
REACH Borates Consortium

Letter of Access

CMK, s.r.o (the Applicant)
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SLOVAKIA

Letter of Access in respect of data relevant to the registration of the substance Boric acid (EC number: 233-139-2, CAS number: 10043-35-3) for the tonnage band 10-100T under Regulation 1907/2006 (REACH)

The Applicant intends to submit a REACH registration in respect of Boric acid (EC number: 233-139-2, CAS number: 10043-35-3).

As co-ordinator of the REACH Borates Consortium, Industrial Minerals Association – Europe aisbl (IMA) has received a request from the Applicant for the right to refer to certain data and study summaries.

1. INTERPRETATION

1.1 For the purposes of this letter:

Data means the full study reports specified in Annex 1 to this letter in respect of which IMA has been licensed to issue letters of access for the purposes of REACH.

Dossier means the data to be jointly submitted pursuant to Article 11(1) of REACH in respect of the Substance.

Intellectual property rights ("IPRs") means (a) copyright, database rights and unregistered rights in trade marks and designs (b) the right to apply for registration of any of the same (c) commercial and industrial know-how, confidential information and trade secrets and (d) all other intellectual property rights and equivalent or similar forms of protection existing anywhere in the world in the Licensed Studies. **Right to refer** means, in respect of the Data, the "right to refer" as required for compliance with Article 10 of REACH, but it does not include the right to modify, adapt, reproduce, copy, communicate to the public or distribute the Data.

2. RIGHT TO REFER

2.1 IMA grants to the Applicant a right to for the purposes of registering the substance Boric acid under REACH subject to the following conditions:

- (a) the right to refer to the Data granted by this letter is restricted only for the purpose of allowing the Applicant to make a REACH registration of the Substance (the Purpose);
- (b) the right to refer is solely granted in favour of the Applicant and the Applicant shall not assign, transfer, auction, charge, mortgage, sublicense or encumber the whole or any part of this letter of access or its obligations under it; and

- (c) This letter of access shall in no event be construed as granting the Applicant any property or ownership rights whatsoever in the Dossier or in any parts thereof.
- 2.2 The Applicant is not authorised to receive any copies of the Dossier [except for the Chemical Safety Report] or Information contained therein nor is the Applicant authorised to inspect or view the Dossier or any related specific document in whole or in part [except for the Chemical Safety Report].
- 3. CONFIDENTIALITY**
- 3.1 The Applicant shall, and shall procure that any of its employees, directors, subcontractors or professional advisers [and any employees, directors, subcontractors or professional advisers] (together, the **Permitted Users**) keep secret and confidential the Data and any information (whether or not technical) of a confidential nature communicated to it by (or on behalf of) IMA (in each case in any medium or format whatsoever, whether marked "confidential" or not) (together, the **Confidential Information**), either preparatory to or as a result of this letter and, subject to paragraph [3.3] of this letter, shall not disclose the same or any part of the same to any person.
- 3.2 The Applicant may only use the Confidential Information for the purposes of, and in accordance with, this letter. The Applicant may, with IMA's prior written consent (not to be unreasonably withheld or delayed), provide its Permitted Users with access to the Confidential Information on a strict "need to know" basis only. The Applicant shall ensure that each of its Permitted Users is bound to hold all Confidential Information in confidence to the standard required under this letter. Where a Permitted User is not an employee or director of the Applicant, or is not under a professional duty to protect confidentiality, the Applicant shall ensure that the Permitted User shall enter into a written confidentiality undertaking with IMA on substantially equivalent terms to this letter, a copy of which shall be provided to IMA upon request.
- 3.3 Paragraph [3.1] shall not apply to any Confidential Information which:
- (a) at the time of its supply by (or on behalf of) IMA is in the public domain;
 - (b) subsequently comes into the public domain, except through breach of any of the undertakings set out in this letter; or
 - (c) is required to be disclosed by law, regulation or any governmental or competent regulatory authority (including without limitation, any REACH enforcement authorities), provided that, to the extent reasonably practicable, the Applicant shall consult in advance with the relevant owner of the IPRs and IMA on the proposed form, timing, nature and purpose of the disclosure.
- 3.4 In the event that any unlicensed activities are carried on by any third party which could constitute unauthorised disclosure or the misuse of any of the Data, the party becoming aware of such a matter, or suspected matter, shall forthwith notify the other of it, and the Applicant shall join IMA and/or the relevant owner of the IPRs in taking all steps (if any) as, in the total discretion of IMA, shall be desirable for the protection of the IPRs. IMA and/or the relevant owner of the IPRs shall have the sole right and at IMA's absolute discretion, to determine the steps (if any) to be taken to protect or enforce the IPRs or any of them. The expenses incurred in taking such steps, and any profits or, damages, costs or other expenses which may be obtained, shall be (in the absence of agreement to the contrary) for the account of IMA and the relevant owner of the IPRs.

