

Draft Assessment Report (DAR)

- public version -

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

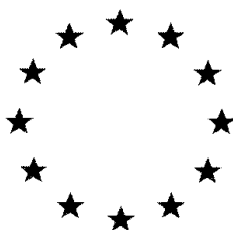
SODIUM HYPOCHLORITE

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

Volume 2, Annex A

February 2009

European Commission



SODIUM HYPOCHLORITE

VOLUME 2

ANNEX A

Rapporteur Member State: The Netherlands

May 2008

Draft Assessment Report and Proposed Decision of the Netherlands prepared in the context of the possible inclusion of sodium hypochlorite in Annex I of Council Directive 91/414/EEC

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A List of the tests 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)

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Lists of Annex IIA and Annex IIIA submitted data and studies are based on the reference lists provided by the notifier. In addition to the references given below, the notifier submitted Documents A-I, J, L, M, N and O.

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)

Confidential references are listed in Volume 4, Annex C.

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

References for the active substance

Author(s)	Annex point/ reference no.	Year	Title Company, report no. Source (where different from company) GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
ECB	IIA 2.13; 2.15	n.r.	For classification via ECB website	N	ECB
EU- ECB	IIA 2.1; 2.9	2000	IUCLID Dataset, sodium hypochlorite 19 Feb 2000 non GLP Published (via ECB website)	N	ECB
Guerisoli	IIA 2.4; 2.5	1998	GUERISOLI, D.M.Z.; SILVA, R.S.; PÉCORÁ, J.D. Evaluation of some physico-chemical properties of different concentrations of sodium hypochlorite solutions. <i>Braz. Endod. J.</i> 3(2): 21-3, 1998. Non GLP Published	N	-
Merck	IIA 2.6; 2.13	2001	Merck Index 13 th edition, 2001 Merck Research Laboratories, Whitehouse Station, New York, USA Senior Editor M.J. O'Neil non GLP Published	N	Merck
RAR (unknown)	IIA 2	2007	RISK ASSESSMENT REPORT FOR SODIUM HYPOCHLORITE, DRAFT November 2007 Italy non GLP Published (via ECB website)	N	ECB

Author(s)	Annex point/ reference no.	Year	Title Company, report no. Source (where different from company) GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
T.C.I.	IIA 2.1; 2.2; 2.9	2006	Pamphlet 96, Sodium Hypochlorite Manual The Chlorine Institute inc. Edition 3, April 2006 Non GLP Published (http://www.chlorineinstitute.org/)	N	The Chlorine Institute
Urban	IIA 2.7	1999	Bretherick's handbook of reactive chemical hazards, 6 th edition editor: P.G. Urben Butterworth-Heinemann, Linacre house, Jordan hill, Oxford OX2 *DP, Engeland published	N	BH
WHO	IIA 2.9	2000	Environmental Health Criteria 216, DISINFECTANTS AND DISINFECTANT BY-PRODUCTS Version November 30, 2000 Published non-GLP	N	WHO

References for the plant protection product

Author(s)	Annex point/ reference no.	Year	Title Company, report no. Source (where different from company) GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
ECB	IIIA 2.2	n.r.	for classification via ECB website	N	ECB
EU- ECB	IIIA 2.6	2000	IUCLID Dataset, sodium hypochlorite 19 Feb 2000 non GLP Published (via ECB website)	N	ECB
Guerisoli	IIIA 2.6	1998	GUERISOLI, D.M.Z.; SILVA, R.S.; PÉCOR, J.D. Evaluation of some physico-chemical properties of different concentrations of sodium hypochlorite solutions. <i>Braz. Endod. J.</i> 3(2): 21-3, 1998. Non GLP Published	N	-

Author(s)	Annex point/ reference no.	Year	Title Company, report no. Source (where different from company) GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
Merck	IIIA 2.2	2001	Merck Index 13 th edition, 2001 Merck Research Laboratories, Whitehouse Station, New York, USA Senior Editor M.J. O'Neil non GLP Published	N	Merck
RAR (unknown)	IIIA 2	2007	RISK ASSESSMENT REPORT FOR SODIUM HYPOCHLORITE, DRAFT November 2007 Italy non GLP Published (via ECB website)	N	ECB
T.C.I.	IIIA 2.7	2006	Pamphlet 96, Sodium Hypochlorite Manual The Chlorine Institute inc. Edition 3, April 2006 Non GLP Published (http://www.chlorineinstitute.org/)	N	The Chlorine Institute
Unknown	IIIA 2.5	Unknown	Wikipedia on internet, English version Published	N	Wikipedia

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

References for the active substance

Author(s)	Annex point/ reference no.	Year	Title Company, report no. Source (where different from company) GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
IPCS	IIA 3.8	1999	International Chemical Safety cards, Sodium hypochlorite (solution, active chlorine>10%) No. ICSC 1119 October 19, 1999 Published (internet) non-GLP	N	IPCS

Author(s)	Annex point/ reference no.	Year	Title Company, report no. Source (where different from company) GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
T.C.I.	IIA 3.8	2006	Pamphlet 96, Sodium Hypochlorite Manual The Chlorine Institute inc. Edition 3, April 2006 Non GLP Published (http://www.chlorineinstitute.org/)	N	The Chlorine Institute

References for the plant protection product

Author(s)	Annex point/ reference no.	Year	Title Company, report no. Source (where different from company) GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
T.C.I.	IIIA 4.1	2006	Pamphlet 96, Sodium Hypochlorite Manual The Chlorine Institute inc. Edition 3, April 2006 Non GLP Published (http://www.chlorineinstitute.org/)	N	The Chlorine Institute

Section A.4 Proposals for classification and labelling (Annex IIA 10; Annex IIIA 12.3 and 12.4)

The proposed classification and labelling for the active substance and the formulation is based on the physico-chemical, toxicological and ecotoxicological evaluation as presented in section B.2, B.6 and B.9 respectively.

