



# **Draft Assessment Report (DAR)**

**- public version -**

**Initial risk assessment provided by the rapporteur Member State  
Austria for the existing active substance**

**FLUAZINAM**

**of the third stage (part A) of the review programme  
referred to in Article 8(2) of Council Directive 91/414/EEC**

**Volume 2, Annex A**

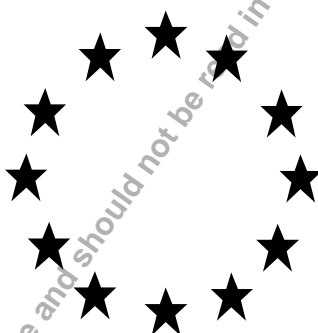
**July 2006**

**Federal Office for Food Safety**

**Spargelfeldstraße 191  
1226 Vienna  
Austria**

**Monograph prepared in the context of inclusion of following active substance in Annex I of the  
Council Directive 91/414/EEC**

# **Fluazinam**



**Volume 2**

**Annex A**

**List of Tests and Studies**

**Draft: December 2005**

## Fluazinam - Annex A: List of tests and studies

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**A List of the test and studies submitted and of information available** (Annex IIA and Annex IIIA), Dossier Documents J, I, K-II, L-II, K-III and L-III and other information available to or brought to the attention of the Rapporteur Member State

**A.1 Identity (Annex IIA 1, Annex IIIA 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-R/NR	Owner
<b>Annex II Data and Information</b>					
Anonymous	All, 1.8/04	2005a	Statement on the technical specifications for fluazinam ISK Biosciences SA, report no. IBE-1216-CI0905-02, September 28, 2005 Not GLP, unpublished	Y	ISK
Anonymous	All, 1.10/02	2005b	Identification of AI and impurities Report N° ISK Biosciences SA, report no. IBE-1216-CI0506-01, June 21, 2005 Not GLP, unpublished	Y	ISK
Anonymous	IIA, 1.11/04	2005c	Overview of batches used in toxicological studies ISK Biosciences SA, report no. IBE-1216-CI0506-03, August 22, 2005 Not GLP, unpublished	Y	ISK
Bramstedt, W. R., Kogovsek, L. M	All, 1.9/01	1999	Characterization of B-1457 (IKF-1216 Impurity, Lot 9604). Ricerca, Inc., Report No. 4039-98-0177-AS-001 GLP, unpublished	Y	ISK
Lorence, P. J.	All, 1.11/01	1999	Fluazinam (IKF-1216) — Five-Batch Analysis. Ricerca, Inc., unpublished, Report No. 4039-98-0204-AS-001 GLP, unpublished	Y	ISK
Nomura, N., Fujii Y.	IIA, 1.10/01	2005	Statement of non-relevancy of Impurity-5 in Technical Fluazinam Safety Science Research Laboratory, report no. FR-2538, July 12, 2005 Not GLP, unpublished	Y	ISK
Okabayashi, T.	IIA, 1.9/03	2004	Certificate of composition of Fluazinam Ishihara Sangyo Kaisha Ltd, report no. F-1332, December 10, 2004 Not GLP, unpublished	Y	ISK
Okabayashi, T.	IIA, 1.8/02	2005a	Statement of the intermediates in manufacturing process of fluazinam technical Ishihara Sangyo Kaisha Ltd, no report	Y	ISK

Annex A: List of tests and studies

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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-R/NR	Owner
			number, September 28, 2005 Not GLP, unpublished		
Okabayashi, T.	IIA, 1.8/03	2005b	Statement of manufacturing process of fluazinam technical Ishihara Sangyo Kaisha Ltd, no report number, September 28, 2005 Not GLP, unpublished	Y	ISK
Shimura, T.	All, 1.4/01	1998a	Product Identity and Composition Technical Fluazinam (IKF-1216). Ishihara Sangyo Kaisha, Ltd., Report No. 1216-98-06101-3 Non GLP, unpublished	N	ISK
Shimura, T.	IIA, 1.8/01	1998b	Description of Beginning Materials and Manufacturing Process Technical Fluazinam (IKF-1216). Ishihara Sangyo Kaisha, Ltd., Report No. 216-98-06102-3 Non GLP, unpublished	N	ISK
Shimura, T.	All, 1.9/02	1998c	Certified Limits Technical Fluazinam (IKF-1216). Ishihara Sangyo Kaisha, Ltd., Report No. 1216-98-06202-1 Non GLP, unpublished	N	ISK
Shimura, T.	IIA, 1.8/05	2005	Description of [REDACTED] Ishihara Sangyo Kaisha Ltd, report no. FR-1335, September 27, 2005 Not GLP, unpublished	Y	ISK
Stienon, S.	All, 1.2 All, 1.8 All, 1.9 All, 1.10	2005	Reply to data gaps identified by RMS ISK Biosciences SA, report no. IBE-1216-CI1005-01, October 07, 2005 Not GLP, unpublished	Y	ISK
Weber, H.A.	All, 1.11/02	2003	IKF-1216 Technical, Five Batch Analysis. Midwest Research Institute, unpublished, Report No. 310260.1.019 GLP, unpublished	Y	ISK
Weber, H.A.	IIA, 1.11/03	2004	Fluazinam Technical, Analysis of Five Batches (Sample group B) Midwest Research Institute, report no. 310260.1027, February 16, 2004 GLP, unpublished	Y	ISK
<b>Annex III Data and Information</b>					
Anonymous	AIll, 1.4.1/04	2005	Fluazinam 500 SC content ISK Biosciences Europe, Report No. IBE1216-CI0506-02, 21 June 2005 Not GLP, unpublished	Y	ISK

Annex A: List of tests and studies

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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-R/NR	Owner
DeWitt, R.C.	AIII, 1.4.1/02	1995	Characterization of Fluazinam 500SC. Ricerca, Inc. Report No. 4214-95-0082-AS-001 GLP, unpublished	N	ISK
DeWitt, R.C.	AIII, 1.4.1/03	1996	Characterization of Fluazinam 500SC Lot 9831). Ricerca, Inc. Report No. 4039-96-0047-AS-001 GLP, unpublished	N	ISK
Flechel, B.	AIII, 1.4.1/01	1991	Fluazinam Formulation [500SC]. ICI Agrochemicals, Report No. RIC1543 Non GLP, unpublished	N	ISK
Stienon, S.	AIII, 1.2	2005b	Reply to data gaps identified by RMS ISK Biosciences Europe S.A., Document no. IBE-1216-CI1005 Not GLP, unpublished	Y	ISK
Stienon, S.	AIII, 1.4.1/05	2005	Fluazinam 500 SC Composition of the Formulations used for Testing/Studies ISK Biosciences SA, report no. IBE-1216-CI0905-03, August 2005 Not GLP, unpublished	Y	ISK

**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-R/NR	Owner
<b>Annex II Data and Information</b>					
Angly H.	IIA, 2.13/02	2005	Determination of the explosive properties of Fluazinam TGAI (IKF-1216) Institute of Safety and Security, report no. 2005.4004.EXP, May 3, 2005 GLP, unpublished	Y	ISK
Asai, N.	All, 2.4.1/04	1991	IKF-1216 (Pure Grade) - Determination of Physical State. Ishihara Sangyo Kaisha, Ltd., Report No. 1216-90-06303-1 Not GLP, unpublished	N	ISK
Asai, N.	All, 2.4.2/02	1991	IKF-1216 (Pure Grade) - Determination of Odor. Ishihara Sangyo Kaisha, Ltd., Report No. 1216-90-06304-1 Not GLP, unpublished	N	ISK
Atkinson, R.	All, 2.10/01	1993	Estimation of Hydroxyl Radical Reaction Rate Constants: Fluazinam. Ricerca Inc., Report No. RIC 1832 Not GLP, unpublished	N	ISK
Brekelmans, M.J.C.	All, 2.6/01	2002	IKF-1216 PAI, Determination of the Water Solubility at 3 pH Values. Notox B.V., Report No. 341189 GLP, unpublished	Y	ISK
De Smet B.	IIA, 2.8/02	2005	Determination of the partitioning coefficient (n-Octanol/water) of IKF-1216 at pH 4-10 ISK Biosciences Europe S.A., report no. IBE1216-PC0507-02, July 12, 2005 Not GLP, unpublished	Y	ISK
Flude, P., Evans, J.D.H.L., Cavell, B.D.	IIA, 2.9.1/01	1985	B 1216: Hydrolysis at pH5, pH7 and pH9 at 22 °C. Zeneca, Report No. RJ0383B Not GLP, unpublished	N	ISK
Gallacher, A.C.	All, 2.5.1/01	1997	IKF-1216 - UV-VIS Absorption. Ricerca, Inc., Report No. 4039-97-0017-AS-001 GLP, unpublished	N	ISK
Gallacher, A.C.	All, 2.9.4/01	1992	Fluazinam (IKF-1216) (ASC-66825) - Dissociation Constant. Ricerca, Inc., Report No. 4039-91-0387-AS-001 GLP, unpublished	N	ISK

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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-R/NR	Owner
Kimura, T.	All, 2.4.1/01	1991	IKF-1216 (Pure Grade) - Determination of Physical State. Ishihara Sangyo Kaisha, Ltd., Report No. 91 0508KT Not GLP, unpublished	N	ISK
Kimura, T.	All, 2.4.1/02	1991	IKF-1216 (Pure Grade) - Determination of Color. Ishihara Sangyo Kaisha, Ltd., Report No. 91 0509KT Not GLP, unpublished	N	ISK
Kimura, T.	All, 2.4.2/01	1991	IKF-1216 (Pure Grade) - Determination of Odor. Ishihara Sangyo Kaisha, Ltd., Report No. 91 0510KT Not GLP, unpublished	N	ISK
Lentz, N.R., Korsch, B.H.	All, 2.9.2/01	1995	A Photolysis Study of IKF-1216 (Fluazinam) in Water at pH 5. Ricerca, Inc., Report No. 5312-94-0119-EF-002 GLP, unpublished	N	ISK
McFadden, J.J.	All, 2.3.2/01	2000	Henry's Law Constant for Fluazinam. Ricerca, Inc., Report No. F-150-A Not GLP, unpublished	N	ISK
Oguri, M.	All, 2.4.1/03	1991	IKF-1216 (Pure Grade) - Determination of Color. Ishihara Sangyo Kaisha, Ltd., Report No. 1216-90-06302-1 Not GLP, unpublished	N	ISK
Sanders, J.M.	All, 2.7/01	1993	Fluazinam (IKF-1216) (ASC-66825) – Solubility. Ricerca, Inc., Report No. 4039-91-0384-AS-001 GLP, unpublished	N	ISK
Sanders, J.M.	All, 2.8/01	1992	Fluazinam (IKF-1216) (ASC-66825) - Octanol/Water Partition Coefficient. Ricerca, Inc., Report No. 4039-91-0386-AS-001 GLP, unpublished	N	ISK
Sawaki, M., Haga, T.	All, 2.9.4/02	1991	Report of Measurement: Dissociation Constant of Fluazinam & HYP A. Ishihara Sangyo Kaisha, Ltd., Report No. RIC0372 Not GLP, unpublished	N	ISK
van der Baan-Treur J.	IIA, 2.15/02	2005	Statement on the oxidizing properties of Fluazinam Notox, report no. 435072, June 15, 2005 Non-GLP, unpublished	Y	ISK



