

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2008-310-Rev 02

1 *Name of the substance:*

2 **BORIC ACID**

3 Granular and powder

4 *Name of holder:*

5 **BORAX FRANCAIS**

6 89 route de Bourbourg

7 France-59210 Coudekerque-Branche

8 *Site(s) of production:*

9 **SEE ANNEX 1**

10 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
11 **R1-CEP 2008-310-REV 01**

12 After examination of the information provided on the manufacturing method and subsequent
13 processes (including purification) for this substance on the site(s) of production listed in annex, we
14 certify that the quality of the substance is suitably controlled by the current version of the
15 monograph **BORIC ACID** no. 1 of the European Pharmacopoeia, current edition including
16 supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical
17 procedure(s) given in annex.

18 In the last steps of the synthesis water is used as solvent.

19 A risk management summary for elemental impurities has been provided. (Annex 2)

20 – Test for particle size by sieve retention (Annex 3)

21 Granular: not more than 2% of particles more than 1000 µm

22 Powder: not more than 3% of particles more than 250 µm

23 The re-test period of the substance is 36 months for the granular grade if stored in
24 polyethylene bags and for the powder grade if stored in a multiwall paper bag with a
25 polyethylene liner or for both grades if stored in a polyethylene bag placed in a fibre drum.

26 The holder of the certificate has declared the absence of use of material of human or animal
27 origin in the manufacture of the substance.

28 The submitted dossier must be updated after any significant change that may alter the quality,
29 safety or efficacy of the substance.