicity test on dodecylguanidine acetate technical <i>in vivo</i> mammalian micronucleus assay Hazleton Washington, USA Report no. 14710-0-455 GLP Unpublished	Yes	CAG
Henwood S.M.	IIA, 5.6.1/01	1996	Two-generation reproduction study with dodine in rats Corning Hazleton, USA Report no. HWI 6224-218 GLP Unpublished	Yes	CAG
Kangas L.	IIA, 5.3.2/02	1994	A 13-week dietary toxicity study of Dodecylguanidine acetate (dodine) in the albino mouse Bio-Research Laboratories, Canada Report no. 84582 GLP Unpublished	Yes	CAG
Kenny T., Fensome Z.	IIA, 5.2.3	1999	Dodine technical : acute (four hour) inhalation study in rats Huntingdon Life Sciences, UK Report no. RNP 605/992051 GLP Unpublished	Yes	CAG
Kern T.G.	IIA, 5.2.1/01	1999	Acute oral toxicity study of dodine technical material in albino rats WIL Research Laboratories, USA Report no. WIL-21130 GLP Unpublished	Yes	CAG
Kern T.G.	IIA, 5.2.2	1999	Acute dermal toxicity study of dodine technical material in albino rats WIL Research Laboratories, USA Report no. WIL-21131 GLP Unpublished	Yes	CAG
Kern T.G.	IIA, 5.2.4	1999	Acute dermal irritation study of dodine technical material in albino rabbits WIL Research Laboratories, USA Report no. WIL-21132 GLP Unpublished	Yes	CAG
Kern T.G.	IIA, 5.2.5	1999	Acute eye irritation study of dodine technical material in Albino rabbits WIL Research Laboratories, USA Report no. WIL-21133 GLP Unpublished	Yes	CAG

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Section A.4 Classification, packaging and labelling (Annex IIA 10; Annex IIIA 12.3 and 12.4)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Kern T.G.	IIA, 5.3.3/01	1999	A 28-day dermal toxicity study of dodine technical material in rats WIL Research Laboratories, USA Report no. WIL-21140 GLP Unpublished	Yes	CAG
Lina B.A.R., Til H.P., <i>et al.</i>	IIA, 5.3.2/01	1984	Sub-chronic (90-day) oral toxicity study with dodine in rats TNO, Netherlands Report no. V83.130/220623 GLP Unpublished	Yes	CAG
Manciaux X.	IIA, 5.2.6	1999	Dodine technical : skin sensitization test in guinea-pigs (Maximization method of Magnusson, B. and Kligman, A.M.) Centre International de Toxicologie, France Report no. 17473 TSG GLP Unpublished	Yes	CAG
Mc Cay C., Hazelden K.P.	IIA, 5.6.2/03	1989a	Dodine : dose range finding study in rabbits preliminary to teratogenicity study Inveresk Research International, Scotland Report no. 5687 GLP Unpublished	Yes	CAG
Mc Cay C., Hazelden K.P.	IIA, 5.6.2/04	1989b	Dodine : teratogenicity study in rabbits Inveresk Research International, Scotland Report no. 5861 GLP Unpublished	Yes	CAG
Mulhern M., Perry C.J., Snodgrass E.	IIA, 5.3.1/05	1988	Dodine : 8 week dietary dose range finding study in mice Inveresk Research International, Scotland IRI Report no. 5411 GLP Unpublished	Yes	CAG
Semino G.	IIA, 5.5/01 <i>bis</i>	2000	Dodine : Evaluation of clinical signs in the rat chronic study Aventis CropScience, France Unpublished Statement	Yes	CAG
Smith S.Y.	IIA, 5.3.1/06	1994	An oral capsule range-finding study of dodecylguanidine acetate (dodine) in the beagle dog Bio-Research Laboratories, Canada Report no. 84796 GLP Unpublished	Yes	CAG
Spanjers M.Th., Til H.P.	IIA, 5.2.1/02	1985	The acute oral toxicity of dodine in mice TNO, Netherlands Report no. V85.169/250208 GLP Unpublished	Yes	CAG

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Section A.4 Classification, packaging and labelling (Annex IIA 10; Annex IIIA 12.3 and 12.4)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Trutter J.A.	IIA, 5.3.2/03	1996	52-Week toxicity study in dogs with dodine Corning Hazleton, USA Report no. CHV 656-192 GLP Unpublished	Yes	CAG
Verspeek-Rip C.M.	IIA, 5.4.1/02	2003	Evaluation of the mutagenic activity of dodine technical in the <i>Escherichia Coli</i> reverse mutation assay (with independent repeat) Notox, Netherlands Report no. 394482 GLP Unpublished	Yes	CAG
Willems M.I.	IIA, 5.4.1/01	1981	Evaluation of dodine tech 95% for mutagenic activity in the Ames test TNO, Netherlands Report no. V81.102/210064-7 GLP Unpublished	Yes	CAG
Willems, M.I.	IIA, 5.4.2/01	1985	Examination of dodine in the micronucleus test TNO, Netherlands Report no. V85.198/250208 GLP Unpublished	Yes	CAG
Williams K.D.	IIA, 5.5/02	1998	78-week dietary oncogenicity study with dodine in mice Covance Laboratories, USA Report no. 6224-220 GLP Unpublished	Yes	CAG
Wilmer J.W.G.M.	IIA, 5.4.1/03	1985	Chromosome analysis of cultured human lymphocytes treated <i>in vitro</i> with dodine TNO, Netherlands Report no. V85.164/250209 GLP Unpublished	Yes	CAG

