

# **Draft Assessment Report (DAR)**

**- public version -**

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

**POTASSIUM HYDROGEN CARBONATE**

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

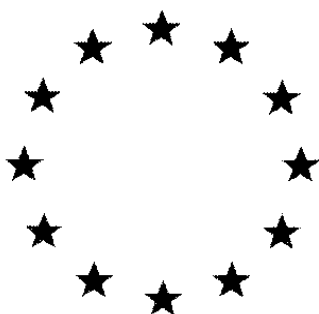
**Volume 2, Annex A**

**August 2008**

# **European Union**

## **Programme for Inclusion of Active Substances in Annex I to Council Directive 91/414/EEC**

(Articles 5 and 6 of Council Directive 91/414/EEC)



## **Bicarbonate, Salts of (Potassium)**

### **Volume 2 Annex A**

### **to the Draft Report and Proposed Decision**

List of tests and studies submitted and information  
available

April 2006



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Author(s)	Annex point/reference number	Year	Title Source (where different from company) Company name, Report No., date GLP status (where relevant), published or not	Data protection claimed	Owner
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**Identity of active substance**

Anonymous	IIA 1.11.1/02	2004	The United States Pharmacopoeia 1511/Official Monographs/Potassium No report number Not GLP Published	N	Public
Anonymous	IIA 1.11.1/03	2004	The United States Pharmacopoeia 2202/Limit Tests/Arsenic/{211} No report number Not GLP Published	N	Public
Anonymous	IIA 1.11.1/04	2004	The United States Pharmacopoeia 2204/Limit Tests/Heavy Metals/{231} No report number Not GLP Published	N	Public
Anonymous	IIA 1.11/05	Not stated	MSL-212: Determination of 'Specks' and 'Floaters' in Potassium Bicarbonate Armand Products Company Armand Products Company Report number MSL-212 Not GLP Unpublished	Y	Armand Products Company
Anonymous	IIA 1.11.1/06	Not stated	MSL-210: Determination of Grease, Oil and Metals in Potassium Bicarbonate Armand Products Company Armand Products Company Report number MSL-210 Not GLP Unpublished	Y	Armand Products Company
Church & Dwight Company Inc.	IIA 1.11.1/01	1994	Product chemistry: Armicarb™ Potassium Bicarbonate F.C.C Church & Dwight Company Inc. No report number Not GLP Unpublished	Y	Armand Products Company

**Physical/Chemical properties**

Anonymous	IIA 2.10 IIA 2.11.1 IIA 2.11.2	Not stated	Armand products Company Potassium Bicarbonate Handbook Armand Products Company No report number Not GLP Published	N	Armand Products Company
Church & Dwight Company Inc.	IIA 2.1.1 IIA 2.1.2 IIA 2.1.3 IIA 2.2 IIA 2.3.1 IIA	1994	Product chemistry: Armicarb™ Potassium Bicarbonate F.C.C Church & Dwight Company Inc. No report number GLP Unpublished	Y	Armand Products Company

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	2.4.1/02IIA				
	A				
	2.6/02IIA				
	2.8.1IIA				
	2.9.1IIA				
	2.9.2IIA				
	2.9.5				
Committee on Food Chemicals Codex	IIA 2.4.1/01IIA	1996	Food Chemicals Codex – Fourth Edition 313/FCC IV/Monograph Specifications No report number Not GLP Published	N	Public
Guillosson L	IIA 2.13	2005	Explosive Properties of Potassium Bicarbonate Swift Consulting, F11420, Belpech Armand products Company Report number ARM 001 Not GLP Unpublished	Y	Armand Products Company
Guillosson L	IIA 2.15	2005	Oxidizing Properties of Potassium Bicarbonate Swift Consulting, F11420, Belpech Armand Products Company Report number ARM 003 Not GLP Unpublished	Y	Armand Products Company
Lange N A	IIA 2.6/01	1961	Handbook of Chemistry – Tenth Edition No report number not GLP published	N	Public
Stoudt J	IIA 2.16	1997a	Measurement of the pH and the Bulk Density of Armicarb 100 Benchmarks Analytics, Center Valley, PA. 18034, USA Armand Products Company Report number CD0697-1 GLP Unpublished	Y	Armand Products Company
Stoudt J	IIA 2.17.2	1997b	Determination of the Storage Stability of the Active Ingredient in Armicarb 100 Benchmarks Analytics, Center Valley, PA. 18034, USA Armand Products Company Report number CD0697-2 GLP Unpublished	Y	Armand Products Company
Weaver S	IIA 2.17.1	1999	Determination of the Two Year Storage Stability of the Active Ingredient in Armicarb 100 Benchmarks Analytics, Center Valley, PA. 18034, USA Armand Products Company Report number CD06897-1 GLP Unpublished	Y	Armand Products Company