Annex A: List of tests and studies

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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-R/NR	Owner
van der Gaauw, A.	IIA, 2.9.1/02	2003	14C-Fluazinam: Hydrolysis at Three Different pH Values. RCC Ltd, Report No. 846211 GLP, unpublished	Y	ISK
van Helvoirt, J.A.M.W.	All, 2.1.1/01	1993	Determination of the Melting Point/Melting Range of IKF-1216 (PAI). RCC NOTOX, Report No. 089033 GLP, unpublished	N	ISK
van Helvoirt, J.A.M.W.	All, 2.1.2/01	1993	On the Determination of the Boiling Point/Boiling Range of IKF-1216 (PAI). RCC NOTOX, Statement No. 089044 Not GLP, unpublished	N	ISK
van Rijsbergen, L.M.	All, 2.2/01	2002	Determination of the Density of IKF-1216 PAI. Notox B.V., Report No. 341123 GLP, unpublished	Y	ISK
van Rijsbergen, L.M.	All, 2.3.1/02	2002	Determination of the Vapor Pressure of IKF- 1216 PAI. Notox B.V., Report No. 341123 GLP, unpublished	Y	ISK
van Rijsbergen, L.M.	All, 2.5.1/02	2002	Determination of the UV-VIS Absorption Spectra of IKF-1216 PAI. Notox B.V., Report No. 341167 GLP, unpublished	Y	ISK
van Rijsbergen, L.M.	All, 2.5.1/03	2002	Determination of the 1H NMR Spectrum of IKF-1216 PAI. Notox B.V., Report No. 341156 GLP, unpublished	Y	ISK
van Rijsbergen, L.M.	All, 2.5.1/04	2002	Determination of the Mass Spectrum of IKF- 1216 PAI. Notox B.V., Report No. 341178 GLP, unpublished	Y	ISK
van Rijsbergen, L.M.	All, 2.5.1/05	2002	Determination of the IR Absorption Spectrum of IKF-1216 PAI. Notox B.V., Report No. 341145 GLP, unpublished	Y	ISK
van Rijsbergen, L.M.	All, 2.11.1/01	2002	Determination of the Flammability of IKF- 1216 TGAI. Notox B.V., Report No. 341191 GLP, unpublished	Y	ISK
van Rijsbergen, L.M.	All, 2.11.2/01	2002	Determination of the Relative Self-Ignition Temperature of IKF-1216 TGAI. Notox B.V., Report No. 341202 GLP, unpublished	Y	ISK

Annex A: List of tests and studies

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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-R/NR	Owner
van Rijsbergen, L.M.	All,2.14/01	2002	Determination of the Surface Tension of an Aqueous Solution of IKF-1216 TGAI. Notox B.V., Report No. 341213 GLP, unpublished	Y	ISK
Wadley, A.M..	All, 2.9.3/01	1992	Fluazinam: Quantum Yield Calculation. Zeneca Report No. F4.1/3 Not GLP, unpublished	N	ISK
Wojcieck, B.C.	All, 2.1.1/02	1993	Fluazinam (IKF-1216)- Color, Physical State, Odor, Melting Point, Bulk Density, Oxidation- Reduction, Impact Explodability. Ricerca, Inc., Report No. 4039-92-0500-AS-001 GLP, unpublished	N	ISK
Wojcieck, B.C.	All, 2.4.1/05	1993	Fluazinam (IKF-1216)- Color, Physical State, Odor, Melting Point, Bulk Density, Oxidation- Reduction, Impact Explodability. Ricerca, Inc., Report No. 4039-92-0500-AS-001 GLP, unpublished	N	ISK
Wojcieck, B.C.	All, 2.4.2/03	1993	Fluazinam (IKF-1216)- Color, Physical State, Odor, Melting Point, Bulk Density, Oxidation- Reduction, Impact Explodability. Ricerca, Inc., Report No. 4039-92-0500-AS-001 GLP, unpublished	N	ISK
Wojcieck, B.C.	All, 2.13/01	1993	Fluazinam (IKF-1216)- Color, Physical State, Odor, Melting Point, Bulk Density, Oxidation- Reduction, Impact Explodability. Ricerca, Inc., Report No. 4039-92-0500-AS-001 GLP, unpublished	N	ISK
Wojcieck, B.C.	All, 2.15/01	1993	Fluazinam (IKF-1216)- Color, Physical State, Odor, Melting Point, Bulk Density, Oxidation- Reduction, Impact Explodability. Ricerca, Inc., Report No. 4039-92-0500-AS-001 GLP, unpublished	N	ISK
Yoder, S.J.	IIA, 2.3.1/01	1992	Fluazinam (IKF-1216) (ASC-66825) - Vapor Pressure. Ricerca, Inc. Report No. 4039-91-0385-AS- 001. GLP, unpublished	N	ISK
<b>Annex III Data and Information</b>					
Bird, N.R.	AIll, 2.4.2/01	1993	Fluazinam: Determination of the Accelerated Storage Stability and Physico-Chemical Characteristics of a 500 g/L Suspension Concentrate Formulation. ICI Agrochemicals, Report No. RY0013B GLP, unpublished	N	ISK

Annex A: List of tests and studies

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Bird, N.R.	AIII, 2.6.1/01 = AIII, 2.4.2/01	1993	Fluazinam: Determination of the Accelerated Storage Stability and Physico-Chemical Characteristics of a 500 g/L Suspension Concentrate Formulation. ICI Agrochemicals, Report No. RY0013B GLP, unpublished	N	ISK
Bird, N.R.	AIII, 2.7.1/02 = AIII, 2.4.2/01	1993	Fluazinam: Determination of the Accelerated Storage Stability and Physico-Chemical Characteristics of a 500 g/L Suspension Concentrate Formulation. ICI Agrochemicals, Report No. RY0013B GLP, unpublished	N	ISK
Bird, N.R.	AIII, 2.8.8.2/01 = AIII, 2.4.2/01	1993	Fluazinam: Determination of the Accelerated Storage Stability and Physico-Chemical Characteristics of a 500 g/L Suspension Concentrate Formulation. Ishihara Sangyo Kaisha, Ltd., Report No. RY0013B GLP, unpublished	N	ISK
Bird, N.R., Swaine, H.	AIII, 2.7.1/01	1993	Fluazinam: Determination of the Accelerated Storage Stability and Physico-Chemical Characteristics of a 500 g/L Suspension Concentrate Formulation. ICI Agrochemicals, Report No. RY0003B GLP, unpublished	N	ISK
Bird, N.R., Swaine, H.	AIII, 2.7.3/01	1995	Fluazinam: Determination of the Long-Term Storage Stability of a 500 g/L Suspension Concentrate Formulation in Sales Packs. ICI Agrochemicals, Report No. RY0072B GLP, unpublished	N	ISK
De Smet B.	IIIA, 2.2.2/01	2005	Expert statement on the oxidizing properties of IKF-1216 500 SC under consideration of the formulants ISK Biosciences Europe SA, report no. IBE1216-PC0507-01, July 07, 2005 Not GLP, unpublished	Y	ISK
Fletcher, N.	AIII, 2.9.1/01	1992	Shirlan 50SC (Fluazinam 500SC): Compatibility Testing. Evaluation of the Physical Compatibility of Tank Mixture ICI Agrochemicals, Report No. RIC 1778 GLP, unpublished	N	ISK
Fragu, E.	AIII, 4.1.2/01	2002	Mechanical Tests on a Type of Packaging Bureau de Vérifications Techniques, Report No. 5409 Not GLP, unpublished	Y	ISK

Annex A: List of tests and studies

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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-R/NR	Owner
Fragu, E.	AIII, 4.1.2/02	2002	Mechanical Tests on a Type of Packaging Bureau de Vérifications Techniques, Report No. 5401 Not GLP, unpublished	Y	ISK
Schiffers, B.	AIII, 2.7.2/01	2002	IKF-1216 500SC: Storage Stability at Low Temperature. Chimie analytique et Phytopharmacie, Cellule-Formulation, Faculte Universitaire des Sciences Agronomiques, Report No. 7- FLUAZINA 02/01 GLP, unpublished	Y	ISK
Stanley, R.D., Johnson, P.S.	AIII, 2.4.2/02	1992	Fluazinam: Physico-Chemical Properties of a 500 g/L Suspension Concentrate. Imperial Chemical Industries PLC, Group Environmental Laboratory, Report No. BL4535/B GLP, unpublished	N	ISK
Stanley, R.D., Johnson, P.S.	AIII, 2.5.2/01 = AIII, 2.4.2/02	1992	Fluazinam: Physico-Chemical Properties of a 500 g/L Suspension Concentrate. Imperial Chemical Industries PLC, Group Environmental Laboratory, Report No. BL4535/B GLP, unpublished	N	ISK
Stanley, R.D., Johnson, P.S.	AIII, 2.6.1/02 = AIII, 2.4.2/02	1992	Fluazinam: Physico-Chemical Properties of a 500 g/L Suspension Concentrate. Imperial Chemical Industries PLC, Group Environmental Laboratory, Report No. BL4535/B GLP, unpublished	N	ISK
Stanley, R.D., Johnson, P.S.	AIII, 2.7.1/03 = AIII, 2.4.2/02	1992	Fluazinam: Physico-Chemical Properties of a 500 g/L Suspension Concentrate. Imperial Chemical Industries PLC, Group Environmental Laboratory, Report No. BL4535/B GLP, unpublished	N	ISK
van Rijsbergen, L. M.	AIII, 2.1/01	2002	Determination of the Appearance of IKF- 1216 500SC. NOTOX, Report No. 341224 GLP, unpublished	Y	ISK
van Rijsbergen, L. M.	AIII, 2.3/01	2002	Determination of the Auto-Ignition Temperature (Liquids) of IKF-1216 500SC. NOTOX, Report No.341235 GLP, unpublished	Y	ISK
van Rijsbergen, L. M.	AIII, 2.5.3/01	2002	Determination of the Surface Tension of an Aqueous Solution of IKF-1216 500SC. NOTOX, Report No. 341246 GLP, unpublished	Y	ISK

Annex A: List of tests and studies

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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-R/NR	Owner
van Rijsbergen, L. M.	AIII, 2.8.3/01	2002	Spontaneity of Dispersion of IKF-1216 500SC in Aqueous Suspension. NOTOX, Report No. 341257 GLP, unpublished	Y	ISK
Versmissen C.	IIIA, 2.9.2/01	2005	Compatibility assurance statement on products that could be tank mixed with Fluazinam 500 SC ISK Biosciences Europe SA, report no. IBE1216-PC0705-01, July, 2005 Not GLP, unpublished	Y	ISK
Widmer H.	IIIA, 2.2.1/01	2005	Expert statement on the explosive properties of Fluazinam 500 SC (IBE 3876) RCC Ltd, report no. A22904, July 14, 2005 Not GLP, unpublished	Y	ISK

Annex A: List of tests and studies

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**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-R/NR	Owner
<b>Annex II Data and Information</b>					
BIG	AII, 3.7	2003	Safety data sheet Fluazinam tech Brandweerinformatiecentrum voor Gevaarlijke Stoffen vzw (BIG)	N	ISK
<b>Annex III Data and Information</b>					
Fragu, E.	AIII, 4.1.2/01	2002	Mechanical Tests on a Type of Packaging Bureau de Vérifications Techniques, Report No. 5409 Not GLP, unpublished	Y	ISK
Fragu, E.	AIII, 4.1.2/02	2002	Mechanical Tests on a Type of Packaging Bureau de Vérifications Techniques, Report No. 5401 Not GLP, unpublished	Y	ISK

WARNING: This document forms part of an EC evaluation data package and should not be used as the basis for registration. Registration must not be granted on the basis of this document.