Annex III A

Blagden S.M.	IIIA, 7.1.3	1992	EXP 10343: Acute inhalation toxicity study four-hour exposure (nose only) in the rat Safepharm Laboratories, UK Report no. 282/146 GLP Unpublished	Yes	CAG
Dreher D.M.	IIIA, 7.1.1	1991	EXP 10343: Acute oral toxicity (limit test) in the rat Safepharm Laboratories, UK Report no. 282/141 GLP Unpublished	Yes	CAG

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Section A.4 Classification, packaging and labelling (Annex IIA 10; Annex IIIA 12.3 and 12.4)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Dreher D.M.	IIIA, 7.1.2	1991	EXP 10343: Acute dermal toxicity (limit test) in the rat Safepharm Laboratories, UK Report no. 282/142 GLP Unpublished	Yes	CAG
Dreher D.M.	IIIA, 7.1.4/01	1991	EXP 10343: Acute dermal irritation test in the rabbit Safepharm Laboratories, UK Report no. 282/143 GLP Unpublished	Yes	CAG
Dreher D.M.	IIIA, 7.1.5/01	1991	EXP 10343: Acute eye irritation test in the rabbit Safepharm Laboratories, UK Report no. 282/144 GLP Unpublished	Yes	CAG
Dreher D.M.	IIIA, 7.1.6	1992	EXP 10343: Buehler delayed contact hypersensitivity study in the guinea pig Safepharm Laboratories, UK Report no. 282/145 GLP Unpublished	Yes	CAG
Manciaux X.	IIIA, 7.1.4/02	1999	Acute dermal irritation in rabbits Centre International de toxicologie, France Report no. 18689TAL GLP Unpublished	Yes	CAG
Manciaux X.	IIIA, 7.1.5/02	1999	Acute eye irritation in rabbits Centre International de toxicologie, France Report no. 18690TAL GLP Unpublished	Yes	CAG

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Section A.5 Methods of analysis (Annex IIA 4; Annex IIIA 5)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

Bacher R.	IIA, 4.2.5/01	2004	Dodine: Development and Validation of an Analytical method for the determination of dodine and its metabolite in body fluids and tissues. PTRL Europe / Germany. Chimac-Agriphar, Report no. P/B603G GLP, unpublished	Y	CAG
Duchene, P.; Goller, G.	IIA, 4.2.1/03	1998	Analytical method validation of dodine residues in Peach, Pear, Apple, Cherry and plum samples. ADME Bioanalyses, France Chimac-Agriphar, Report no. RPA/DOD/97112 code 97-176/AR 156-97 GLP, unpublished	Y	CAG
Duff, S.	IIA, 4.1 (1.10 + 1.11/03)	2002	CONFIDENTIAL INFORMATION – See volume 4 Analytical profile of technical dodine Chimac-Agriphar, Report no. CHI-030407 GLP, unpublished	Y	CAG
Duff, S.	IIA, 4.1.2/03	2002	CONFIDENTIAL INFORMATION – See volume 4	Y	CAG
Herzig, R.	IIA, 4.2.1/02	1996	Independent Laboratory Confirmation of the Tolerance Enforcement Method by EPA PR Notice 88-5 for “Dodine – Validation of method of analysis for dodine in fruit. Method 45137”. Agvise Lab, USA Chimac-Agriphar, Report no. RES9608 GLP, unpublished	Y	CAG
Loeffen, H.; Schoutsen, T.P.	IIA, 4.2.4/01	2002	Validation of an analytical method for the determination of dodine residues in air. Notox, NL Chimac-Agriphar, Report no. 335069 GLP, unpublished	Y	CAG
Pittman, J.H.	IIA, 4.2.1/01	1996	Dodine – Validation of method of analysis for dodine in fruit. Method 45137. Rhône-Poulenc Ag, USA Chimac-Agriphar, Report no. EC-96-342 GLP, unpublished	Y	CAG
Reynaud, R.	IIA, 4.1.1/01	1997a	Technical dodine HPLC determination of active ingredient, Method D-867-06-96 {E} Rhône-Poulenc Agro, France Chimac-Agriphar, Report no. part of study # 96-59 GLP, unpublished	Y	CAG
Reynaud, R.	IIA, 4.1.2/01	1997b	CONFIDENTIAL INFORMATION – See volume 4	Y	CAG
Reynaud, R.	IIA, 4.1.2/02	1997c	CONFIDENTIAL INFORMATION – See volume 4	Y	CAG
Ryckel, de B.	IIA, 4.1.1/03 4.1.2/04 (1.10 + 1.11/05)	2006	Validation of specificity of HPLC method of determination of impurities in Dodine technical (quality analysis by LC/MS/MS) Walloon Agricultural Research Centre, Belgium Chimac-Agriphar, Report no. FO 21257/Ch.3196/2006A Not GLP, unpublished CONFIDENTIAL INFORMATION – See volume 4	Y	CAG

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Section A.5 Methods of analysis (Annex IIA 4; Annex IIIA 5)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Schoutsen, T.P.; Wierda, F.	IIA, 4.2.3/01	2001	Validation of an analytical method for the determination of dodine residues in water. Notox, NL Chimac-Agriphar, Report no. 335058 GLP, unpublished	Y	CAG
Unspecified	IIA, 4.1.1/02	1983	Analysis of technical and formulated pesticides, method MT 101: Dodine; p. 1802-1804 No GLP, published CIPAC Handbook 1B	N	-
Unspecified	IIA, 4.2.1/04	2003	Chimac-Agriphar statement concerning the applicability of a multi-residue method for dodine	N	CAG
Yang, Ju	IIA, 4.2.2/01	1998	Validation of Method of analysis for dodine in soil using GC-MSD. Rhône-Poulenc Ag, USA Chimac-Agriphar, Report no. EC-97-384 GLP, unpublished	Y	CAG

Annex III A (SYLLIT 400 SC)