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**Data on application and further information**

Grove G., Nelson M., Xiao C-L.	IIA 3.6	2005	Stewardship of Powdery Mildew Fungicides in Perennial Crops <a href="http://fruit.wsu.edu/Diseases/stewardship.htm">http://fruit.wsu.edu/Diseases/stewardship.htm</a> Washington State University Irrigated Agriculture Research and Extension Center, Prosser, WA and Tree Fruit Research and Extension Center No report number Not GLP Published	N	Public
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**Methods of analysis**

Anonymous	IIA 4.2.1/03	2004	The United States Pharmacopoeia 1511/Official Monographs/Potassium No report number Not GLP Published	N	Public
Anonymous	IIA 4.2.1/04	2004	The United States Pharmacopoeia 2202/Limit Tests/Arsenic/{211} No report number Not GLP Published	N	Public
Anonymous	IIA 4.2.1/05	2004	The United States Pharmacopoeia 2204/Limit Tests/Heavy Metals/{231} No report number Not GLP Published	N	Public
Church & Dwight Company Inc.	IIA 4.2.1/02	1994	Product chemistry: Armicarb™ Potassium Bicarbonate F.C.C Church & Dwight Company Inc. No report number Not GLP Unpublished	Y	Armand Products Company
Olexa S	IIA 4.2.1/01	1997	Validation of the Analytical Method for the Quantitation of Potassium Bicarbonate Active Ingredient Benchmark Analytics, Center Valley, PA, USA Report number CD0497-1 GLP Unpublished	Y	Armand Products Company

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<b>Mammalian toxicology and metabolism</b>					
Beynen A.C., Van Wanrooy- Stroeken C.T.M	IIA 5.3.2/03	1981	Relations between dietary salt type, acidosis and hyperlipemia in rabbits on casein containing semipurified diets. Zeitschrift fur Tierphysiologie, Tierernaeh-rung und Futtermittelkunde, 46, 240-246, 1981. Report No : not stated Not GLP, Published.	No	-
Church & Dwight Co- Anonymous1	IIA 5.1/02IIA 5.3.3/02IIA 5.4IIA 5.5/03IIA 5.6/01IIA 5.11.1/01IIA 5.11.3/01	1994	ArmcarbTM , A safe and efficacious Pest Management Alternative. Dossier submitted by Church & Dwight Co, Inc. to US EPA for review under Safer Pesticide Policy. Not GLP, Unpublished	No	Armand Products Company
Church & Dwight Co- Anonymous2	IIA 5.1/03IIA 5.3.3/03IIA 5.6/02IIA 5.11.1/02	1994	Food Grade Sodium Bicarbonate, and Potassium Carbonate : A Safe and efficacious Pest Management Alternative. Dossier submitted by Church & Dwight Co, Inc. to US EPA for review under Reduced Risk Pesticide Initiative. Not GLP, Unpublished	No	Armand Products Company
Cohen S.	IIA 5.1/01IIA 5.5/02	1994	Review of the Carcinogenic Risk of Bicarbonates and Carbonates. University of Nebraska Medical Center, 600 South 42nd Street, Omaha, NE 68198-3135. Not GLP, Unpublished	No	Armand Products Company
De Groot A.P., Feron V.J. , Immel H.R.	IIA 5.3.2/02	1998	Induction of hyperplasia in the bladder epithelium of rats by a dietary excess of acid or base : implications for toxicity/ carcinogenicity testing. Food and Chemical Toxicology 26 (5) 425-434, 1988. Report No : not stated Not GLP, Published.	No	-
Environ Corp.	IIA 5.3.3/01	1993	Safety of Sodium Bicarbonate Supplementation of Animal Feeds. Environ Corporation, Arlington, Virginia Not GLP, Unpublished	No	Armand Products Company.