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

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<b>Annex II Data and Information</b>					
Cummins H. A.	IIA, 5.2.6	1984	Delayed contact hypersensitivity study in guinea-pigs [REDACTED] Report No.: 84/ISK054/686 GLP: yes Unpublished	Y	ISK
Pritchard V.	IIA, 5.2.6	1986	Skin sensitisation to the guinea-pig of both the purified and technical material [REDACTED] UK Report No.: CTL/P/1493 GLP: yes Unpublished	Y	ISK
Shults S. K.	IIA, 5.2.5	1992	Primary eye irritation study in albino rabbits with IKF-1216 [REDACTED] Report No.: 5016-91-0280-TX-002 GLP: yes Unpublished	Y	ISK
Tobeta Y.	IIA, 5.2.3	1988	Acute inhalation toxicity test of fluazinam in rats [REDACTED] Report No.: D-1775E GLP: yes Unpublished	Y	ISK
Willoughby C. R.	IIA, 5.6.2	1985	B-1216: Teratology study in the rat [REDACTED] Report No.: 84/ISK047/606; Amended Final Report No.: 91/ISK047/0820 GLP: yes Unpublished	Y	ISK
<b>Annex III Data and Information</b>					
Lees D., Robinson P.	IIIA 7.1.6	1991	ICIAO192: Skin sensitisation t the guinea pig of a 500 g/l SC formulation [REDACTED] Report No.: CTL/P/3227 GLP: yes Unpublished	Y	ISK

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<b>Author(s)</b>	<b>Annex point/ reference number</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not</b>	<b>Data Protection Claimed  Y/N-R/NR</b>	<b>Owner</b>
Smith K. D.	IIIA 7.1.6	1990	IKF-1216 50 % SC: Dermal sensitisation study in guinea pigs Life Science Research Ltd. Report No.: 90/ISK159/1205; GLP: yes Unpublished	Y	ISK
Willoughby C. R.	IIA, 5.6.2	1985	B-1216: Teratology study in the rat Life Science Research Ltd. Report No.: 84/ISK047/606; Amended Final Report No.: 91/ISK047/0820 GLP: yes Unpublished	Y	ISK



**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-R/NR	Owner
<b>Annex II Data and Information</b>					
Beale, M. J.	All, 4.2.4/02	1994	Yalding Environmental Method for the Determination of Fluazinam in Air. Zeneca Agrochemicals, Report No. YEM/006/01 GLP, unpublished	N	ISK
Brachet, A., Nésa, C.	All, 4.2.1/05	2002	Independent Laboratory Validation (ILV) of the Analytical method RCC-845972 for the Determination of Residues of Fluazinam (IKF-1216) in Potato Battelle, Report No. A22-02-04 GLP, unpublished	Y	ISK
Burke, S., Sapiets, A., Gentle, W.	All, 4.2.2/02	1993	The Determination of the Fluazinam Metabolite "HYPA" in Soil, A High Performance Liquid Chromatography Method. ICI Agrochemicals, SOP No. RAM/218/01 GLP, unpublished	N	ISK
Kenyon, R. G.	All, 4.2.5/01	1994	Analytical Procedure for the Determination of Fluazinam Residues in Cow Muscle and Liver. Ricerca, Inc., Report No. 6068-94-0088-MD-001 GLP, unpublished	N	ISK
Rhoads, W. D.	All, 4.2.1/01	1995	PAM I Multiresidue Testing for Fluazinam. Colorado Analytical Research & Development Corporation, Report No. Ricerca No. 6582-95-0190-EF GLP, unpublished	N	ISK
Ryan J., Sapiets, A.	All, 4.2.1/02	1991	The Determination of Residues of Fluazinam in Crops, a gas-liquid chromatography method. ICI Agrochemicals, Report No. ARAM 87/1. Not GLP, unpublished	N	ISK
Ryan, J., Sapiets, A.	All, 4.2.2/01	1992	The Determination of Residues of Fluazinam in Soil (A gas liquid chromatography method). ICI Agrochemicals, Report No. ARAM 211 GLP, unpublished	N	ISK
Ryan, J., Sapiets, A.	All, 4.2.3/01	1994	Fluazinam: Validation of a Method for the Determination of Residues in Water. Zeneca Agrochemicals, Report No. RJ 1576B GLP, unpublished	N	ISK

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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-R/NR	Owner
Ryan, J., Sapiets, A.	All, 4.2.3/02	1992	The Determination of Residues of Fluazinam in Water. ICI Agrochemicals, Report No. ARAM 210 GLP, unpublished	N	ISK
Ryan, J., Sapiets, A.	All, 4.2.4/01	1993	Fluazinam: Validation of a Stepped Model to Determine Residues in Air. Zeneca Agrochemicals, Report No. RF1529B GLP, unpublished	N	ISK
Sapiets, A.	All, 4.2.2/03	2005	Statement on the analytical methods for soil Syngenta, no report number, Non-GLP, unpublished	Y	ISK
Schulz H.	All, 4.2.1/03	1992	Determination of the Residues of IKF-1216 (Fluazinam) and Its Metabolites in Grapes, Wine and Potatoes; Amendments 7, 8, 9 and 10. RCC Umweltchemie AG, Report No. 284670 GLP, unpublished	N	ISK
Shults, S. K., Brock, A. W., Laveglia, J.	All, 4.2.3/04 (All, 8.2.2.3/01)	1995	Technical Fluazinam (IKF-1216)- The Chronic Toxicity to the Fathead Minnow ( <i>Pimephales promelas</i> ) During a Full Life-Cycle Exposure. Report No. 5107-92- 0035-TX-002 GLP, unpublished	N	ISK
Specht, W.	All, 4.2.1/07	1992	Überprüfung der Anwendbarkeit der DFG- multimethode S 19 für die Rückstands- bestimmung von fluazinam in Kartoffeln Dr. Specht and Partner Chemische Laboratorien Report No. 92856/92 GLP, unpublished	N	ISK
Tillkes, M.	All, 4.2.5/02	1995	Validation of DFG Method S 19 (Modified Extraction) for the Determination of Residues of Fluazinam in Milk, Muscle, Kidney, Liver and Egg. Dr. Specht & Partner, Chemische Laboratorien GMBH, Report No. ZEN-9504V GLP, unpublished	N	ISK
Wais, A.	All, 4.2.1/04	2002	Validation of the Residue Analytical Method for Fluazinam in Potato (RAC Tubers), Grapes and Wine RCC Ltd., Report No. 845972 GLP, unpublished	Y	ISK
Wais, A.	All, 4.2.1/06	2005	1st Amendment to compilation report Validation of the Residue Analytical Method for Fluazinam in Potato (RAC Tubers), Grapes and Wine RCC Ltd., Report No. 845972 GLP, unpublished	Y	ISK

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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-R/NR	Owner
Wais, A.	All, 4.2.3/03	2001	Validation of A Residue Analytical Method for Fluazinam (IKF-1216) in Surface Water. RCC Ltd, unpublished, Report No. 823803 GLP, unpublished	Y	ISK
<b>Annex III Data and Information</b>					
Krainz, A.	AIII, 5.1.1/01	2001	Validation of an Analytical Method for the Determination of Fluazinam (Active Ingredient) in IKF-1216 500SC. RCC Umweltchemie AG, Report No. 838923 GLP, unpublished	Y	ISK
Flade, D.	AIII, 5.1.2/01	2003	Validation Of An Analytical Method For The Determination Of B-1457 In Fluazinam 500SC RCC Ltd, Itingen, Switzerland. Report No. 848595 unpublished	Y	ISK
Tandy, M. J.	AIII, 5.1.3/01	1996	The Determination of Fluazinam in Technical and Formulated Materials by High Performance Liquid Chromatograph. Zeneca Agrochemicals, Jealott's Hill Research Station, Report No. PAM 600 Not GLP, unpublished	N	ISK

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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-R/NR	Owner
<b>Annex II Data and Information</b>					
Amyes S. J.	IIA, 5.3.2	1983	Four-week toxicity study in mice [REDACTED] Report No.: 83/ISK036/067 GLP: LSR Quality Assurance Unit Unpublished	Y	ISK
Andre J. C.	IIA, 5.1.1	1994	Study to measure the pharmacokinetics of phenyl- <sup>14</sup> C-IKF-1216 in the blood of rats [REDACTED] Report No.: 5319-92-0262-AM-001 GLP: yes Unpublished	Y	ISK
Andre J. C.	IIA, 5.1.1	1994	Study to evaluate the distribution and excretion of (phenyl- <sup>14</sup> C)-IKF-1216 ( <sup>14</sup> C (B)- IKF-1216) in rats [REDACTED] Report No.: 5304-92-0185-AM-001 GLP: yes Unpublished	Y	ISK
Andre J. C.	IIA, 5.1.1	1994	Study to evaluate the distribution and excretion of (phenyl- <sup>14</sup> C)-IKF-1216 in rats following repeated dosing [REDACTED] Report No.: 5317-93-0021-AM-001 GLP: yes Unpublished	Y	ISK
Broadmeadow A.	IIA, 5.3.1	1983	Four-week toxicity study in dietary administration to CD rats [REDACTED] Report No.: 82/ISK035/544 GLP: LSR Quality Assurance Unit Unpublished	Y	ISK
Broadmeadow A.	IIA, 5.3.1	1985	B-1216: 13-week liver toxicity and 4- week reversibility study in dietary administration to CD rats [REDACTED] Report No.: 84/ISK045/581 GLP: yes Unpublished	Y	ISK

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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-R/NR	Owner
Broadmeadow A.	IIA, 5.3.1	1985	B-1216: 13-week toxicity study in dietary administration to CD rats [REDACTED] Report No.: 84/ISK046/635; Amended Final Report No.: 91/ISK046/0830; Addendum 3 GLP: yes Unpublished	Y	ISK
Broadmeadow A.	IIA, 5.3.3	1984	Four-week preliminary toxicity study in oral administration to beagle dogs [REDACTED] Report No.: 84/ISK038/140; 85/ISK038/050 (Addendum I); 85/ISK038/248 (Addendum II) GLP: LSR Quality Assurance Unit Unpublished	Y	ISK
Broadmeadow A.	IIA, 5.3.3	1985	13-week toxicity study in oral administration to beagle dogs [REDACTED] Report No.: 84/ISK048/692; Amended Final Report No.: 91/ISK048/0832; Addendum 3 GLP: yes Unpublished	Y	ISK
Broadmeadow A.	IIA, 5.3.3	1987	52-week toxicity study in oral administration to beagle dogs [REDACTED] Report No.: 86/ISK055/512; Addendum 1 GLP: yes Unpublished	Y	ISK
Bruynzeel D. et al	IIA, 5.9.2	1994	Contact dermatitis due to a new fungicide used in the tulip bulb industry Contact Dermatitis 1995: 33, 8-11	N	
Chambers P. R.	IIA, 5.3.2	1994	Toxicity to mice by dietary administration for 4 weeks [REDACTED] [REDACTED] Report No.: ISK49/921049, Addendum 1 – 4; GLP: yes Unpublished	Y	ISK
Chambers P. R.	IIA, 5.3.2	1998	Toxicity to mice by dietary administration for 4 weeks [REDACTED] [REDACTED] Report No.: ISK49/921049, Addendum 5 GLP: yes Unpublished	Y	ISK