Le Gren, I.	IIIA, 5.1.1a/01	1997	Dodine: Determination by HPLC analysis in formulation EXP10343A (SC). Method reference D-930-11-97. Rhône-Poulenc Agro, France. Chimac-Agriphar, Report no. R&D/CRLD/AN /9716711 GLP, Unpublished	Y	CAG
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Section A.6 Toxicology and metabolism (Annex IIA 5; Annex IIIA 7)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

Auletta C.S.	IIA, 5.3.3/02	1989	A 21-day dermal toxicity study in rats with CT-334-87 Bio/dynamics Inc., USA Report no. 4932-88 GLP Unpublished	Yes	CAG
Batham P.	IIA, 5.3.1/01	1994a	A 4 week oral (gavage) toxicity study of dodecylguanidine acetate (dodine) in the albino rat Bio-Research Laboratories, Canada Report no. 84568 GLP Unpublished	Yes	CAG
Batham P.	IIA, 5.3.1/02	1994b	A 4 week oral (diet) toxicity study of dodecylguanidine acetate (dodine) in the albino rat Bio-Research Laboratories, Canada Report no. 84569 GLP Unpublished	Yes	CAG
Cameron B.D., Milner N.P., Dunsire J.P.	IIA, 5.1/01	1985	The residue kinetics of n-dodecylguanidine acetate (dodine) in the rat Inveresk Research International, Scotland IRI Report no. 4066 GLP Unpublished	Yes	CAG
Chimac-Agriphar	IIA, 5.9.1	2002	Report on medical surveillance of manufacturing plant personnel Chimac-Agriphar Unpublished Statement	Yes	CAG
Dange M.	IIA, 5.3.1/03	1997	Dodecylguanidine acetate (dodine) - 28-day toxicity study in the rat by dietary administration Rhône-Poulenc Agrochimie, France Report no. SA94448 GLP Unpublished	Yes	CAG
Dange M.	IIA, 5.3.1/04	1996	Dodecylguanidine acetate (dodine) - Assessment of gut motility following dietary administration of dodine in the rat Rhône-Poulenc Agrochimie, France Report no. SA94453 GLP Unpublished	Yes	CAG
Dange M.	IIA, 5.5/01	1998	Chronic toxicity and carcinogenicity study of dodecylguanidine acetate (dodine) in the Sprague-Dawley rat by dietary administration Rhône-Poulenc Agro, France Report no. SA95083 GLP Unpublished	Yes	CAG

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Section A.6 Toxicology and metabolism (Annex IIA 5; Annex IIIA 7)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Davis P.B.	IIA, 5.4.1/04	1985	An investigation into the possible induction of point mutation at the HGPRT locus of Chinese hamster ovary cells by dodine TNO, Netherlands Report no. R85/105 GLP Unpublished	Yes	CAG
Hazelden K.P., Wilson J.A.	IIA, 5.6.2/01	1989a	Dose range finding study in rats preliminary to teratogenicity study Inveresk Research International, Scotland Report no. 5596 GLP Unpublished	Yes	CAG
Hazelden K.P., Wilson J.A.	IIA, 5.6.2/02	1989b	Dodine : teratogenicity study in rats Inveresk Research International, Scotland Report no. 5965 GLP Unpublished	Yes	CAG
Hemalatha Murli	IIA, 5.4.2/02	1992	Mutagenicity test on dodecylguanidine acetate technical <i>in vivo</i> mammalian micronucleus assay Hazleton Washington, USA Report no. 14710-0-455 GLP Unpublished	Yes	CAG
Henwood S.M.	IIA, 5.6.1/01	1996	Two-generation reproduction study with dodine in rats Corning Hazleton, USA Report no. HWI 6224-218 GLP Unpublished	Yes	CAG
Kangas L.	IIA, 5.3.2/02	1994	A 13-week dietary toxicity study of Dodecylguanidine acetate (dodine) in the albino mouse Bio-Research Laboratories, Canada Report no. 84582 GLP Unpublished	Yes	CAG
Kenny T., Fensome Z.	IIA, 5.2.3	1999	Dodine technical : acute (four hour) inhalation study in rats Huntingdon Life Sciences, UK Report no. RNP 605/992051 GLP Unpublished	Yes	CAG
Kern T.G.	IIA, 5.2.1/01	1999	Acute oral toxicity study of dodine technical material in albino rats WIL Research Laboratories, USA Report no. WIL-21130 GLP Unpublished	Yes	CAG

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Section A.6 Toxicology and metabolism (Annex IIA 5; Annex IIIA 7)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Kern T.G.	IIA, 5.2.2	1999	Acute dermal toxicity study of dodine technical material in albino rats WIL Research Laboratories, USA Report no. WIL-21131 GLP Unpublished	Yes	CAG
Kern T.G.	IIA, 5.2.4	1999	Acute dermal irritation study of dodine technical material in albino rabbits WIL Research Laboratories, USA Report no. WIL-21132 GLP Unpublished	Yes	CAG
Kern T.G.	IIA, 5.2.5	1999	Acute eye irritation study of dodine technical material in Albino rabbits WIL Research Laboratories, USA Report no. WIL-21133 GLP Unpublished	Yes	CAG
Kern T.G.	IIA, 5.3.3/01	1999	A 28-day dermal toxicity study of dodine technical material in rats WIL Research Laboratories, USA Report no. WIL-21140 GLP Unpublished	Yes	CAG
Lina B.A.R., Til H.P., <i>et al.</i>	IIA, 5.3.2/01	1984	Sub-chronic (90-day) oral toxicity study with dodine in rats TNO, Netherlands Report no. V83.130/220623 GLP Unpublished	Yes	CAG
Manciaux X.	IIA, 5.2.6	1999	Dodine technical : skin sensitization test in guinea-pigs (Maximization method of Magnusson, B. and Kligman, A.M.) Centre International de Toxicologie, France Report no. 17473 TSG GLP Unpublished	Yes	CAG
Mc Cay C., Hazelden K.P.	IIA, 5.6.2/03	1989a	Dodine : dose range finding study in rabbits preliminary to teratogenicity study Inveresk Research International, Scotland Report no. 5687 GLP Unpublished	Yes	CAG
Mc Cay C., Hazelden K.P.	IIA, 5.6.2/04	1989b	Dodine : teratogenicity study in rabbits Inveresk Research International, Scotland Report no. 5861 GLP Unpublished	Yes	CAG