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Author(s)	Annex point/reference number	Year	Title Source (where different from company) Company name, Report No., date GLP status (where relevant), published or not	Data protection claimed	Owner
Fettman M.J.	IIA 5.9.3/03	2000	Dietary instead of pharmacological management to counter the adverse effects of physiological adaptations to space flight. Pflügers Arch – Eur J Physiol, 441 [suppl] :R15-R20, 2000. Report No : not stated Not GLP, Published	No	
Glaza S. M.	IIA 5.2.1	1993	Acute Oral Toxicity Study of Product 5649 Potassium Bicarbonate Lot # 1268M2 in Rats [REDACTED] Report N° HWI 30100993 GLP, Unpublished	Yes	Armand Products Company.
Glaza S. M.	IIA 5.2.2	1993	Acute Dermal Toxicity of Product 5649, Potassium Bicarbonate - Lot # 1268M2 in Rabbits [REDACTED] Report N° HWI 30100994. GLP, Unpublished	Yes	Armand Products Company.
Glaza S. M.	IIA 5.2.4	1993	Primary Dermal Irritation Study of Product 5649, Potassium Bicarbonate, Lot # 1268M2 in [REDACTED] Report No HWI 30100995. GLP, Unpublished	Yes	Armand Products Company.
Glaza S. M.	IIA 5.2.5	1993	Primary Eye Irritation Study of Product 5649, Potassium Bicarbonate, Lot # 1268M2 in rabbits [REDACTED] Report No HWI 30100996. GLP, Unpublished	Yes	Armand Products Company.
Glaza S. M.	IIA 5.2.6/01	1993	Dermal Sensitization Study of Product 5649, Potassium Bicarbonate, Lot # 1268M2 in guinea pigs- Closed Patch [REDACTED] Report No HWI 30100997. GLP, Unpublished	Yes	Armand Products Company.
Lemann J., Gray R. W. Pleuss J. A.	IIA 5.9.3/01	1989	Potassium bicarbonate, but not sodium bicarbonate, reduces urinary calcium excretion and improves calcium balance in healthy men. Kidney International, 35:688-695, 1989. Report No : not stated Not GLP, Published	No	-

Author(s)	Annex point/ reference number	Year	Title Source (where different from company) Company name, Report No., date GLP status (where relevant), published or not	Data protection claimed	Owner
Lindinger M.I.Franklin T.W.Lands L.C.Pedersen P.K.Welsh D.G.Heigenh auser G.J.	IIA 5.9.3/04	2000	NaHCO <sub>3</sub> and KHCO <sub>3</sub> ingestion rapidly increases renal electrolyte excretion in humans.J Appl. Physiol., 88:540-550, 2000. Report No : not stated Not GLP, Published	No	
Lina B.A.R., Kuijpers M.H.M.	IIA 5.3.IIIA 5.3.2/01II A 5.5/01	2004	Toxicity and carcinogenicity of acidogenic or alkalogenic diets in rats; effects of feeding NH <sub>4</sub> Cl, KHCO <sub>3</sub> or KCl.Food and Chemical Toxicology 42 (2004) 135-153. Report No : not stated Not GLP, Published	No	-
Sebastian A.Harris S.T.Ottaway J.H.Todd K.M.Morris R.C.	IIA 5.9.3/02	1994	Improved mineral balance and skeletal metabolism in postmenopausal women treated with potassium bicarbonate.New England journal of medicine, 330: 1776-1781, 1994. Report No : not stated, Not GLP, Published	No	-
Shapiro R.	IIA 5.2.3	1993	EPA Acute Inhalation Limit Test: Potassium Bicarbonate, Lot # [REDACTED] [REDACTED] Report No T-2630. GLP, Unpublished	Yes	Armand Products Company.
<b>Residue data</b> Anon.	IIA 6.9	2002	The World's Healthiest Foods. High-potassium foods. <a href="http://www.whfoods.com/genpage.php?tname=nutrient&amp;dbid=90">http://www.whfoods.com/genpage.php?tname=nutrient&amp;dbid=90</a> The World's Healthiest Foods No report number Not GLP Published	N	Public
Rutherford P.	IIA 6.9	2002	Potassium-40 in food <a href="http://www.philrutherford.com/K-40.pdf">http://www.philrutherford.com/K-40.pdf</a> No report number Not GLP Published	N	Public