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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-R/NR	Owner
Chambers P. R.	IIA, 5.5.1	1993	B-1216: Toxicity to rats by dietary administration for two years [REDACTED] Report No.: ISK/43/920649 GLP: yes Unpublished	Y	ISK
Chambers P. R.	IIA, 5.5.2	1998	Potential tumorigenic effects in prolonged dietary administration to mice [REDACTED] Report No.: ISK50/950671 GLP: yes Unpublished	Y	ISK
Cummins H. A.	IIA, 5.2.1	1988	Acute oral toxicity study in the mouse [REDACTED] Report No.: 87/ISK106/860 GLP: yes Unpublished	Y	ISK
Cummins H. A.	IIA, 5.2.1	1988	Acute oral toxicity study in the rat [REDACTED] Report No.: 87/ISK105/859 GLP: yes Unpublished	Y	ISK
Cummins H. A.	IIA, 5.2.2	1984	Acute percutaneous toxicity in the rat [REDACTED] Report No.: 84/ISK051/586 GLP: yes Unpublished	Y	ISK
Cummins H. A.	IIA, 5.2.6	1984	Delayed contact hypersensitivity study in guinea-pigs [REDACTED] Report No.: 84/ISK054/686 GLP: yes Unpublished	Y	ISK
Cummins H. A.	IIA, 5.3.4	1985	21-Day percutaneous toxicity study in CD rats [REDACTED] Report No.: 84/ISK052/690; Amended Final Report No.: 91/ISK052/0824 GLP: yes Unpublished	Y	ISK
Dawe S.	IIA, 5.3.2	1985	B-1216: Preliminary toxicity study in mice by dietary administration for 13 weeks [REDACTED] Report No.: ISK7/85172 GLP: yes Unpublished	Y	ISK

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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-R/NR	Owner
Hughes E. W.	IIA, 5.7	1997	IKF-1216: Neurotoxicity to rats by dietary administration for 13 weeks [REDACTED] Report No.: ISK 251/971800; GLP: yes Unpublished	Y	ISK
Hull R. M.	IIA, 5.3.3	1986	11-week oral toxicity study in dogs to investigate possible changes in retinal function and morphology and the reversibility of such changes [REDACTED] Report No.: CTL/C/1778 GLP: yes Unpublished	Y	ISK
Inouye T.	IIA, 5.8.1	1989	G-450: Micronucleus test in male mice [REDACTED] Report No.: IET 89-0015 GLP: yes Unpublished	Y	ISK
Inouye T.	IIA, 5.8.1	1989	G-450: Micronucleus test in female mice [REDACTED] Report No.: IET 89-0016 GLP: yes Unpublished	Y	ISK
Kajiwara Y.	IIA, 5.4.1	1988	Chromosomal aberration test of fluazinam technical using cultured mammalian cells Hita Research Laboratories, Chemical Biotesting Center Chemicals Inspection and Testing Institute, Japan Report No.: T-1663E GLP: yes Unpublished	Y	ISK
Kitching J.	IIA, 5.4.1	2000	IKF-1216 Bacterial mutation assay Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England Report No.: RIA 015/003043 GLP: yes Unpublished	Y	ISK
Liggett M. P.	IIA, 5.2.1	1988	Acute oral toxicity to rats of B-1216 technical [REDACTED] Report No.: 881246D/ISK20/AC GLP: yes Unpublished	Y	ISK

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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-R/NR	Owner
Liggett M. P.	IIA, 5.8.1	1988	Acute oral toxicity to mice of G-450 [REDACTED] Report No.: 881245D/ISK19/AC GLP: yes Unpublished	Y	ISK
Liggett M. P.	IIA, 5.8.1	1988	Acute oral toxicity to mice of G-525 [REDACTED] Report No.: 881248D/ISK19/AC GLP: yes Unpublished	Y	ISK
Liggett M. P.	IIA, 5.8.2	1988	Acute oral toxicity to rats of [REDACTED] [REDACTED] Report No.: 881247D/ISK20/AC GLP: yes Unpublished	Y	ISK
Liu Y.	IIA, 5.1.1	1993	Pilot study to evaluate the excretion of radiolabel following a single oral dose of <sup>14</sup> C-IKF-1216 to rats [REDACTED] Report No.: 5204-92-0034-AM-001 GLP: yes Unpublished	Y	ISK
Maebashi H.	IIA, 5.8.3	1988	Effects on biological function of fluazinam technical MECT Co. Ltd. and Matsumoto Dental College Report No.: FR-2501 GLP: Yes Unpublished	Y	ISK
Marciniszyn J.	IIA, 5.1.1	1995	Study of the biliary excretion of radiolabel following oral administration (phenyl- <sup>14</sup> C)-IKF-1216 to male Sprague-Dawley rats [REDACTED] Report No.: 5318-92-0321-AM-001 GLP: yes Unpublished	Y	ISK
Matsumoto K.	IIA, 5.4.2	1999	IKF-1216 technical: Micronucleus test in mice [REDACTED] Report No.: IET 98-0139 GLP: yes Unpublished	Y	ISK



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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-R/NR	Owner
May K.	IIA, 5.8.1	2002	HYPA: Bacterial reverse mutation test Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England Report No.: ISK 270/024536 GLP: yes Unpublished	Y	ISK
Mayfield R.	IIA, 5.5.1	1988	B-1216: Potential carcinogenicity and chronic toxicity study in dietary administration to rats for 104 weeks [REDACTED] Report No.: ISK8/87263, Report and Addendums 1 - 7 GLP: yes Unpublished	Y	ISK
Mayfield R.	IIA, 5.5.2	1988	B-1216: Potential carcinogenicity study in dietary administration to mice for 104 weeks [REDACTED] Report No.: ISK9/87264 GLP: yes Unpublished	Y	ISK
McClanahan R.	IIA, 5.1.1	1995	Study to identify the metabolites of IKF-1216 (fluazinam) in rats [REDACTED] Report No.: 5306-92-0191-AM-002 GLP: yes Unpublished	Y	ISK
Nakashima N.	IIA, 5.8.2	1998	[REDACTED] (Impurity 5): Comparative study on Susceptibility to Neurotoxicity in mice, rats and dogs [REDACTED] Report No.: IET 98-0020 GLP: yes Unpublished	Y	ISK
Nomura M.	IIA, 5.8.2	1998	[REDACTED] Impurities in Fluazinam technical: Toxicological effect on brain of mice following a single oral administration [REDACTED] Report No.: AN-1375/1411/1486 GLP: no Unpublished	Y	ISK

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Nomura M.	IIA, 5.8.2	1998	Impurity 5, [REDACTED] Toxicological effect on brain and optic nerves of mice following a single oral administration at various stages of animal age [REDACTED] Report No.: AN-1480 GLP: no Unpublished	? Y	ISK
Nomura M.	IIA, 5.8.2	1998	Impurity 5, [REDACTED] Sensitivity comparison on brain of mice and rats following 14 day oral administrations [REDACTED] Report No.: AN-1481 GLP: no Unpublished	? Y	ISK
Nomura M.	IIA, 5.8.2	1998	Impurity 5, [REDACTED] Sensitivity comparison on brain of rats and mice in 3 and 10 weeks old following 14 day oral administrations [REDACTED] Report No.: AN-1492 GLP: no Unpublished	? Y	ISK
Nomura M.	IIA, 5.8.3	1998	Fluazinam technical: Toxicological effect on brain of rats and its reversibility by dietary administration for 14 days followed by a 25 day recovery period [REDACTED] Report No.: AN-1323 GLP: no Unpublished	Y	ISK
Nomura M.	IIA, 5.8.3	1998	Fluazinam technical: Toxicological effect on brain of mice and its reversibility by dietary administration for 4 or 28 days followed by a 56 day recovery period [REDACTED] Report No.: AN-1333 GLP: no Unpublished	Y	ISK
Nomura M.	IIA, 5.8.3	1998	Fluazinam: Overview Document on CNS Toxicological Finding due to an Impurity 5 [REDACTED] [REDACTED] Ishihara Sangyo Kaisha, Ltd., Osaka, Japan	Y	ISK

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Ohtsuka M.	IIA, 5.4.1	1988	Bacterial reverse mutation test of fluazinam technical Hita Research Laboratories, Chemical Biotesting Center Chemicals Inspection and Testing Institute, Japan Report No.:T-1674E GLP: yes Unpublished	Y	ISK
Ohtsuka M.	IIA, 5.4.1	1989	Bacterial reverse mutation test of fluazinam technical Hita Research Laboratories, Chemical Biotesting Center Chemicals Inspection and Testing Institute, Japan Report No.:T-1673E GLP: yes Unpublished	Y	ISK
Ohtsuka M.	IIA, 5.4.1	1988	DNA repair test of fluazinam technical in bacillus subtilis Hita Research Laboratories, Chemical Biotesting Center Chemicals Inspection and Testing Institute, Japan Report No.:T-1595E GLP: yes Unpublished	Y	ISK
Ohtsuka M.	IIA, 5.8.1	1989	Bacterial reverse mutation test of G-450 Hita Research Laboratories, Chemical Biotesting Center Chemicals Inspection and Testing Institute, Japan Report No.:T-1676E GLP: yes Unpublished	Y	ISK
Ohtsuka M.	IIA, 5.8.1	1989	Bacterial reverse mutation test of G-525 Hita Research Laboratories, Chemical Biotesting Center Chemicals Inspection and Testing Institute, Japan Report No.:T-1677E GLP: yes Unpublished	Y	ISK
Ohtsuka M.	IIA, 5.8.2	1989	Bacterial reverse mutation test of G-624 Hita Research Laboratories, Chemical Biotesting Center Chemicals Inspection and Testing Institute, Japan Report No.:T-1740E GLP: yes Unpublished	Y	ISK

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Pritchard V.	IIA, 5.2.6	1986	Skin sensitisation to the guinea-pig of both the purified and technical material [REDACTED] Report No.: CTL/P/1493 GLP: yes Unpublished	Y	ISK
Ransome S.	IIA, 5.4.1	2000	IKF-1216 Mammalian cell mutation assay Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England Report No.:RIA 017/004090 GLP: yes Unpublished	Y	ISK
Serrone D. M.	IIA, 5.7	1995	An acute neurotoxicity screening study in rats with technical fluazinam (IKF-1216) [REDACTED] Report No.: 5603-93-0075-TX-003 GLP: yes Unpublished	Y	ISK
Shults S. K.	IIA, 5.2.4	1992	Primary dermal irritation study in albino rabbits with IKF-1216 [REDACTED] Report No.: 5016-91-0281-TX-001 GLP: yes Unpublished	Y	ISK
Shults S. K.	IIA, 5.2.5	1992	Primary eye irritation study in albino rabbits with IKF-1216 [REDACTED] Report No.: 5016-91-0280-TX-002 GLP: yes Unpublished	Y	ISK
Tesh J. M.	IIA, 5.6.1	1987	B-1216: Effects upon reproductive performance of rats treated continuously throughout two successive generations [REDACTED] Report No.: 87/ISK068/097 GLP: yes Unpublished	Y	ISK
Tesh J. M.	IIA, 5.6.2	1985	B-1216: Teratology study in the rabbit [REDACTED] Report No.: 85/ISK049/045 GLP: yes Unpublished	Y	ISK