3.5 The provisions of paragraphs [3.1] to [3.4] of this letter shall remain in force notwithstanding the expiry or earlier termination of this letter.

4. TERMINATION

4.1 This letter shall automatically terminate with immediate effect in the event that the Applicant:

- (a) uses the Data for any purpose other than the Purpose;
- (b) assigns, transfers, charges, mortgages or encumbers the whole or any part of this letter of access or its obligations under it this letter; or
- (c) grants sub-licences under this letter.

4.2 The expiry or termination of this letter howsoever arising shall not limit any rights or liabilities of either party which may have accrued by, at or up to the date of such termination, nor shall it prevent the continuance in force of any provision of this letter which is expressly or by implication intended to come into force or continue in force on or after termination.

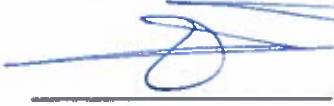
5. GOVERNING LAW

5.1 This letter and any disputes of claims arising out of or in connection with its subject matter are governed by and construed in accordance with the law of Belgium. The Belgian courts have exclusive jurisdiction to settle any dispute arising out of or in connection with this letter (including a dispute relating to any non-contractual obligations arising out of or in connection with this letter) and each party submits to the exclusive jurisdiction of the Belgian courts.



Please acknowledge your agreement to be bound by the above terms of this letter by signing and returning the enclosed copy.

Yours faithfully



Dr Roger Doome

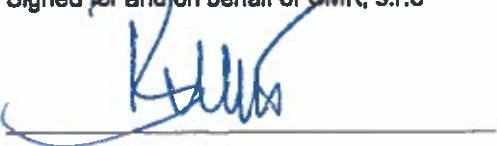
Signed for and on behalf of IMA-Europe aisbl

15 JUL 2019

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We hereby acknowledge and agree to the terms of this letter:

Signed for and on behalf of CMK, s.r.o



Name

DR. LABOS BENO

Position

CEO

Date

27/06/2019



ANNEX I

Boric acid - List of studies (Tonnage band 10-100T)

