ZINC OXIDE

CAS No: 1314-13-2

EINECS No: 215-222-5

SUMMARY RISK ASSESSMENT REPORT

PART I - ENVIRONMENT

Final report, May 2008

The Netherlands

This document has been prepared by the Ministry of Housing, Spatial Planning and the Environment (VROM) in consultation with the Ministry of Social Affairs and Employment (SZW) and the Ministry of Public Health, Welfare and Sport (VWS), on behalf of the European Union.

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NOTE:

Part II (Human Health) of the Summary Risk Report for zinc oxide has been published already in 2004 by the European Commission (see http://ecb.jrc.it).

PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance zinc oxide that has been prepared by The Netherlands in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances.

For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references the reader is referred to the comprehensive Final Risk Assessment Report (Final RAR) that can be obtained from the European Chemicals Bureau[1]. The Final RAR should be used for citation purposes rather than this present Summary Report.

It is noted that in the context of Council Regulation (EEC) No. 793/93 risk assessments were carried out for zinc metal (CAS No. 7440-66-6), zinc distearate (CAS No. 557-05-1 / 91051-01-3), zinc oxide (CAS No.1314-13-2), zinc chloride (CAS No.7646-85-7), zinc sulphate (CAS No.7733-02-0) and trizinc bis(orthophosphate) (CAS No.7779-90-0). All six substances are EU priority substances within Council Regulation (EEC) No. 793/93. For each compound a separate RAR and Summary RAR have been prepared. It should be noted, however, that the RAR Zinc metal contains specific sections (as well in the exposure part as in the effect part) that are relevant for the other zinc compounds as well. For these aspects, the reader is referred to the RAR Zinc metal.

[1] European Chemicals Bureau – Existing Chemicals – http://ecb.jrc.it

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1 GENERAL SUBSTANCE INFORMATION

See Part II – Human Health for data on ‘identification’, purity, impurities and additives’ and ‘physico-chemical properties’ of the substance.

Note: The following section on Classification and Labelling replaces the classification and labelling section that is included in Chapter 1 of the Human Health part of the Summary Risk Report for Zinc oxide (published in 2004), as the classification and labelling mentioned below is now included in Annex 1 of Directive 67/548/EEC.

CLASSIFICATION AND LABELLING

Annex 1 of Directive 67/548/EEC contains a list of harmonised classifications and labellings for substances or groups of substances, which are legally binding within the EU.
For zinc oxide the current Annex 1 classification and labelling (29^{th} ATP, 2004) is as follows:

<u>Classification</u>
N; R50-53

<u>Labelling</u>
N;
R50/53
S60-61

2 GENERAL INFORMATION ON EXPOSURE

2.1 PRODUCTION

Zinc oxide is produced (>1000t/y) at around thirty known sites in the European Union.

The total consumption volume of zinc oxide in the EU for 1995 is about 230,000 tonnes. The imported and exported volume of zinc oxide in the EU are 32,000 tonnes and 16,600 tonnes, respectively. With these figures an available use volume of approximately 250,000 tonnes per year can be calculated for the EU market. The production volume is about 241,000 tonnes per year, when it is based on the latest production volumes of each separate zinc oxide production plant. It is clear that both production volume estimates lead to comparable figures.

2.2 USE PATTERN

Table 2.1 shows the industrial and use categories of zinc oxide. Zinc oxide has a great scope of usages, for instance for the manufacture of rubber, tyres and general rubber goods (36%), glass and ceramics (27%), ferrites[2], varistors[3] and catalysts (12%), animal feed (9%), raw material for the production of zinc chemicals (4.5%), fuel and lubricants additives (4.5%), paints (4.5%) and cosmetics and pharmaceuticals (2%). The quantitative estimates, mentioned in between brackets, are from the year 1995 . The main types of use categories of zinc oxide can be characterised as non dispersive, wide dispersive and use resulting in inclusion into or onto matrix.