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Section A.6 Toxicology and metabolism (Annex IIA 5; Annex IIIA 7)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Mulhern M., Perry C.J., Snodgrass E.	IIA, 5.3.1/05	1988	Dodine : 8 week dietary dose range finding study in mice Inveresk Research International, Scotland IRI Report no. 5411 GLP Unpublished	Yes	CAG
Reddy V., Litle L., Murril E.	IIA, 5.1/02	1992	Disposition and metabolism of ¹⁴ C labeled dodine in rats (preliminary and definitive study) Midwest Research Institute, USA MRI Report no. 9938-F GLP Unpublished	Yes	CAG
Semino G.	IIA, 5.5/01 bis	2000	Dodine : Evaluation of clinical signs in the rat chronic study Aventis CropScience, France Unpublished Statement	Yes	CAG
Smith S.Y.	IIA, 5.3.1/06	1994	An oral capsule range-finding study of dodecylguanidine acetate (dodine) in the beagle dog Bio-Research Laboratories, Canada Report no. 84796 GLP Unpublished	Yes	CAG
Spanjers M.Th., Til H.P.	IIA, 5.2.1/02	1985	The acute oral toxicity of dodine in mice TNO, Netherlands Report no. V85.169/250208 GLP Unpublished	Yes	CAG
Trutter J.A.	IIA, 5.3.2/03	1996	52-Week toxicity study in dogs with dodine Coming Hazleton, USA Report no. CHV 656-192 GLP Unpublished	Yes	CAG
Verspeek-Rip C.M.	IIA, 5.4.1/02	2003	Evaluation of the mutagenic activity of dodine technical in the <i>Escherichia Coli</i> reverse mutation assay (with independent repeat) Notox, Netherlands Report no. 394482 GLP Unpublished	Yes	CAG
Willems M.I.	IIA, 5.4.1/01	1981	Evaluation of dodine tech 95% for mutagenic activity in the Ames test TNO, Netherlands Report no. V81.102/210064-7 GLP Unpublished	Yes	CAG
Willems, M.I.	IIA, 5.4.2/01	1985	Examination of dodine in the micronucleus test TNO, Netherlands Report no. V85.198/250208 GLP Unpublished	Yes	CAG

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Section A.6 Toxicology and metabolism (Annex IIA 5; Annex IIIA 7)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Williams K.D.	IIA, 5.5/02	1998	78-week dietary oncogenicity study with dodine in mice Covance Laboratories, USA Report no. 6224-220 GLP Unpublished	Yes	CAG
Wilmer J.W.G.M.	IIA, 5.4.1/03	1985	Chromosome analysis of cultured human lymphocytes treated <i>in vitro</i> with dodine TNO, Netherlands Report no. V85.164/250209 GLP Unpublished	Yes	CAG

Annex III A

Blagden S.M.	IIIA, 7.1.3	1992	EXP 10343: Acute inhalation toxicity study four-hour exposure (nose only) in the rat Safepharm Laboratories, UK Report no. 282/146 GLP Unpublished	Yes	CAG
Bounds S.V.J.	IIIA, 7.3/01	1995	Dodine formulation: Absorption study in the male rat after topical application Pharmaco LSR, England Report no. 95/RHA552/0850 GLP Unpublished	Yes	CAG
Dreher D.M.	IIIA, 7.1.1	1991	EXP 10343: Acute oral toxicity (limit test) in the rat Safepharm Laboratories, UK Report no. 282/141 GLP Unpublished	Yes	CAG
Dreher D.M.	IIIA, 7.1.2	1991	EXP 10343: Acute dermal toxicity (limit test) in the rat Safepharm Laboratories, UK Report no. 282/142 GLP Unpublished	Yes	CAG
Dreher D.M.	IIIA, 7.1.4/01	1991	EXP 10343: Acute dermal irritation test in the rabbit Safepharm Laboratories, UK Report no. 282/143 GLP Unpublished	Yes	CAG
Dreher D.M.	IIIA, 7.1.5/01	1991	EXP 10343: Acute eye irritation test in the rabbit Safepharm Laboratories, UK Report no. 282/144 GLP Unpublished	Yes	CAG
Dreher D.M.	IIIA, 7.1.6	1992	EXP 10343: Buehler delayed contact hypersensitivity study in the guinea pig Safepharm Laboratories, UK Report no. 282/145 GLP Unpublished	Yes	CAG

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Section A.6 Toxicology and metabolism (Annex IIA 5; Annex IIIA 7)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Esdaile D.	IIIA, 7.3/02	1999	<i>In vivo</i> absorption and skin distribution study of a dodine formulation after topical exposure in the rat Rhône-Poulenc Agro, France Report no. SA99254 GLP Unpublished	Yes	CAG
Macy L.J.	IIIA, 7.2.3.2	2000	Dodine: Dissipation of dislodgeable foliar dodine residue from peaches treated with Syllit 65 W ABC Laboratories California, USA + Southeast Agresearch/Georgia USA + Horizon Laboratories Columbia USA Report no. 99X17415 GLP Unpublished	Yes	CAG
Manciaux X.	IIIA, 7.1.4/02	1999	Acute dermal irritation in rabbits Centre International de toxicologie, France Report no. 18689TAL GLP Unpublished	Yes	CAG
Manciaux X.	IIIA, 7.1.5/02	1999	Acute eye irritation in rabbits Centre International de toxicologie, France Report no. 18690TAL GLP Unpublished	Yes	CAG