Section A.5 Methods of analysis (Annex IIA 4; Annex IIIA 5)**References for the active substance**

Author(s)	Annex point/ reference no.	Year	Title Company, report no. Source (where different from company) GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
ISO	IIA 4.2.3	unknown	ISO method 7393:1985- Water quality -- Determination of free chlorine and total chlorine (part 1 to 3, part 1 corrected in 2001) available from www.iso.org published	N	ISO
Niosh	IIA 4.2.4	unknown	Niosh method 6011 for the determination of chlorine in air (www.cdc.gov/niosh/nmam/).	N	Niosh
RAR (unknown)	IIA 4.1	2007	RISK ASSESSMENT REPORT FOR SODIUM HYPOCHLORITE, DRAFT November 2007 Italy non GLP Published (via ECB website)	N	ECB
T.C.I.	IIA 4.1.1; 4.1.2	2006	Pamphlet 96, Sodium Hypochlorite Manual The Chlorine Institute inc. Edition 3, April 2006 Non GLP Published (http://www.chlorineinstitute.org/)	N	The Chlorine Institute
T.C.I.	IIA 4.2.4	2003	Pamphlet 73, atmospheric monitoring equipment for chlorine The Chlorine Institute inc. Edition 7, June 2003 Non GLP Published (http://www.chlorineinstitute.org/)	N	The Chlorine Institute

References for the plant protection product

Author(s)	Annex point/ reference no.	Year	Title Company, report no. Source (where different from company) GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
RAR (unknown)	IIA 5.1	2007	RISK ASSESSMENT REPORT FOR SODIUM HYPOCHLORITE, DRAFT November 2007 Italy non GLP Published (via ECB website)	N	ECB

Section A.6 Toxicology and metabolism (Annex IIA 5; Annex IIIA 7)**References for the active substance**

Author(s)	Annex point/ reference no.	Year	Title Company, report no. Source (where different from company) GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
RAR (unknown)	IIA 5	2007	RISK ASSESSMENT REPORT FOR SODIUM HYPOCHLORITE, DRAFT November 2007 Italy non GLP Published (via ECB website)	N	ECB

Section A.7 Residue data (Annex IIA 6; Annex IIIA 8 and 12.2)**References for the active substance**

Author(s)	Annex point/ reference no.	Year	Title Company, report no. Source (where different from company) GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
RAR (unknown)	IIA 6	2007	RISK ASSESSMENT REPORT FOR SODIUM HYPOCHLORITE, DRAFT November 2007 Italy non GLP Published (via ECB website)	N	ECB

Section A.8 Environmental fate and behaviour (Annex IIA 7; Annex IIIA 9)**References for the active substance**

Author(s)	Annex point / reference number	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien (AISE)	IIA 7.2.1; 7.2.2	1997	Technical Task Force HYPOCHLORITE BENEFITS AND SAFETY ASPECTS OF HYPOCHLORITE FORMULATED IN DOMESTIC PRODUCTS SCIENTIFIC DOSSIER March 1997	N	AISE
EPA RED facts	IIA 7.2.1	1991	R.E.D. Facts Sodium and Calcium Hypochlorite Salts United States environmental Protection Agency, Pesticides And Toxic Substances (7508W), 738-F-91-108, September 1991.	N	EPA
RAR (unknown)	IIA 7	2007	RISK ASSESSMENT REPORT FOR SODIUM HYPOCHLORITE, DRAFT November 2007 Italy non GLP Published (via ECB website)	N	ECB
T.C.I.	IIA 7.2.1	2006	Pamphlet 96: Sodium Hypochlorite Manual The Chlorine Institute inc. Edition 3, April 2006 Non GLP Published (http://www.chlorineinstitute.org/)	N	The Chlorine Institute
WHO	IIA 7.2.1	2000	Environmental Health Criteria 216, DISINFECTANTS AND DISINFECTANT BY-PRODUCTS Version November 30, 2000 Published non-GLP	N	WHO

References for the plant protection product

Author(s)	Annex point / reference number	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien (AISE)	IIIA 9.2.2; 9.3	1997	Technical Task Force HYPOCHLORITE BENEFITS AND SAFETY ASPECTS OF HYPOCHLORITE FORMULATED IN DOMESTIC PRODUCTS SCIENTIFIC DOSSIER March 1997	N	AISE

Section A.9 Ecotoxicology (Annex IIA 8; Annex IIIA 10)**References for the active substance**

Author(s)	Annex point/ reference no.	Year	Title Company, report no. Source (where different from company) GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
RAR (unknown)	IIA 8	2007	RISK ASSESSMENT REPORT FOR SODIUM HYPOCHLORITE, DRAFT November 2007 Italy non GLP Published (via ECB website)	N	ECB