European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2009-207-Rev 03

Name of the substance:
BORAX
Granular and powder

Name of holder:
BORAX FRANCAIS
89 route de Bourbourg
France-59210 Coudekerque-Branche

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2009-207-REV 02

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

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

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

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

Granular:	not more than 2% of particles	more than 1000 µm
Powder:	not more than 2.5% of particles	more than 315 µm

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

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

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

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