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Annex A

List of data and information submitted

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Section A.7 Residue data (Annex IIA 6; Annex IIIA 8 and 12.2)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

Baker F., McKemie D., Kimmel E.C.	IIA, 6.1/03	1998	A metabolism Study with [¹⁴ C]-Dodine on pecans PTRL-West Inc / USA, study # 643W-1 GLP Unpublished	Y	CAG
Baudet L., Yslan F.	IIA, 6.3.1/05-12	1999a	Dodine: formulation EXP10343A (SC). North/France 1998 – 4 reverse curve trials, South/France 1998 – 4 reverse curve trials. Residues in apple (fruit). (season 1998) Rhone Poulenc Agrochimie / France, study #98-677 GLP Unpublished	Y	CAG
Baudet L., Yslan F.	IIA, 6.3.2/01-06	1999b	Dodine: formulation EXP10343A (SC). North/France 1998 – 4 decline study trials, South/France 1998 – 2 decline study trials. Residues in pear (fruit). (season 1998) Rhone Poulenc Agro / France, study # 98-678 GLP Unpublished	Y	CAG
Baudet L., Yslan F.	IIA, 6.3.3/08-09	1999c	Dodine: formulation EXP10343A (SC). North/France 1998 – 1 harvest trial, South/France 1998 – 1 harvest trial. Residues in cherry (flesh). (season 1998) Rhone Poulenc Agro / France, study #98-510 GLP Unpublished	Y	CAG
Baudet L., Yslan F.	IIA, 6.3.3/10-11	1999d	Dodine: formulation EXP10343A (SC). North/France 1998 – 1 decline study trial, South/France 1998 – 1 decline study trial. Residues in cherry (whole fruit, flesh). (season 1998) Rhone Poulenc Agro / France, study #98-511 GLP Unpublished	Y	CAG
Baudet L., Yslan F.	IIA, 6.3.4/05-06	1999e	Dodine: formulation EXP10343A (SC). South/France 1998 – 2 harvest trials. Residues in peach (flesh). (season 1998), Rhone Poulenc Agrochimie / France, study #98-530 GLP Unpublished	Y	CAG
Baudet L., Yslan F.	IIA, 6.3.4/07-08	1999f	Dodine: formulation EXP10343A (SC). South/France 1998 – 2 decline study trials. Residues in peach (whole fruit, flesh) (season 1998) Rhone Poulenc Agrochimie / France, study #98-531 GLP Unpublished	Y	CAG
Langford-Pollard A.D.	IIA, 6.2/01	1996	¹⁴ C-Dodine: Metabolism in the goat. Huntingdon Life Sciences / UK, study # RNP477/961299 GLP Unpublished	Y	CAG
Macy L.J.	IIA, 6.8.c/01	2000	Dodine: dissipation of dislodgeable foliar dodine residues from Peaches treated with Syllit 65W ABC Lab + Southeast Ag + Horizon Lab / USA, study #99X17415 GLP Unpublished	Y	CAG

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Section A.7 Residue data (Annex IIA 6; Annex IIIA 8 and 12.2)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Maestracci M.	IIA, 6.3.1/01-04	1998a	Dodine: Formulation EXP10343A (SC). Trials France 1997. Residues in apple. Decline study. (season 1997) Rhone Poulenc Agrochimie / France, study # 97-528 GLP Unpublished	Y	CAG
Maestracci M.	IIA, 6.3.3/01-02	1998b	Dodine: formulation EXP10343A (SC). Trials France 1997. Residues in cherry. Decline study. (season 1997) Rhone Poulenc Agro / France, study # 97-547 GLP Unpublished	Y	CAG
Maestracci M.	IIA, 6.3.3/03	1998c	Dodine: formulation EXP10343A (SC). Trials France 1997. Residues in cherry. Decline study. (season 1997) Rhone Poulenc Agro / France, study #97-548 GLP Unpublished	Y	CAG
Maestracci M.	IIA, 6.3.3/04-05	1998d	Dodine: formulation EXP10343A (SC). Trials France 1997. Residues in cherry. (season 1997) Rhone Poulenc Agro / France, study #97-549 GLP Unpublished	Y	CAG
Maestracci M.	IIA, 6.3.3/06-07	1998e	Dodine: formulation EXP10343A (SC). Trials France 1997. Residues in cherry. (season 1997) Rhone Poulenc Agro / France, study #97-550 GLP Unpublished	Y	CAG
Maestracci M.	IIA, 6.3.4/01-02	1998f	Dodine: formulation EXP10343A (SC). Trials France 1997. Residues in Peach. Decline study. (season 1997) Rhone Poulenc Agrochimie / France, study #97-512 GLP Unpublished	Y	CAG
Maestracci M.	IIA, 6.3.4/03-04	1998g	Dodine: formulation EXP10343A (SC). Trials France 1997. Residues in peach. (season 1997) Rhone Poulenc Agrochimie / France, study #97-513 GLP Unpublished	Y	CAG
Mohseni R., Ewing A. et al.	IIA, 6.1/01	1992	A metabolism study with [¹⁴ C]- Dodine on apples, PTRL-West Inc / USA, study #286W-1 GLP Unpublished	Y	CAG
Mohseni R., Kimmel E.C. et al.	IIA, 6.1/02	1993	A metabolism study with [¹⁴ C]- Dodine on strawberries PTRL-West Inc / USA, study #287W-1 GLP Unpublished	Y	CAG
Noorloos, B. van	IIA, 6.5.1/01	2004	Nature of the Residue of [¹⁴ C] dodine after Thermal Processing. Notox B.V: Lab./NL, study #397507 GLP Unpublished	Y	CAG
Pigeon O.	IIA, 6.3.2/15-16	2002a	Determination of residues of dodine in pear after treatment with Syllit. Final report. (season 2001) Departement de phytopharmacie / Belgium, study #20238 GLP Unpublished	Y	CAG
Pigeon O.	IIA, 6.3.3/15-16	2002b	Determination of residues of dodine in cherry after treatment with dodine 400SC. (season 2001) Department of phytopharmacy / Belgium, study #20253 GLP Unpublished	Y	CAG

