

Certification of Substances Department

**Certificate of suitability
No. R1-CEP 2010-083-Rev 01**

1 *Name of the substance:*

2 **SODIUM CHLORIDE**

3 *Name of holder:*

4 **K+S FRANCE SAS**

5 1 rue des Docks Rémois

6 France-51100 Reims

7 *Site(s) of production:*

8 **SEE ANNEX 1**

9

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE

10

R1-CEP 2010-083-REV 00

11 After examination of the information provided on the manufacturing method and subsequent
12 processes (including purification) for this substance on the site(s) of production listed in annex, we
13 certify that the quality of the substance is suitably controlled by the current version of the
14 monograph **SODIUM CHLORIDE** no. 193 of the European Pharmacopoeia, current edition
15 including supplements.

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

17 The re-test period of the substance is 3 years if stored either in paper bags internally coated
18 with polyethylene or in a polyethylene bag placed in a paper bag.

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

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

23 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice
24 and in accordance with the dossier submitted.

25 Failure to comply with these provisions will render this certificate void.

26 This certificate is renewed from **8 March 2016** according to the provisions of Resolution AP-CSP
27 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,
28 and the related guidelines.

29 This certificate has one annex of 1 page.

30 This certificate has:

31 lines.



On behalf of the
Director of EDQM



Strasbourg, 8 July 2021

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

K+S FRANCE SAS, as holder of the certificate of suitability

R1-CEP 2010-083 Rev 01 for Sodium chloride

hereby authorises
(name of the pharmaceutical company)

to use the above-mentioned certificate of suitability in support of their application(s) for the following
Marketing Authorisation(s): *(name of product(s) and marketing number(s), if known)*

Unapproved Copy
For official approval
please contact us

The holder also certifies that no significant changes to the operations as described in the CEP dossier
have been made since the granting of this version of the certificate.

Date and Signature *(of the CEP holder)*:

Address: 7 Allée Kastner, CS 30026

F-67081 Strasbourg (France)

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Internet: <http://www.edqm.eu>

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Annex 1: Site(s) of production for R1-CEP 2010-083-Rev 01

Production of Sodium chloride:

K+S FRANCE SAS

Site Saline de Dombasle

ZA Solvay Porte Est - Route des Digues

France-54110 Dombasle-sur-Meurthe