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**Environmental Fate And Behaviour**

Barak, P.	IIA 7.1/02 IIA 7.4.1	1999	Essential Elements for Plant Growth: Potassium <a href="http://www.soils.wisc.edu/~barak/soilscience326/potassium.htm">http://www.soils.wisc.edu/~barak/soilscience326/potassium.htm</a> University of Wisconsin No report number Not GLP Published Salts and Salinization of surface waters <a href="http://www.gemswater.org/atlas-gwq/salts_e.html">http://www.gemswater.org/atlas-gwq/salts_e.html</a>	N	Public
Anon.	IIA 7.8	2002	No report number Not GLP Published Measure and manage: Soiless mixes, Testing and Nutrition Guidelines <a href="http://www.agtest.com/articles/soiless_mixes.htm">http://www.agtest.com/articles/soiless_mixes.htm</a>	N	Public
Cowan D.	IIA 7.1/01	Not stated	Agri-Food Laboratories CCA No report number Not GLP Published Soil Test Interpretation Guide <a href="http://eesc.orst.edu/agcomwebfile/edmat/EC1478.pdf">http://eesc.orst.edu/agcomwebfile/edmat/EC1478.pdf</a>	N	Public
Marx E.S., Hart J., Stevens R.G.	IIA 7.1/03	1996	Oregon State University Extension Service No report number Not GLP Published	N	Public
Meybeck, M.	IIIA 9.2.3	1979	Concentrations des eaux fluviales en element majeurs et apports en solution aux oceans. Rev. Geol. Dyn. Geogr. Phys., v. 21, p. 215-246.	N	Public
Meybeck, M.	IIIA 9.2.3	1980	Pathways of major elements from land to ocean through rivers. Proceedings of the Review and Workshop on River Inputs to Ocean Systems. Ed. J.-M., Martin, J. D. Burton and D. Eisma, pp. 18-30. Rome: FAO	N	Public

**Ecotoxicology**

Michael J. Bettencourt	IIA 8.2.1.1	1993a	Potassium Bicarbonate - Acute Toxicity To Rainbow Trout ( <i>Oncorhynchus mykiss</i> ) Under Flow-through Conditions [REDACTED] [REDACTED] [REDACTED] Report number 93-6-4812 GLP Unpublished	Yes	Armand Products Company.
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Michael J. Bettencourt	IIA 8.2.1.2	1993b	Potassium Bicarbonate - Acute Toxicity To Bluegill Sunfish ( <i>Lepomis macrochirus</i> ) Under Flow-through Conditions [REDACTED] Report number 93-5-4804 GLP Unpublished	Yes	Armand Products Company.
Maura K. Collins	IIA 8.7.2	1999	Armcarb® Sodium Bicarbonate - Acute Contact Toxicity test with Honey Bees Springborn Laboratories, Inc. 790 Main Street Wareham, Massachusetts 02571 Report number 98-11-7553 GLP Unpublished	Yes	Armand Products Company.
Environ Corp.	IIA 8.1	1993	Safety of Sodium Bicarbonate Supplementation of Animal Feeds. Environ Corporation, Arlington, Virginia Not GLP, Unpublished	No	Armand Products Company.
Arthur E. Putt	IIA 8.3.1.1	1993	Potassium Bicarbonate - Acute Toxicity To Daphnids ( <i>Daphnia Magna</i> ) Under Flow-Through Conditions Springborn Laboratories, Inc. Environmental Sciences Division 790 Main Street Wareham, Massachusetts 02571 Report number 93-6-4798 GLP Unpublished	Yes	Armand Products Company.