

**Certification of Substances Department**

**Certificate of suitability**  
**No. R1-CEP 2012-347 - Rev 01**

1 *Name of the substance:*

2 **ZINC OXIDE**

3 *Name of holder:*

4 **EVERZINC NEDERLAND B.V.**

5 Muggenweg 2

6 The Netherlands-6245 AB Eijsden

7 *Site(s) of production:*

8 **SEE ANNEX 1**

9 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**

10 **R1-CEP 2012-347 - 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 **ZINC OXIDE** no. 252 of the European Pharmacopoeia, current edition including  
15 supplements.

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

17 The re-test period of the substance is 18 months if stored either in a four layer bag  
18 (paper/paper/polyethylene/paper) or in a polypropylene bag or in a triple layer paper bag  
19 placed in a polyethylene bag or in a four layer bag (polyethylene  
20 terephthalate/aluminium/polyamide/polyethylene) placed in a cardboard box.

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

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

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

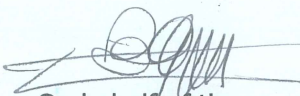
27 Failure to comply with these provisions will render this certificate void.



28 This certificate is renewed from **18 March 2019** according to the provisions of Resolution  
29 AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent  
30 amendment, and the related guidelines.

31 This certificate has two annexes, the first and the second of 1 page each.

32 This certificate has:  
33 lines.

  
On behalf of the  
Director of EDQM



Strasbourg, 13 April 2022

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

**EVERZINC NEDERLAND B.V.**, as holder of the certificate of suitability

**R1-CEP 2012-347 - Rev 01 for Zinc oxide**

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)*

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)*:



**Certification of Substances Department**

**Annex 1: Site(s) of production for R1-CEP 2012-347 - Rev 01**

**Production of Zinc oxide:**

EVERZINC NEDERLAND B.V.

Muggenweg 2

The Netherlands-6245 AB Eijsden



## Zinc Oxide

### Risk management summary.

Element	Class	Intentionally added	considered in risk management	conclusion
Cd	I	no	yes	$\leq 5$ ppm <sup>*1</sup>
Pb	I	no	yes	$\leq 10$ ppm <sup>*1</sup>
As	I	no	yes	$\leq 1$ ppm
Hg	I	no	yes	$\leq 1$ ppm
Co	2A	no	yes	$\leq 1$ ppm
V	2A	no	yes	$\leq 1$ ppm
Ni	2A	no	yes	$\leq 1$ ppm
Tl	2B	no	yes	$\leq 5$ ppm <sup>*1</sup>
Au	2B	no	no	-
Pd	2B	no	no	-
Ir	2B	no	no	-
Os	2B	no	no	-
Rh	2B	no	no	-
Ru	2B	no	no	-
Se	2B	no	yes	$\leq 1$ ppm
Ag	2B	no	no	-
Pt	2B	no	no	-
Li	3	no	no	-
Sb	3	no	no	-
Ba	3	no	no	-
Mo	3	no	no	-
Cu	3	no	yes	$\leq 1$ ppm
Sn	3	no	no	-
Cr	3	no	yes	$\leq 1$ ppm

\*1 is de specification of EP 10.6 Monograph 0252