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Tesh J. M.	IIA, 5.6.2	1988	B-1216: Teratology study in the rabbit [REDACTED] Report No.: 86/ISK069/324 GLP: yes Unpublished	Y	ISK
Tobeta Y.	IIA, 5.2.3	1988	Acute inhalation toxicity test of fluazinam in rats [REDACTED] Report No.: D-1775E GLP: yes Unpublished	Y	ISK
Tominaga K. et al	IIA, 5.9.1	1990	Systemic contact dermatitis due to fluazinam Skin Research 1991: 33 (suppl 11) 364-368	N	
Van Ginkel C. et al	IIA, 5.9.2	1994	Allergic contact dermatitis from the newly introduced fungicide fluazinam Contact Dermatitis 1995: 32, 160-162	N	
Willoughby C. R.	IIA, 5.6.2	1985	B-1216: Teratology study in the rat [REDACTED] Report No.: 84/ISK047/606; Amended Final Report No.: 91/ISK047/0820 GLP: yes Unpublished	Y	ISK
<b>Annex III Data and Information</b>					
Barber J. E.	IIIA 7.1.1	1985	B1216: Acute oral and dermal toxicities of a 50 % suspension formulation to the rat [REDACTED] Report No.: CTL/P/1226 GLP: yes Unpublished	Y	ISK
Barber J. E.	IIIA 7.1.2	1985	B-1216: Acute oral and dermal toxicities of a 50 % suspension formulation to the rat [REDACTED] Report No.: CTL/P/1226 GLP: yes Unpublished	Y	ISK
Chester G.	IIIA 7.2.1.1	1991	Fluazinam estimation of absorbed dose and risk assessment for mixer-loader-applicators in france [REDACTED] [REDACTED] Report No.: RIC0840; GLP: yes Unpublished	Y	ISK

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Cracknell S.	IIIA 7.1.3	1991	IKF-1216 50 % SC: Acute inhalation toxicity study in the rat [REDACTED] Report No.: 91/ISK161/0270; GLP: yes Unpublished	Y	ISK
Cummins H. A.	IIIA 7.1.2	1992	IKF-1216: Acute percutaneous toxicity study in the rat [REDACTED] Report No.: LSR 90/ISK156/0990; GLP: yes Unpublished	Y	ISK
Ebino K.	IIIA 7.1.3	2001	IKF-1216 500 SC: Acute inhalation toxicity study in rats [REDACTED] Report No.: IET 00-0048 GLP: yes Unpublished	Y	ISK
Kenyon R. G.	IIIA 7.2.3.1	2001	Fluazinam 500F on potato – dislodgeable foliar residue study – USA in 2000 Ishihara Sangyo Kaisha, Ltd., Osaka, Japan Report No.: 012207-2 GLP: yes Unpublished	Y	ISK
Lees D., Robinson P.	IIIA 7.1.6	1991	ICI192: Skin sensitisation t the guinea pig of a 500 g/l SC formulation [REDACTED] Report No.: CTL/P/3227 GLP: yes Unpublished	Y	ISK
Roper C. S.	IIIA 7.3	2000	The in vitro percutaneous absorption of radiolabelled fluazinam in two formulations through rat skin [REDACTED] Report No.: 18992; GLP: yes Unpublished	Y	ISK
Roper C. S., Gedik L.	IIIA 7.3	2000	The in vitro percutaneous absorption of radiolabelled fluazinam in two formulations through human skin [REDACTED] Report No.: 18924; GLP: yes Unpublished	Y	ISK

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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-R/NR	Owner
Roper C. S., Madden S.	IIIA 7.3	2000	Dermal absorption of <sup>14</sup> C-fluazinam in two formulations in the rat [REDACTED] Report No.: 19612; GLP: yes Unpublished	Y	ISK
Scott R. C., Ward R. J.	IIIA 7.3	1985	B-1216: In vitro absorption through human epidermis from the 50 % suspension concentrate (JF9550) and spray dilution [REDACTED] Report No.: CTL/P/1284 GLP: yes Unpublished	Y	ISK
Scott R. C., Ward R. J.	IIIA 7.3	1985	B-1216: In vitro absorption of technical material through human epidermis [REDACTED] Report No.: CTL/P/1285 GLP: yes Unpublished	Y	ISK
Smith K. D.	IIIA 7.1.4	1990	IKF-1216 50 % SC: Primary dermal irritation study in the rabbit [REDACTED] Report No.: 90/ISK157/1280; GLP: yes Unpublished	Y	ISK
Smith K. D.	IIIA 7.1.4	1990	IKF-1216 50 % SC (1:500 dilution): Primary dermal irritation study in the rabbit [REDACTED] Report No.: 90/ISK173/1282; GLP: yes Unpublished	Y	ISK
Smith K. D.	IIIA 7.1.4	1990	IKF-1216 50 % SC (1:1000 dilution): Primary dermal irritation study in the rabbit [REDACTED] Report No.: 90/ISK175/1284; GLP: yes Unpublished	Y	ISK
Smith K. D.	IIIA 7.1.5	1990	IKF-1216 50 % SC: Primary eye irritation study in the rabbit [REDACTED] Report No.: 90/ISK158/1281; GLP: yes Unpublished	Y	ISK

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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-R/NR	Owner
Smith K. D.	IIIA 7.1.5	1990	IKF-1216 50 % SC (1:500 dilution): Primary eye irritation study in the rabbit [REDACTED] Report No.: 90/ISK174/1283; GLP: yes Unpublished	Y	ISK
Smith K. D.	IIIA 7.1.5	1990	IKF-1216 50 % SC (1:1000 dilution): Primary eye irritation study in the rabbit [REDACTED] Report No.: 90/ISK176/1309; GLP: yes Unpublished	Y	ISK
Smith K. D.	IIIA 7.1.6	1990	IKF-1216 50 % SC: Dermal sensitisation study in guinea pigs [REDACTED] Report No.: 90/ISK159/1205; GLP: yes Unpublished	Y	ISK
Southwood J.	IIIA 7.1.4	1985	B-1216 50 % suspension formulation: Skin irritation and eye irritation studies [REDACTED] Report No.: CTL/P/1238 GLP: yes Unpublished	Y	ISK
Southwood J.	IIIA 7.1.5	1985	B-1216 50 % suspension formulation: Skin irritation and eye irritation studies [REDACTED] Report No.: CTL/P/1238 GLP: yes Unpublished	Y	ISK
Ueda H.	IIIA 7.1.5	2003	Fluazinam 500 SC: Eye irritation study in rabbits [REDACTED] Report No.: IET 02-0111 GLP: yes Unpublished	Y	ISK



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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-R/NR	Owner
<b>Annex II Data and Information</b>					
Burke, S. R., Sapiets, A.	All, 6a/03	1993	Fluazinam: Storage Stability of the Residues in Frozen Soil Samples. – Final Report. Zeneca Agrochemicals, Report No. RJ1624B GLP/GEP Yes unpublished	N	ISK
Burke, S.R., Sapiets, A.	All, 6.3/04	1992	Fluazinam: Residue Levels in Potatoes from Trials Carried Out in the United Kingdom During 1989. ICI Agrochemicals, UK, Report No. RJ1161B GLP/GEP Yes unpublished	N	ISK
Cheng, T.	All, 6.2/01	1993/1 994	Nature of the Residue of <sup>14</sup> C-Fluazinam (IKF-1216) in Lactating Goats (Part 1: Animal Dosing, Sample Collection and Radiochemical Analysis, Part 2: Metabolite Identification and Characterization. ██████████ Report No. 5248- 92-0116-EF GLP/GEP Yes unpublished	N	ISK
Cheng, T.	All, 6.2/02	1995	Nature of the Residue of <sup>14</sup> C-Fluazinam (IKF-1216) in Laying Hens. ██████████ Report No. 5309-92-0241-EF GLP/GEP Yes unpublished	N	ISK
Clarke, D.M.	All, 6.3/03	1997	Fluazinam: Residue Levels in Early Potatoes from Trials Carried Out in the United Kingdom During 1996. Zeneca Agrochemicals, UK, Report No. RJ2308B GLP/GEP Yes unpublished	N	ISK
Dvorak, R.S., Kenyon, R.G.	All, 6.3/05	1996	Magnitude of Residue of Fluazinam in Potatoes – Greece – 1995. Ricerca, Inc. USA, Report No. 6530-96- 0020-CR-001 GLP/GEP Yes unpublished	N	ISK

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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-R/NR	Owner
Flückiger, J.	All, 6.1/03	1993	14C-Fluazinam: Plant Metabolism Study in Field Grown Grape Study A (1992) [Biological Phase]. RCC Umweltchemie AG, Report No. 328735 GLP/GEP Yes unpublished	N	ISK
Hartman, D. A.	All, 6.1/02	1995	A Peanut Plant Metabolism Study with [ <sup>14</sup> C]IKF-1216 (Fluazinam); (Final Report). Ricerca, Inc., Report No. 5012-91-0330-EF-002 GLP/GEP Yes unpublished	N	ISK
Jentoft, N. H.	All, 6.1/01	1997	[ <sup>14</sup> C]IKF-1216 (Fluazinam) Plant Metabolism Study in Potatoes. Ricerca, Inc., Report No. 6775-96-0053-EF-001 GLP/GEP Yes unpublished	N	ISK
Jentoft, N.H.	All, 6.6/03	1995	Confined Rotational Crop Study on [ <sup>14</sup> C]Fluazinam (IKF-1216) Reincorporation of Radioactivity into Natural Products. Ricerca, Inc., Report No.5032-92-0093-EF-002 GLP/GEP Yes unpublished	N	ISK
Kenyon, R.G.	All, 6.3/06	1998	Magnitude of Residue of Fluazinam in Potatoes – Greece – 1996. Ricerca, Inc. USA, Report No. 6953-97-0087-CR-001 GLP/GEP Yes unpublished	N	ISK
McClanahan, R.H.	All, 6.1/05	1996	<sup>14</sup> C-IKF-1216 (Fluazinam): Plant Metabolism Study in Apple Trees. Ricerca, Inc., Report No. 6021-94-0050-EF-001 GLP/GEP Yes unpublished	N	ISK
McFall, D. D.	All, 6a/01	1999	Stability of Fluazinam in Potatoes and Potato Processed Fractions after Freezer Storage – Final Report. Ricerca, Inc., Report No. 6166-94-0148-CR-002 GLP/GEP Yes unpublished	Y	ISK