- Conine D (1982). An acute inhalation toxicity of boric acid in the rat. Testing laboratory: Bio/Dynamics Inc., Po Box 43 Mettlers Road, East, Millstone, New Jersey, 08873, USA for Hill Top research Inc, PO Box 42501, Cincinnati, Ohio 45242. Report no.: 82-7583. Owner company: U. S. Borax, Inc.
- Cordia JA, Bal EA, Mak WA & Wils ERJ (2003). Determination of some physico-chemical properties of Optibor EP. Testing laboratory: TNO Prlnz Maurits Laboratory. Report no.: PML 2002-C42rr. Owner company: Borax Europe Ltd. Report date: 2003-08-18.
- Culver BD, Shen PT, Taylor TH, Feldstein AL, Anton-Culver H & strong P. (1993). Absorption of boron by sodium and borate and boric acid production workers. Owner company: US Borax. Report date: 1993-08-10.
- Cuperus L (1990). Evaluation of the ocular irritation of anhydrous boric acid in rabbits. Testing laboratory: Biological Test Centre, 2525 McGaw Avenue, Irvine, CA 92714. Owner company: U. S. Borax Research. Report date: 1990-03-08.
- Denton SM (1995). Anhydrous boric acid acute oral toxicity study in the rat final report. Testing laboratory: Corning Hazleton (Europe), Otley Road, Harrogate, North Yorkshire UK. Report no.: 1341/3-1032. Owner company: Borax Europe Limited. Report date: 1995-10-18.
- Denton SM (1996). Acute oral toxicity study in the rat: anhydrous boric acid. Final report. Testing laboratory: Corning Hazleton (Europe) Otley Road, Harrogate, North Yorkshire, UK. Report no.: 1341/7-1032. Owner company: Borax Europe Ltd. Report date: 1996-03-06.
- Doyle RL (1989). Primary eye irritation of boric acid. Testing laboratory: Hill Top Biolabs Inc. Owner company: US Borax Chemical Corporation. Study number: 88-3444-21. Report date: 1989-02-07.
- Estep, CL (1968). Acute application of sample 713 123A to the eyes of rabbits. Testing laboratory: Hill Top Research Inc. Report no.: S-152A. Owner company: US Borax Research Corporation. Report date: 1968-05-16.
- Hanstveit, AO and H Oldersma (2000). Determination of the effect of Boric acid, Manufacturing grade on the growth of the fresh water green alga *Selenastrum capricornutum*. Testing laboratory: TNO Nutrition and Food Research Institute. Report no.: V99.157. Owner company: Borax Europe Limited. Study number: IMW-99-9047-05. Report date: 2000-03-06.
- Hanstveit AO and Schoonmade JA (2000). Screening of the effect of Boric acid, manufacturing grade on the respiration rate of activated sludge. TNO report IMW 99-9047-06. Testing laboratory: TNO nutrition and food research Institute, delft, The Netherlands. Report no.: V99.156. Owner company: Borax Europe limited. Study number: RespRateActSI/190299. Report date: 2000-01-05.
- Hartway T, Wester RC & Maibach HI (1997). In vitro percutaneous absorption of boric acid,



borax and octaborate tetrahydrate (DOT) in man. Testing laboratory: Surge Laboratory, Department of Dermatology, University of California, San Francisco. Report no.: UCSF95SU02. Owner company: U. S. Borax. Report date: 1997-07-28.

- Hui, X, Wester, RC & Maibach, HI. (1996). In vivo percutaneous absorption of boric acid, borax and octaborate tetrahydrate (DOT) in man. Testing laboratory: Surge Laboratory, Department of Dermatology, University of California, Box 0989, San Francisco, CA 94143. Report no.: H832-11830-01. Owner company: Borax Europe Ltd.
- Keller JG (1962). Acute Oral Administration - Rats Final Report. Testing laboratory: Hazleton Laboratories Inc. Owner company: Borax Europe Ltd. Study number: TX1962005. Report date: 1962-03-19.
- Keller, JG (1962). Boric acid acute oral administration - Dogs. Testing laboratory: Hazleton Nuclear Science Corporation, Palo Alto, CA 67500. Report no.: TX-62-4. Owner company: US Borax Chemical Corporation. Report date: 1962-03-16.
- Meyding GD. (1962). Boric acid. Acute Oral Administration -Rats Final Report. Testing laboratory: Hazleton Laboratories Inc., Falls Church, VA. Owner company: U. S. Borax, Inc. Study number: TX-61-2. Report date: 1961-01-25.
- O'Loughlin KG (1991). Bone Marrow Erythrocyte Micronucleus Assay of Boric Acid In Swiss Webster Mice. Testing laboratory: SRI International. Report no.: 2389-C400-91. Owner company: US Borax Inc. Report date: 1991-08-19.
- Pahl MV & Culver BD (2000). The effect of pregnancy on renal clearance of boron in humans: A study based on normal dietary intake of boron. Testing laboratory: Department of Nephrology, University of California, Irvine CA. Owner company: U. S Borax. Report date: 2000-04-04.
- Rudd CJ (1991). Mouse lymphoma cell mutagenesis assay of boric acid. Testing laboratory: SRI International. Report no.: 2389-G300-91. Owner company: US Borax Inc.
- Soucek, D, A Dickinson, K Major (2010). Acute and chronic toxicity of boron to freshwater organisms. Testing laboratory: Illinois Natural History Survey, University of Illinois, Champaign, Illinois. Owner company: Illinois Natural History Survey, University of Illinois.
- Spruit WET (2006). Determination of the water solubility of Boric Acid. Testing laboratory: TNO. Owner company: Borax Europe Ltd. Study number: TNO-DV2006 GLP240. Report date: 2006-06-11.
- Steber J., 1991, Ökologische Information zu Bor (Natriumtetraborat), Henkel KGaA, Fachabteilung Ökologie for Borax Research. Unpublished.
- Stewart KR (1991). Salmonella/microsome plate incorporation assay of boric acid. Testing laboratory: SRI International. Report no.: 2389-A200-91. Owner company: U. S. Borax. Report date: 1991-08-12.
- Taylor et al. (1985). The Acute Toxicity of Nine 'Grey List' Metals (Arsenic, Boron, Chromium, Copper, Lead, Nickel, Tin, Vanadium and Zinc) to Two Marine Fish Species: Dab (*Limanda*