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Section A.7 Residue data (Annex IIA 6; Annex IIIA 8 and 12.2)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Venet C., Yslan F.	IIA, 6.3.1/13-20	2000a	Dodine: formulation EXP10343A (SC). North/France 1999 – 4 reverse curve trials, South/France 1999 – 4 reverse curve trials. Residues in apple (fruit). (season 1999) Aventis Cropscience / France, study #99-517 GLP Unpublished	Y	CAG
Venet C., Yslan F.	IIA, 6.3.2/07-14	2000b	Dodine: formulation EXP10343A (SC). North/France 1999 – 2 decline study trials, South/France 1999 – 6 decline study trials. Residues in pear (fruit). (season 1999) Aventis CropScience / France, study #99-518 GLP Unpublished	Y	CAG
Venet C., Yslan F.	IIA, 6.3.3/12-13	2000c	Dodine: formulation EXP10343A (SC). North/France 1999 – 1 decline curve trial, South/France 1999 – 1 decline curve trial. Residues in cherry (fruit and stoned fruit). (season 1999) Aventis cropscience / France, study #99-514 GLP Unpublished	Y	CAG
Venet C., Yslan F.	IIA, 6.3.3/14	2000d	Dodine: formulation EXP10343A (SC). South/France 1999 – 1 harvest trial. Residues in cherry (stoned fruit). (season 1999) Aventis cropscience / France, study # 99-515 GLP Unpublished	Y	CAG
Wargo J.P.	IIA, 6.5.2/01	1996	Magnitude of the residues of Dodine (n-Dodecylguanidine acetate) in/on apple processed fractions after ground treatment with Syllit 65W. Rhone Poulenc Ag Company / USA , study #US95X05R / File N° 45177 GLP Unpublished	Y	CAG
Yang J.	IIA, 6.0/01	1998	Storage Stability of the Residue of Dodine (n-dodecylguanidine acetate) in/on Fruits and their Processed Fractions. Rhone Poulenc Ag Company / USA , study # EC-96-357 GLP Unpublished	Y	CAG
Zenide D.	IIA, 6.0/02	2001	Dodine: Freezer Storage Stability in Apples and Cherries. Battelle / Switzerland, study # 97-174 (ID # A-01-99-02) GLP Unpublished	Y	CAG

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Section A.8 Environmental fate and behaviour (Annex IIA 7; Annex IIIA 9)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

Cady C., Cranor W.	IIA, 7.2.1.3.2/01	1992	Aerobic aquatic metabolism of Metasol DGH ABC Laboratories, report # 38682, GLP, Unpublished	Y	CAG
Cady C.	IIA, 7.1.1.1.2/01	1993	Anaerobic aquatic metabolism of Metasol DGH. ABC Lab, report # 38684, GLP, Unpublished	Y	CAG
Cooper J.D.L. <i>et al</i>	IIA, 7.1.1.1.1/01	1996	14C-Dodine: Aerobic soil metabolism in two soils at 25°C. Rhone-Poulenc Agriculture, report # P94/162, GLP, Unpublished	Y	CAG
Desmares-Koopmans M.J.E	IIA, 7.2.1.3.1/01	2002	Determination of ready biodegradability: carbon dioxide (CO ₂) evolution test (modified Sturm test) with dodine technical. Notox, NL, report # 327105, GLP, Unpublished	Y	CAG
Lowden P <i>et al.</i>	IIA, 7.1.1.1.1/02	1997	C14-dodine: Rate and route of degradation in three soil types under aerobic conditions with C14-guanidine labelled dodine and in one soil under aerobic conditions with C14-chain labelled dodine. Rhone Poulenc Agriculture, report # 10521, GLP, Unpublished	Y	CAG
Mislankar S.G.	IIA, 7.1.1.1.2/02	2001	Dodine: photodegradation on soil. Aventis Crop Science, report # 2000X18609, GLP, Unpublished	Y	CAG
Norris F.A.	IIA, 7.1.1.2.2/01	1999	Terrestrial Soil Dissipation after application of Syllit Brand 65W fruit fungicide to bare ground plots simulating an orchard or grove. Rhone Poulenc Ag, report # 45751-96X10342, GLP, Unpublished	Y	CAG
Slangen P.J.	IIA, 7.2.1.3.2/02	2004	The fate of Dodine in two water/sediment systems. Notox / NL, report # 344677, GLP, Unpublished	Y	CAG
Van Noorloos B, Slangen P.J.	IIA, 7.1.3.2/01	2002	Aged leaching of Dodine. Notox, NL, report #327094, GLP, Unpublished	Y	CAG
Williams M, Hargadine S.	IIA, 7.1.2/01	1991	Soil/sediment adsorption-desorption of DGH, ABC Laboratories, report # 38683 GLP, Unpublished	Y	CAG

Annex III A

Corman C.	IIIA 9.6.0/01	2006	Determination of DT50 of dodine in soils	Y	CAG
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Annex A