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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-R/NR	Owner
Mirbach, M.J., Ullrich, A.	All, 6.3/10	1992	Determination of the Residues of IKF-1216 (Fluazinam) and its Metabolites in Grapes, Wine and Potatoes. 1 <sup>st</sup> Amendment to Report: Determination of the Residues of MAPA and HYPA in potatoes. RCC Project No. 284670 (FZM/SOLTU 11/F/90) GLP/GEP Yes unpublished	N	ISK
Neal, T. R.	All, 6.1/04	1996	[ <sup>14</sup> C]Fluazinam: Plant Metabolism Study in Field Grown Grape - Study A (1992) [Analytical Phase] Final Report. Ricerca, Inc., Report No. 5431-92-0423-EF-003 GLP/GEP Yes unpublished	N	ISK
Robinson, R.A., Hoffman, S.L.	All, 6.6/01	1994	Confined Rotational Crop Study on Fluazinam (IKF-1216) Part 1: Total Radioactive Residue Determination, Residue Extraction and Profiling, and Isolation and Identification of Trifluoroacetic Acid (Preliminary Report). XenoBiotic Laboratories, Inc., Report No. 5032-92-0093 XBL Report No. RPT00207 GLP/GEP Yes unpublished	N	ISK
Robinson, R.A., Hoffman, S.L.	All, 6.6/02	1995	Confined Rotational Crop Study on Fluazinam (IKF-1216). XenoBiotic Laboratories, Inc., Report No. 5032-92-0093 XBL Report No. RPT00207 GLP/GEP Yes unpublished	N	ISK
Ryan, J., Sapiets, A.	All, 6a/02	1993	Fluazinam: Storage Stability of the Residues in Frozen Crop Samples. – Final Report. Zeneca Agrochemicals, Report No. RJ1538B GLP/GEP Yes unpublished	N	ISK
Ryan, J., Sapiets, A.	All, 6b/01	1993	Fluazinam: Storage Stability of the Residues in Frozen Crop Samples. – Final Report. Zeneca Agrochemicals, Report No. RJ1538B GLP/GEP Yes unpublished	N	ISK
Ryan, J., Sapiets, A.	All, 6.3/01	1991	Fluazinam: Residue Levels in Potatoes from Trials Carried Out in Germany During 1990. ICI Agrochemicals, UK, Report No. RJ1023B GLP/GEP Yes unpublished	N	ISK

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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-R/NR	Owner
Ryan, J., Sapiets, A.	All, 6.3	1991	Fluazinam: Residue Levels in Potatoes from Trials Carried Out in Germany During 1989. ICI Agrochemicals, UK, Report No. RJ1025B GLP/GEP Yes unpublished	N	ISK
Ryan, J., Sapiets, A.	All, 6.3	1992	Fluazinam: Residue Levels in Potatoes from Trials Carried Out in France During 1991. ICI Agrochemicals, UK, Report No. RJ1105B GLP/GEP Yes unpublished	N	ISK
Ryan, J., Sapiets, A.	All, 6.3	1992	Fluazinam: Residue Levels in Potatoes from Trials Carried Out in France During 1991. ICI Agrochemicals, UK, Report No. RJ1106B GLP/GEP Yes unpublished	N	ISK
Schulz, H.	All, 6.3	1992	Determination of the Residues of IKF-1216 (Fluazinam) and its Metabolites in Grapes, Wine and Potatoes. 7 <sup>th</sup> Amendment to Report: Determination of the Residues of IKF-1216 (Fluazinam) in potatoes. RCC Project No. 284670 (FZM/SOLTU 12/F/90) GLP/GEP Yes unpublished	N	ISK
<b>Annex III Data and Information</b>					
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**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-R/NR	Owner
<b>Annex II Data and Information</b>					
Atkinson, R.	All, 7.2.2	1993	Estimation of Hydroxyl Radical Reaction Rate Constants: Fluazinam. Ricerca Inc., Report No. RIC 1832 Not GLP, unpublished	N	ISK
Bharti H., Bewick, D.W.	All, 7.1.1.1.1	1985	B-1216 (PP192): Degradation in Soil. ICI Plant Protection Division, Report No. RJ0444B. GLP, unpublished	N	ISK
Bharti H., Bewick, D.W.	All, 7.1.1.2.1 = All, 7.1.1.1.1	1985	B-1216 (PP192): Degradation in Soil. ICI Plant Protection Division, Report No. RJ0444B. GLP, unpublished	N	ISK
Burke, S. R., Sapiets, A.	All, 7.1.1.2.2	1992	Fluazinam: Soil Dissipation Study (Germany, 1991-1992). ICI Agrochemicals, Report No. RJ1368B GLP, unpublished	N	ISK
Burke, S. R., Sapiets, A.	All, 7.1.1.2.2	1993	Fluazinam: Residue Levels of the Metabolite R270682 ("HYPA") in Soil From a Dissipation Study Carried Out in Germany During 1991-1992. ICI Agrochemicals., Report No. RJ1443B GLP, unpublished	N	ISK
Crawford, C. J., Dillon, K. A.	All, 7.1.1.2.2	1995a	Dissipation of Residues of Fluazinam and Its Metabolites (MAPA, HYPA and CAPA) from Soil in Washington. Ricerca, Inc., Report No. 5687-93-0091-CR-001 GLP, unpublished	N	ISK
Crawford, C. J., Dillon, K. A.	All, 7.1.1.2.2	1995b	Dissipation of Residues of Fluazinam and Its Metabolites (MAPA, HYPA and CAPA) from Soil in North Dakota. Ricerca, Inc., Report No. 5687-93-0111-CR-001 GLP, unpublished	N	ISK
Crawford, C. J., Dillon, K. A.	All, 7.1.1.2.2	1995c	Dissipation of Residues of Fluazinam and Its Metabolites (MAPA, HYPA and CAPA) from Soil in California. Ricerca, Inc., Report No. 5687-93-0108-CR-001 GLP, unpublished	N	ISK
Crawford, C. J., Dillon, K. A.	All, 7.1.1.2.2	1995d	Dissipation of Residues of Fluazinam and Its Metabolites (MAPA, HYPA and CAPA) from Soil in Georgia. Ricerca, Inc., Report No. 5687-93-0104-CR-001 GLP, unpublished	N	ISK

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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-R/NR	Owner
Flude, D.	All, 7.2.1.1 = All, 2.9.1	1985	B-1216: Hydrolysis at pH 5, pH 7 and pH 9 at 22°C. ICI Plant Protection Division, Report No. RJ0383B Not GLP, unpublished	N	ISK
Galicía, H., Völkl, S.	All, 7.1.2	1991	Soil Adsorption/ Desorption of Fluazinam (IKF-1216) on Four Soils. RCC Umweltchemie AG, Report No. 282306 GLP, unpublished	N	ISK
Goodyear, A.	All, 7.2.1.3.2	1997	<sup>14</sup> C-Fluazinam: Biodegradation in Natural Water-Sediment Systems. Covance Laboratories, Report No. 38/188-1015 GLP, unpublished	N	ISK
Grützner, I.	All, 7.2.1.3.1	2000	Ready Biodegradability of Fluazinam in a Manometric Respirometry Test. RCC Ltd, Report No. 774898 GLP, unpublished	Y	ISK
Gurney A.	IIA, 7.1.1.2.1, IIA, 7.1.1.2.2	2005a	Kinetic calculations for degradation of fluazinam in soil under laboratory and field conditions RCC Ltd report no. A07132, July 1, 2005 Not GLP, unpublished	Y	ISK
Kennedy, S.H.	All, 7.1.1.2.2	1996	Fluazinam Soil Degradation Study Following Applications to Potatoes and Bare Ground (UK, 1995). CEM Analytical Services Ltd., Report No. CEMS-451 GLP, unpublished	N	ISK
Lentz, N.R., Korsch, B.H.	All, 7.1.1.1.2	2001	A Photolysis Study of IKF-1216 (Fluazinam) on Soil. Ricerca, Inc., Amended Report No. 5313-95-0011-EF-002 GLP, unpublished	Y	ISK
Lentz N.R., Korsch B.H.	IIA, 7.2.1.2 = IIA, 2.9.2	1994	A photolysis Study of IKF-1216 in water at pH 5 (part 1) Ricerca, report no. 5312-94-0119-EF-001, Interim report, December 20, 1994 GLP, unpublished	N	ISK
Lentz, N.R., Korsch, B.H.	All, 7.2.1.2 = All, 2.9.2	1995	A Photolysis Study of IKF-1216 (Fluazinam) in Water at pH 5. Ricerca, Inc., Report No. 5312-94-0119-EF-002 GLP, unpublished	N	ISK
Mawad, N.	All, 7.1.1.1.1	2003	Metabolism And Degradation Of <sup>14</sup> C-Fluazinam In One Soil Incubated Under Aerobic Conditions. RCC Ltd, Report No.844056 GLP, unpublished	Y	ISK
Mawad, N.	All, 7.1.1.2.1 = All, 7.1.1.1.1	2003	Metabolism And Degradation Of <sup>14</sup> C-Fluazinam In One Soil Incubated Under Aerobic Conditions. RCC Ltd, Report No.844056 GLP, unpublished	Y	ISK

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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-R/NR	Owner
Muller, K., Lane, M. C. G.	All, 7.1.2	1993	Fluazinam: Adsorption and Desorption Properties in Soil of R270682 ("HYPA"), a Major Soil Metabolite. ICI Plant Protection Division, Report No. RJ1308B GLP, unpublished	N	ISK
Ryan, J., Sapiets, A.	All, 7.1.1.2.	1992	Fluazinam: Laboratory Soil Degradation Study (BBA). ICI Agrochemicals, Report No. RJ1391B GLP, unpublished	N	ISK
van der Gaauw, A.	All, 7.1.1.2.1	2002	Degradation Rate of HYPA in Three Soils Incubated Under Aerobic Conditions. RCC Ltd, Report No. 842279 GLP, unpublished	Y	ISK
van der Gaauw, A.	All, 7.2.1.1 = All, 2.9.1	2003	<sup>14</sup> C-Fluazinam: Hydrolysis at Three Different pH Values. RCC Ltd, Report No. 846211 GLP, unpublished	Y	ISK
<b>Annex III Data and Information</b>					
	AIII, 9.1.1.1		See Confidential Bibliography		
	AIII, 9.3		See Confidential Bibliography		
Burke, S. R., Sapiets, A.	AIII, 9.1.1.2 =All, 7.1.1.2.2	1992	Fluazinam: Soil Dissipation Study (Germany, 1991-1992). ICI Agrochemicals, Report No. RJ1368B GLP, unpublished	N	ISK
Burke, S. R., Sapiets, A.	AIII, 9.1.1.2 = All, 7.1.1.2.2	1993	Fluazinam: Residue Levels of the Metabolite R270682 ("HYPA") in Soil From a Dissipation Study Carried Out in Germany During 1991-1992. ICI Agrochemicals., Report No. RJ1443B GLP, unpublished	N	ISK
Burke, S.R., Clarke, D.M.	AIII, 9.1.2.1	1992	Fluazinam: Leaching of Formulated Material in Soil Columns. ICI Agrochemicals, UK, Report No. RJ1234B GLP, unpublished	N	ISK
Crawford, C. J., Dillon, K. A.	AIII, 9.1.1.2 = All, 7.1.1.2.2	1995	Dissipation of Residues of Fluazinam and Its Metabolites (MAPA, HYPA and CAPA) from Soil in Washington. Ricerca, Inc., Report No. 5687-93-0091-CR-001 GLP, unpublished	N	ISK
Crawford, C. J., Dillon, K. A.	AIII, 9.1.1.2 = All, 7.1.1.2.2	1995	Dissipation of Residues of Fluazinam and Its Metabolites (MAPA, HYPA and CAPA) from Soil in North Dakota. Ricerca, Inc., Report No. 5687-93-0111-CR-001 GLP, unpublished	N	ISK