limanda) and Grey Mullet (*Chelon labrosus*). *Aquatic Toxicology*, 7 (1985) 135-144. Testing laboratory: Brixham Laboratory, Imperial Chemical Industries PLC, Freshwater Quarry, Brixham, Devon TQ5 8 BA, and Water Research Centre, Medmenham Laboratory, Henley Road, P. O. Box 16, Marlow, Bucks SL7 2HD, U. K.

- Tremain SP (1998). Boric Acid: Determination of vapour pressure. Testing laboratory: SafePharm Laboratories Ltd. Report no.: 1231-002. Owner company: Borax Europe Ltd.
- Vaziri ND & Ovesisi F (2000). Evaluation of the renal clearance of boric acid in non-pregnant and pregnant Sprague-Dawley rats. Testing laboratory: Department of Nephrology, University of California, Irvine CA. Owner company: Borax Inc. Report date: 2000-04-04.
- Weiner AS, Conine DL & Doyle RL. (1982). Acute Dermal Toxicity Screen in Rabbits; Primary Skin Irritation Study in Rabbits of Boric Acid. Testing laboratory: Hill Top Research, Inc. Report no.: 82-0280-21. Owner company: US Borax Chemical Corporation. Report date: 1982-03-15.
- Wnorowski G (1997). Acute inhalation toxicity limit on boric acid MG. Testing laboratory: Test Product Safety Labs. Report no.: 5257. Owner company: U. S. Borax Inc.
- Wnorowski, G (1994). Acute inhalation toxicity limit test on boric acid. Testing laboratory: Product Safety Labs, US, East Brunswick, New Jersey, 0881. Report no.: 3311. Owner company: U. S. Borax, Inc. Report date: 1994-11-28.
- Wnorowski G (1994). Dermal sensitization test-Buehler method on boric acid. Testing laboratory: Product Safety Labs, US. Report no.: 3310. Owner company: U. S. Borax, Inc.
- Young JA (1973). Corrosivity study on a series of seven materials. Testing laboratory: International Bio-Research. Report no.: 73-641-21. Report date: 1973-12-05.
- Young, JA & Doyle, RL (1973). Corrosivity study on a series of ten materials. Testing laboratory: Hill Top Research Inc., Cincinnati, Ohio 45242. Report no.: 73-630-21. Owner company: U. S. Borax. Report date: 1973-12-03.
- Younis S (2010). REACH and CLP testing on a sample of ETI boric acid. Testing laboratory: Chilworth Technology Ltd. Report no.: GLP104486AR1V1. Owner company: Borates REACH Consortium.
- de Vette HQM, van Asten JG & Hanstveit AO (2000). A study on the adsorption/desorption of Boric acid manufacturing grade to soil particles in four soil types. Testing laboratory: TNO Nutrition and Food Research, Department of Environmental Toxicology. Report no.: IMW-99-9047-02. Owner company: Borax Europe Limited. Report date: 2000-08-24.