List of data and information submitted

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Section A.8 Environmental fate and behaviour (Annex IIA 7; Annex IIIA 9)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Cornille I.	IIIA 9.6/01	2006	Evaluation of predicted environmental concentration in surface water (PEC _{sw}) for dodine following the use of A.S. 400SC, Unpublished	Y	CAG
Cornille I.	IIIA 9.7/01	2006	Evaluation of predicted environmental concentration in surface water (PEC _{gw}) for dodine following the use of A.S. 400SC, Unpublished	Y	CAG

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Section A.9 Ecotoxicology (Annex IIA 8; Annex IIIA 10)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

Bettencourt M.J.	IIA, 8.2.1 /03	1992	Dodine technical : Acute toxicity to sheepshead minnow (<i>Cyprinodon variegates</i>) under flow-through conditions; Springborn Laboratories SLI report # 92-9-4416, GLP Unpublished	Y	CAG
Bettencourt M.J.	IIA, 8.2.4/03	1992	Dodine technical : acute toxicity to mysid shrimp (<i>Mysidopsis bahia</i>) under flow-through conditions; Springborn Laboratories, SLI report # 92-9-4401, GLP, Unpublished	Y	CAG
Caley C.A.	IIA, 8.2.4/02	1989	Dodine : determination of acute toxicity (LC50) to daphnia (48h, semi-static) (EPA); Inveresk Research report # 7069 GLP Unpublished	Y	CAG
Caley C.Y. et al	IIA, 8.2.1/01	1990	Dodine : determination of acute toxicity (LC50) to rainbow trout (96h, semi-static) (EPA); Inveresk Research report # 7068 GLP Unpublished.	Y	CAG
Caley C.Y. et al.	IIA, 8.2.1/02	1991	Dodine : determination of acute toxicity (LC50) to bluegill sunfish (96h, semi-static) (EPA); Inveresk Research report # 7071 GLP Unpublished	Y	CAG
Desmares-Koopmans M.J.E.	IIA, 8.7/01	2001	Activated sludge respiration inhibition test with Dodine technical (Contact time : 30 minutes); Notox project 327138 GLP Unpublished	Y	CAG
Desmares-Koopmans M.J.E.	IIA, 8.2.7/01	2002	Sediment-water chironomid toxicity test using water spiked with Dodine technical; Notox, report #_327127, GLP Unpublished	Y	CAG
Dionne E	IIA, 8.2.4/04	1992	Dodine technical : acute toxicity to eastern oyster (<i>Crassostrea virginica</i>) under flow-through conditions; Springborn Laboratories, SLI report # 92-9-4404, GLP, Unpublished	Y	CAG
Hakin B.	IIA, 8.1.1/01	1990a	The acute oral toxicity (LD50) of dodine to the mallard duck; Huntingdon report # CMK 40/881487, GLP, Unpublished	Y	CAG
Hakin B.	IIA, 8.1.1 /02	1990b	The acute oral toxicity (LD50) of dodine to the bobwhite quail; Huntingdon report # CMK 411881123, GLP, Unpublished	Y	CAG

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Section A.9 Ecotoxicology (Annex IIA 8; Annex IIIA 10)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Hakin B.	IIA, 8.1.2/01	1990a	The dietary toxicity (LC50) of dodine to the bobwhite quail; Huntingdon report # CMK 39/881199, GLP, Unpublished	Y	CAG
Hakin B.	IIA, 8.1.2/02	1990b	The dietary toxicity (LC50) of dodine to the mallard duck; Huntingdon report # CMK 38/881122, GLP, Unpublished	Y	CAG
Hoberg J.R.	IIA, 8.2.6/01	1993	Dodine: toxicity to the freshwater green alga, <i>Selenastrum capricornutum</i> ; Springborn Laboratories, SLI report # 92-12-4550, GLP, Unpublished.	Y	CAG
Hoberg J.R.	IIA, 8.2.6/02	1995	Dodine - Toxicity to the freshwater green alga, <i>Selenastrum capricornutum</i> during a 15-day partial renewal test, Springborn Laboratories, SLI-report # 95-10-6147, GLP, Unpublished	Y	CAG
Jansen, J.-P.	IIA, 8.3.2.2/01	2001	Determination of LD50 of Syllit on protonymphs of the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) on detached bean leaves in the laboratory; Lab. d'Ecotox. Project test # TE.02/2001, GLP Unpublished	Y	CAG
Jansen, J.-P.	IIA, 8.3.2.2/02	2001	Side effects of Syllit on larvae of the green lacewing <i>Chrysoperla carnea</i> (Neuroptera; Chrysopidae) on detached bean leaves in the laboratory; Lab. d'Ecotox. Project test # CCE 01/2001 GLP Unpublished	Y	CAG
Jansen, J.-P.	IIA, 8.3.2.2/03	2001c	Side effects of Syllit on larvae of the ladybird <i>Coccinella septempunctata</i> L. (Coleoptera; Coccinellidae) on detached bean leaves in the laboratory; Lab. d'Ecotox. Project test # CSE.01/2001, GLP, Unpublished	Y	CAG
Jansen, J.-P.	IIA, 8.3.2.2/04	2002	Side effects of Syllit on protonymph of the anthocorid bug <i>Orius insidiosus</i> (Heteroptera; Anthocoridae) on detached bean leaves in the laboratory; Lab. d'Ecotox. Project test # 0101/2001, GLP, Unpublished	Y	CAG
Kölzer, U.	IIA, 8.5/01	2002	Assessment of the side effects of Dodine 400 SC on the activity of the soil microflora; GAB/IFU report # 20011182/01-ABMF, GLP, Unpublished.	Y	CAG