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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-R/NR	Owner
Crawford, C. J., Dillon, K. A.	AIII, 9.1.1.2 = AII, 7.1.1.2.2	1995	Dissipation of Residues of Fluazinam and Its Metabolites (MAPA, HYPA and CAPA) from Soil in California. Ricerca, Inc., Report No. 5687-93-0108-CR-001 GLP, unpublished	N	ISK
Crawford, C. J., Dillon, K. A.	AIII, 9.1.1.2 = AII, 7.1.1.2.2	1995	Dissipation of Residues of Fluazinam and Its Metabolites (MAPA, HYPA and CAPA) from Soil in Georgia. Ricerca, Inc., Report No. 5687-93-0104-CR-001 GLP, unpublished	N	ISK
Görge G.	IIIA, 9.2.3	2005	Estimation of the environmental concentrations of fluazinam and its metabolites AMPA in surface water RCC, report no. A17267, July 20, 2005 Not GLP, unpublished	Y	ISK
Gurney, A.	AIII, 9.2.3	2005c	Estimation of the environmental concentrations of fluazinam in surface water. FOCUS surface water step 4 calculations RCC Ltd., Report No. A44280 Not GLP, unpublished	Y	ISK
Gurney, A.	AIII, 9.2.3	2005b	Fluazinam Defence of water-sediment half-lives used in FOCUS surface water calculations RCC Ltd., Report No. A44280-A Not GLP, unpublished	Y	ISK
Kennedy, S.H.	AIII, 9.1.1.2 = AII, 7.1.1.2.2	1996	Fluazinam Soil Degradation Study Following Applications to Potatoes and Bare Ground (UK, 1995). CEM Analytical Services Ltd., Report No. CEMS-451 GLP, unpublished	N	ISK
Kuet, S.F.	AIII, 9.3	1994	Fluazinam: Volatilization from Soil and Leaf Surfaces Following Application as a SC Formulation. Zeneca Agrochemicals, UK, Report No. RJ1770B GLP, unpublished	N	ISK
McFadden, J.J.	AIII, 9.1.3	2003	Terrestrial and Aquatic PEC Values for Fluazinam (IKF-1216) and Risk-Assessment for the Use on Potato in the EU Ricerca, Inc., Report No. 014891-1. GLP, unpublished	Y	ISK
McFadden, J.J.	AIII, 9.2 = AIII, 9.1.3	2003	Terrestrial and Aquatic PEC Values for Fluazinam (IKF-1216) and Risk-Assessment for the Use on Potato in the EU Ricerca, Inc., Report No. 014891-1. Not GLP, unpublished	Y	ISK
Vercruysse F.	IIIA, 9.2.1	2005	Predicted environmental concentrations in groundwater (PEC <sub>gw</sub> ) after PELMO simulation for the active ingredient fluazinam (IKF-1216) and its metabolite HYPA ISK Biosciences Europe SA, report no. IBE1216-EF0506-01, June 24, 2005 Not GLP, unpublished	Y	ISK



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**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-R/NR	Owner
<b>Annex II Data and Information</b>					
Backus, P.	All, 8.6	1993a	Effect of IKF-1216 (Fluazinam) on Seed Germination/Seedling Emergence (Tier I). Ricerca, Inc., Report No. 5549-92-0483-BE-001 GLP Yes, not published	N	ISK
Backus, P.	All, 8.6	1993b	Effect of IKF-1216 (Fluazinam) on Vegetative Vigor of Plants (Tier I). Ricerca, Inc., Report No. 5549-92-0484-BE-001 GLP Yes, not published	N	ISK
Boeri, R.	All, 8.2.8	2001	IKF-1216: Toxicity to the Duckweed, <i>Lemna gibba</i> . Generated by: T. R. Wilbury Laboratories, Inc. Report No. 2129-SK GLP / GEP: yes unpublished	Y	ISK
Collins, I. G., Gough, H. J., Wilkinson, W.	All, 8.3.1.1	1984	B 1216 (PP192): Acute Contact and Oral Toxicity to Honey Bees ( <i>Apis mellifera</i> ). ICI Plant Protection Division, Report No. RJ0401B GLP Yes, not published	N	ISK
Crosby, K.	All, 8.6	1995	Effect of IKF-1216 on Vegetative Vigor of Plants (Tier II). Ricerca, Inc., Report No. 6363-95-0019-BE-001 GLP Yes, not published	N	ISK
Edwards, P. J., Coulson, J. M.	All, 8.4.1	1985	B 1216 (PP192): Toxicity of Technical Material to the Earthworm ( <i>Eisenia foetida</i> ). Generated by: ICI Plant Protection Division, Report No. RJ0409B GLP / GEP: yes unpublished	N	ISK
Farrelly, E., Vincent, J., Hamer, M. J., Hill, I. R.	All 8.2.4	1984	B 1216 (PP192): Toxicity to First Instar <i>Daphnia magna</i> . Generated by: ICI Plant Protection Division Report No: RJ0392B GLP / GEP: yes unpublished	N	ISK

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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-R/NR	Owner
Fillmore, G. E. & J. Laveglia	All, 8.2.2.2	1993	Technical Fluazinam (IKF-1216) – The Toxicity to Fathead Minnow ( <i>Pimephales promelas</i> ) During Early Life-Stage Exposure. Generated by: [REDACTED] Report No. 5018-91-0425-TX-002 GLP / GEP: yes unpublished	N	ISK
Gelin, M.D, Laveglia, J.	All 8.2.1	1992	Technical Fluazinam (IKF-1216) – Acute Toxicity to Rainbow Trout ( <i>Oncorhynchus mykiss</i> ) Under Flow-Through Conditions. Generated by: [REDACTED] Report No: 5099-91-0422-TX-002 GLP / GEP: yes unpublished	N	ISK
Gelin, M.D, Laveglia, J.	All 8.2.1	1993	Technical Fluazinam (IKF-1216) – Acute Toxicity to Bluegill Sunfish ( <i>Lepomis macrochirus</i> ) Under Flow-Through Conditions. Generated by: [REDACTED] Report No: 5099-91-0421-TX-002 GLP / GEP: yes unpublished	N	ISK
Grützner, I.	All, 8.7	2000	Toxicity of Fluazinam to Activated Sludge in a Respiration Inhibition Test. Generated by: RCC Ltd. Report No. 774887 GLP / GEP: yes unpublished	Y	ISK
Hakin, B., Johnson, A. J., Anderson, A., Dawe, I. S.	All, 8.1.1	1991	B-1216 Technical Acute Oral Toxicity (LD50) to Bobwhite Quail. [REDACTED] Report No. ISK 48/91161 GLP Yes, not published	N	ISK
Hertl, A.	All 4.2.3 All 8.2.1	1997a	Acute Toxicity of AMPA to Zebra Fish ( <i>Brachydanio rerio</i> ) in a 96-Hour Static Test. Generated by: [REDACTED] [REDACTED] Report No: 662512 GLP / GEP: yes unpublished	N	ISK
Hertl, J.	All, 4.2.3 All 8.2.4	1997b	Acute Toxicity of AMPA to <i>Daphnia magna</i> in a 48-Hour Immobilization Test. Generated by: RCC Umweltchemie AG Report No. 662490 GLP / GEP: yes unpublished	N	ISK

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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-R/NR	Owner
Hertl, J.	All 8.2.6	1997c	Toxicity of AMPA to <i>Scenedesmus subspicatus</i> in a 72-Hour Algal Growth Inhibition Test for Poorly Soluble Test Substances. RCC Umweltchemie AG Report No. 662477 GLP / GEP: yes unpublished	N	ISK
Hill, R. W.	All 8.2.1	1985	PP192: Determination of Acute Toxicity to Rainbow Trout ( <i>Salmo gairdneri</i> ). Generated by: [REDACTED] Report No: BL/B/2560 GLP / GEP: yes unpublished	N	ISK
Lentz, N. R., Huhtanen, K. L.	All, 8.2.3	1994	Uptake, Depuration, and Bioconcentration and Metabolism of (Fluazinam) Carbon-14 IKF-1216 in Bluegill Sunfish ( <i>Lepomis macrochirus</i> ) Under Flow Through Test Conditions. Generated by: [REDACTED] Report No. 5311-93-0013-EF-001 GLP / GEP: yes unpublished	N	ISK
Lühns, U.	All, 8.4.1	2000	Acute Toxicity (14 Days) of HYPA to the Earthworm <i>Eisenia fetida</i> (Savigny 1826) in Artificial Soil. Generated by: Institut für Biologische Analytik und Consulting IBACON GmbH Report No. 8691021 GLP / GEP: yes unpublished	Y	ISK
Lühns, U.	All, 8.6	2004	Effects of HYPA on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil Generated by: Institut für Biologische Analytik und Consulting IBACON GmbH Report No. 19161016 GLP / GEP: yes unpublished	Y	ISK
Peither, A.	All 8.2.1	2001a	Acute Toxicity of Fluazinam to Zebra Fish ( <i>Brachydanio rerio</i> ) in a 96-Hour Flow-Through Test. Generated by: [REDACTED] Switzerland Report No: 813431 GLP / GEP: yes unpublished	Y	ISK

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Peither, A.	All 8.2.1	2001b	Acute Toxicity of Fluazinam to Guppy ( <i>Poecilia reticulata</i> ) in a 96-Hour Flow- Through Test. Generated by: [REDACTED] Report No: 813453 GLP / GEP: yes unpublished	N	ISK
Reis, K.	All, 8.5	2002	Effect of HYPA on the Activity of the Soil Microflora in the Laboratory. Generated by: Institut für Biologische Analytik und Consulting IBACON GmbH Report No. 8692080 GLP / GEP: yes unpublished	Y	ISK
Reis, K.	All, 8.5	2004	Effects of HYPA on the Growth of Pure Cultures in Soil Fungi in the Laboratory. Generated by: Institut für Biologische Analytik und Consulting IBACON GmbH Report No. 19164083 GLP / GEP: yes unpublished	Y	ISK
Roberts, N. L., Anderson, A., Dawe, I. S.	All, 8.1.1	1991a	The Acute Oral Toxicity of B1216 to the Mallard Duck. [REDACTED] Report No. ISN 31BT/841207 GLP Yes, not published	N	ISK
Roberts, N. L., Anderson, A., Dawe, I. S.	All, 8.1.2	1991b	The Subacute Dietary Toxicity of B1216 to the Bobwhite Quail. [REDACTED] Report No. ISN 24BT/841206 GLP Yes, not published	N	ISK
Roberts, N. L., Anderson, A., Dawe, I. S.	All, 8.1.2	1991c	The Subacute Dietary Toxicity of B1216 to the Mallard Duck. [REDACTED] Report No. ISN 25BT/841208 GLP Yes, not published	N	ISK
Sankey, S. A., Tapp, J. F., Caunter, J. E., Stanley, R. D.	All, 8.2.2.1	1992	Fluazinam: The 28 Day LC50 to Rainbow Trout ( <i>Oncorhynchus mykiss</i> ). Generated by: [REDACTED] Report No. BL4167/B GLP / GEP: yes unpublished	N	ISK