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Section A.9 Ecotoxicology (Annex IIA 8; Annex IIIA 10)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Kühner C.	IIA, 8.3.2.1/01	1997a	EXP 10343A: acute toxicity to the predatory mite, <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the laboratory; GAB/IFU, report # 97123/02-NLTp, GLP, Unpublished.	Y	CAG
Kühner C.	IIA, 8.3.2.1/02	1997b	EXP 10343A: acute toxicity to the aphid parasitoid, <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) in the laboratory; GAB/IFU, report # 97123/02-NLAp, GLP, Unpublished.	Y	CAG
Maggi V.L.	IIA, 8.6/01	1993a	Tier I : determination of the phytotoxic effects of dodine fungicide on vegetative vigor of non target plants; California Agricultural Research/ USA, Report # CAR 182-92, GLP, Unpublished	Y	CAG
Maggi V.L.	IIA, 8.6/02	1993b	Tier I : determination of the phytotoxic effects of dodine fungicide on seedling emergence of non target plants; California Agricultural Research/ USA, Report # CAR 183-92, GLP, Unpublished	Y	CAG
Maggi V.L.	IIA, 8.6/03	1993c	Tier I : determination of the phytotoxic effects of dodine fungicide on seed germination of non target plants; California Agricultural Research/ USA, Report # CAR 184-92, GLP, Unpublished	Y	CAG
Migchielsen M.H.J.	IIA, 8.2.4/05	2002	Acute toxicity study in <i>Daphnia magna</i> with Dodine in a water-sediment system (Static) Notox. NL: report # 354825 GLP, Unpublished	Y	CAG
Pedersen C.A.	IIA, 8.1.3/02	1994a	Dodecylguanidine acetate (dodine) technical grade : toxicity and reproduction study in bobwhite quail; Bio-Life Associates, report # BLAL Nr 119-008-07, GLP, Unpublished	Y	CAG
Pedersen C.A.	IIA, 8.1.3/05	1994b	Dodecylguanidine acetate (dodine) technical grade: toxicity and reproduction study in mallard ducks. Bio-Life Associates, report # BLAL Nr 119-009-08, GLP, Unpublished	Y	CAG
Pedersen C.A.	IIA, 8.1.3/03	1999	Avian reproductive toxicity study with Dodecylguanidine acetate (dodine) technical in bobwhite quail Bio-Life Associates, report # BLAL Nr 108-029-07. GLP, Unpublished.	Y	CAG

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Section A.9 Ecotoxicology (Annex IIA 8; Annex IIIA 10)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Pedersen C.A., Mumper J.A.	IIA, 8.1.3/01	1993a	Dodecylguanidine acetate (Dodine) technical grade : six-week dietary toxicity and reproduction pilot study in bobwhite quail Bio-Life Associates, report # BLAL Nr 119-006-05, GLP Unpublished	Y	CAG
Pedersen C. A., Mumper J. A.	IIA, 8.1.3/04	1993b	Dodecylguanidine acetate (Dodine) technical grade: six-week dietary toxicity and reproduction pilot study in mallard ducks. Bio-Life Associates, report # BLAL Nr 119-007-06, GLP Unpublished	Y	CAG
Putt A.E.	IIA, 8.2.4/01	1992	Dodine technical: acute toxicity to daphnids (<i>Daphnia magna</i>) under flow-through conditions. Springborn Laboratories SLI report # 92-4-4245, GLP Unpublished.	Y	CAG
Putt A.E.	IIA, 8.2.5/01	1995	Dodine technical: the chronic toxicity to <i>Daphnia magna</i> under flow-through conditions. Springborn Laboratories, SLI report # 95-10-6162, GLP Unpublished.	Y	CAG
Servaje E.	IIA, 8.4.1/01	2004	Determination of contact and oral acute toxicity of dodine to honey bees (<i>Apis mellifera</i>) Phytosafe, report # 04-99-037-ES, GLP Unpublished.	Y	CAG
Sousa J.V.	IIA, 8.2.2.2/01	1995	Dodine technical: the toxicity to fathead minnow (<i>Pimephales promelas</i>) during an early life stage exposure. Springborn Laboratories SLI report # 95-10-6126, GLP Unpublished.	Y	CAG
Suteau, P.	IIA, 8.3.1.1/02	1995	Dodine: Acute toxicity (14 day) to earthworms (<i>Eisenia foetida</i>). Artificial soil method; Rhone-Poulenc Agrochimie report # SA 95248, GLP Unpublished.	Y	CAG

Annex III A

Corman, C.	IIIA, 10.1.0/02	2006	Update risk assessment for long term exposure of birds to dodine Not applicable Unpublished	Y	CAG
Hirth, N.	IIIA, 10.1.0/01	2005	A study to evaluate residues of dodine 400 SC in <i>Tenebrio molitor</i> L. as feed source for wild birds and mammals following an application GAB Biotechnologie GmbH, Germany; report 20051278/01-NHTm GLP Unpublished	Y	CAG

Annex A

List of data and information submitted

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Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
Klein, C., Schmitz, A. Hofer, M.	IIIA, 10.3/01	2006	91/414/EEC Review of dodine: refinement of the long-term mammalian risk assessment. SCC Scientific Consulting Company, Germany; project n° 169-003-02 Unpublished	Y	CAG
Migchielsen M.	IIIA, 10.2.1/01	2004	Acute toxicity study in daphnia magna with Dodine 400 SC (Semi-static). Notox/NL; report # 413213 GLP, Unpublished,	Y	CAG
Migchielsen M.	IIIA, 10.2.1/02	2004	Fresh water algal growth inhibition test with Dodine 400 SC. Notox/NL; report # 413224, GLP Unpublished	Y	CAG
Servajen E.	IIIA, 10.4.1/01	2004	Determination of contact and oral acute toxicity of Syllit 400 SC to honey bees (<i>Apis mellifera</i>). Phytosafe / France; report # 04-99-038-ES. GLP Unpublished	Y	CAG

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