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Sankey, S.A., Coleman, C.A., Tapp, J.F.	All, 8.7	1992	Fluazinam: Toxicity to <i>Pseudomonas putida</i> . Generated by: Imperial Chemical Industries PLC Group Environmental Laboratory Report No. BL4364/B GLP / GEP: yes unpublished	N	ISK
Schmidt, T.	All 8.2.7	2003	Acute Toxicity of Fluazinam Technical to First-Instar Larvae of <i>Chironomus riparius</i> in a 48-Hour Test Generated by: RCC Ltd. Report No. 851182 GLP / GEP: yes unpublished	Y	ISK
Shults, S. K., A. W. Brock & L. Laveglia	All 8.2.1	1993	Acute Toxicity to Sheepshead Minnow ( <i>Cyprinodon variegatus</i> ) Under Flow-Through Conditions with Technical Fluazinam (IKF- 1216). Generated by: [REDACTED] Report No: 5017-91-0415-TX-002 GLP / GEP: yes unpublished	N	ISK
Shults, S. K., Brock, A. W., Laveglia, J.	All, 8.2.2.3	1995	Technical Fluazinam (IKF-1216)– The Chronic Toxicity to the Fathead Minnow ( <i>Pimephales promelas</i> ) During a Full Life- Cycle Exposure. Generated by: [REDACTED] Report No. 5107-92-0035-TX-00 GLP / GEP: yes unpublished	N	ISK
Shults, S. K., Brock, A. W., Laveglia, J.	All 8.2.4	1992	Acute Toxicity to Daphnids ( <i>Daphnia magna</i> ) Under Flow-Through Conditions with Technical Fluazinam (IKF-1216). Generated by: Springborn Laboratories Report No. 5108-91-0418-TX-002 GLP / GEP: yes unpublished	N	ISK
Shults, S. K., Brock, A. W., Laveglia, J.	All, 8.2.5	1993	Chronic Toxicity to <i>Daphnia magna</i> Under Flow-Through Conditions with Technical Fluazinam (IKF-1216). Generated by: Springborn Laboratories, Report No. 5109-91-0419-TX-002 GLP / GEP: yes unpublished	N	ISK

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Smyth, D. V., Tapp, J. F.	All 8.2.6	1987	PP192 (B1216): Determination of Toxicity to the Green Alga <i>Selenastrum capricornutum</i> . Generated by: Imperial Chemical Industries PLC Report No: BL/B/3056 GLP / GEP: yes unpublished	N	ISK
Stewart, K.M., Shillabeer, N.	All, 8.2.7	1997	Fluazinam: Determination of the Effects on Emergence of <i>Chironomus riparius</i> . Generated by: Zeneca Limited Brixham Environmental Laboratory Report No. BL6115/B GLP / GEP: yes unpublished	N	ISK
Sugimoto, K., Hayashi, H.	All, 8.6	2004	Terrestrial Plants, Growth Test assessing HYPA, metabolite of fluazinam  ISK Central Research Laboratory, Japan, Report No. AL-0404-F-01 GLP No, not published	Y	ISK
Turck, P. A., Laveglia, J.	All, 8.1.3	1995a	Technical Fluazinam: A Pilot Reproduction Study with the Northern Bobwhite ( <i>Colinus virginianus</i> ).  Report No. 5511- 92-0453-TX-003 GLP Yes, not published	N	ISK
Turck, P. A., Laveglia, J.	All, 8.1.3	1995b	Technical Fluazinam: A Pilot Reproduction Study with the Mallard ( <i>Anas platyrhynchos</i> ).  Report No. 5511- 92-0452-TX-003 GLP Yes, not published	N	ISK
Turck, P. A., Laveglia, J.	All, 8.1.3	1996a	Technical Fluazinam: A Reproduction Study with the Northern Bobwhite ( <i>Colinus virginianus</i> ) Phases I and II.  Report No. 5512- 92-0455-TX-003 GLP Yes, not published	N	ISK
Turck, P. A., Laveglia, J.	All, 8.1.3	1996b	Technical Fluazinam: A Reproduction Study with the Mallard ( <i>Anas platyrhynchos</i> ) Phases I and II.  Report No. 5512- 92-0454-TX-003 GLP Yes, not published	N	ISK

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van den Bogaaert, M., Farrelly, E., J., Hamer, M.	AII, 8.2.5	1991	Fluazinam: Chronic Toxicity to <i>Daphnia magna</i> . Generated by: ICI Plant Protection Division Report No. RJ0974B GLP / GEP: yes unpublished	N	ISK
<b>Annex III Data and Information</b>					
Canning, L., Lloyd, E.J., Lewis, G.B.	AIII, 10.5.1	1992	Fluazinam – Investigation of the Toxicity of a 50% w/v SC Formulation to the Carabid Beetle <i>Pterostichus melanarius</i> and a Lycosid Spider.  ICI Agrochemicals, UK, Report No. RJ1070B GLP Yes, not published	N	ISK
Coulson, J.M., Lavender, K.H.	AIII, 10.5.1	1996	Investigation into the Toxicity of a 500 g a.i./L Suspension Concentrate Formulation to the Cereal Aphid Parasitoid <i>Aphidius rhopalosiphii</i> .  Zeneca Agrochemicals, UK, Report No. RJ2109B GLP Yes, not published	N	ISK
Farrelly, E., Navet, X., Hamer, M. J.	AIII, 10.2.1	1991	Fluazinam: Acute Toxicity of a 500 g/L SC Formulation to First Instar <i>Daphnia magna</i> . Generated by: ICI Agrochemicals, UK Report No: RJ1024B GLP / GEP: yes unpublished	N	ISK
Gurney, A.	AIII, 10.2	2005	Fluazinam Statement: Aquatic risk assessment for chronic effects on fish using FOCUS Step 4 predicted concentrations in surface water with a 5 m unsprayed buffer. Generated by: RCC Ltd. Report No. A44280-B GLP / GEP: not applicable unpublished	Y	ISK
Jansen, J-P	AIII, 10.5.1	2000a	Side Effects of Fluazinam (IKF-1216) 500 g/L SC Formulation on the Parasitic Wasp <i>Aphidius rhopalosiphii</i> (Hym.; Aphidiidae) in the Laboratory on Potato Detached Leaves Treated in the Field.  Laboratoire d'Ecotoxicologie, Ministry of Agriculture, Belgium, Report No. AE.01/2000 GLP Yes, not published	N	ISK



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Jansen, J-P.	AIII, 10.5.1	2000b	Side Effects of Fluazinam (IKF-1216) 500 g/L SC Formulation on the Predacious Mite <i>Typhlodromus pyri</i> Scheuten (Acari; Phytoseiidae) in the Laboratory on Potato Detached Leaves Treated in the Field.  Laboratoire d'Ecotoxicologie, Ministry of Agriculture, Belgium, Report No. TE.01/2000  GLP Yes, not published	Y	ISK
Jansen, J-P.	AIII, 10.5.1	2000c	Side Effects of Fluazinam (IKF-1216) 500 g/L SC Formulation on Larvae of the Green Lacewing <i>Chrysoperla carnea</i> Steph. (Neuroptera, Chrysopidae) in the Laboratory on Potato Detached Leaves Treated in the Field.  Laboratoire d'Ecotoxicologie, Ministry of Agriculture, Belgium, Report No. CCE.01/2000  GLP Yes, not published	Y	ISK
Klein, S., Meister, A.	AIII, 10.6.2	2002	Effects of IKF-1216 500 SC (Fluazinam 500SC) on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil. Generated by: Institut für Biologische Analytik und Consulting IBACON GmbH, Germany Report No. 13781016 GLP / GEP: yes unpublished	Y	ISK
Kleiner, R..	AIII, 10.4.1	1992	Testing Toxicity to Honey Bee - <i>Apis mellifera</i> L. (laboratory) According to BBA Guideline VI, 23-1.  BioChem GmbH Karlsruhe Labor Cunnersdorf, Germany, Report No. 921048038  GLP Yes, not published	N	ISK
Mills, H.	AIII, 10.6.1.3	2001	Field Study to Determine the Effects of a 500 g/L SC Formulation of Fluazinam on Earthworms. Generated by: Covance Laboratories Ltd, UK Report No. 1883/001-D2143 GLP / GEP: yes unpublished	Y	ISK
Reis, K-H.	AIII, 10.7.1	2002	Effects of Fluazinam 500 SC on the Activity of the Soil Microflora in the Laboratory. Generated by: Institut für Biologische Analytik und Consulting IBACON GmbH, Germany, Report No. 9321080 GLP / GEP: yes unpublished	Y	ISK

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Römbke, J., Moser, Th.	AIII, 10.6.1.2	1999	A Study on the Reproduction Toxicity of Fluazinam 500 g/L SC to the Earthworm <i>Eisenia andrei</i> (Bouche). Generated by: ECT Oekotoxikologie GmbH Report No. F3RR (Reference: WIno. 45373) GLP / GEP: yes unpublished	N	ISK
Sankey, S.A., Tapp, J.F., Caunter, J.E., Penwell, A.J.	AIII, 10.2.1	1991	Fluazinam: Acute Toxicity to Rainbow Trout ( <i>Oncorhynchus mykiss</i> ) of a 500 g/L SC Formulation. Generated by: Imperial Chemical Industries PLC, Group Environmental Laboratory Report No: BL4323/B GLP / GEP: yes unpublished	N	ISK
Smyth, D. V., Sankey, S.A., Stanley, R.D.	AIII, 10.2.1	1991	Fluazinam: Toxicity to the Green Alga <i>Selenastrum capricornutum</i> of a 500 g/L SC Formulation. Generated by: Imperial Chemical Industries PLC, Group Environmental Laboratory, UK Report No: BL4362/B GLP / GEP: yes unpublished	N	ISK
Thompson, B.	AIII, 10.5.1	1996	A Laboratory Evaluation of the Side-Effects of the Fungicide Fluazinam on Larvae of the Lacewing <i>Chrysoperla carnea</i> .  Agrochemical Evaluation Unit, Department of Biology, The University, Southampton, UK, Report No. ZEN-95-3/C  GLP Yes, not published	N	ISK
van Wijngaarden R., Boonstra H.	IIIA, 10.2.2	2004	Fate and effects of the fungicide Shirlan (active ingredient fluazinam) in indoor freshwater microcosms Generated by: Aquatic Ecology and Water Quality Management Group, Wageningen University, Wageningen, NL Report No: WA2004 GLP / GEP: no unpublished	Y	ISK
van Wijngaarden, Cuppen, Arts, Crum, van den Hoorn, van den Brink, Brock	IIIA, 10.2.2	2004	Aquatic risk assessment of a realistic exposure to pesticides used in bulb crops: A microcosm study. Report No: - GLP / GEP: - published: Environmental Toxicology and Chemistry, Vol. 23 No. 6 pp.1479-1498	-	-

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Yearsdon, H. A., Burgess, A. J., Coulson, J. M.	AIII, 10.6.1.1	1991	Fluazinam: Toxicity to the Earthworm ( <i>Eisenia fetida</i> ) of a 500g/litre Suspension Concentrate Formulation. Generated by:ICI Agrochemicals, UK Report No. RJ1087B GLP / GEP: yes unpublished	N	ISK