Table 2.1 Industrial and use categories of zinc oxide in the EU

Industrial category	**EC no.**	**Use category**	**EC no.**
Agricultural	1	Feedstuff additive	41
Chemical Industry: basic chemicals	2		
Chemical industry: chemicals used in synthesis	3	Others: Raw material for the production of zinc chemicals	55
Electrical/electronic engineering industry	4	Insulating materials Electroplating agent	32 17
Personal/domestic	5	Cosmetics Pharmaceuticals	15 41
Mineral oil and fuel industry	8	Lubricants additive	35
Polymers industry	11	Flame retardants and fire preventing agents Process regulators (activators) Stabilisers (UV absorber) Activator for vulcanising	22 43 49 53
Paints, lacquers and varnishes industry	14	Corrosion inhibitor Fillers Stabilisers (UV absorber)	14 20 49
Other: Ceramic industry	15	Insulating materials Construction materials additives	32 13

2 Zinc ferrites are basically zinc ferrite oxide spinals, which are highly magnetic. Ferrites are used in a wide variety of electrical and electronic devices.

3 Varistors are over-voltage protection devices, used in electrical and electronic equipment.

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

3.1.1 General introduction

The EU Technical Guidance Document (TGD, 2003) on risk assessment does not provide detailed information on how to deal with (essential) elements that have a natural background concentration in the environment, such as zinc. In the risk assessment reports (RARs) for zinc metal and zinc compounds, including the RAR for zinc oxide, the "added risk approach" has been used. In this approach both the "Predicted Environmental Concentration" (PEC) and the "Predicted No Effect Concentration" (PNEC) are determined on the basis of the added amount of zinc, resulting in an "*added* Predicted Environmental Concentration" (PEC_{add}) and "*added* Predicted No Effect Concentration" ($PNEC_{add}$), respectively.

In the present environmental exposure assessment, the use of the added risk approach implies that the PEC_{add} values have been calculated from zinc emissions due to anthropogenic activities. In the local exposure scenarios for zinc oxide that are presented in this RAR, the PEC_{add} values (which are expressed as zinc, not as zinc oxide) are based on the local zinc emissions due to the production or use of zinc oxide.
In the environmental effect assessment, the use of the added risk approach implies that the $PNEC_{add}$ values have been derived from toxicity data that are based on the added zinc concentration in the tests. Thus, the $PNEC_{add}$ is the maximum permissible addition to the background concentration. From the background concentration (Cb) and the $PNEC_{add}$, the PNEC can be calculated: $PNEC = Cb + PNEC_{add}$. It is emphasised that the $PNEC_{add}$ values were not derived from ecotoxicity data for zinc oxide (which is a poorly soluble zinc compound, with a water solubility limit of $\leq$1.6 mg/l), but derived from the combined ecotoxicity data for soluble zinc compounds, see further section 3.2.
Finally, in the environmental risk characterisation, the use of the added risk approach implies the evaluation of the PEC_{add} / $PNEC_{add}$ ratios. In case measured environmental concentrations are used in the risk characterisation, either the background concentration has to be subtracted from the measured environmental concentration (resulting in a "PEC_{add} / $PNEC_{add}$" ratio) or the background concentration has to be added to the $PNEC_{add}$ (resulting in a traditional "PEC / PNEC" ratio). See section 3.3.1 for additional explanation on the application of the added risk approach in the risk characterisation.

3.1.2 Environmental releases and fate

A general description about the release and fate of zinc in the environmental compartment is presented only in the RAR Zinc metal, but those data are applicable to all zinc compounds.

3.1.3 Local exposure assessment

Table 3.3 (included in section 3.3) shows the added Predicted Environmental Concentrations, i.e $Clocal_{add}$ and $PEClocal_{add}$ values ($(PE)C_{add}$s) for STP effluent, surface water, sediment and agricultural soil, based on the local exposure scenarios on the emissions of zinc due to the production or use of zinc oxide. The $(PE)C_{add}$s are derived from either modelling or measured exposure data. All concentrations are expressed as zinc and not as zinc oxide. These $(PE)C_{add}$s

have been used in the risk characterisation to calculate the (PE)C_{add} / $PNEC_{add}$ ratios (see section 3.3).
It is noted that the PEC_{add}s for agricultural soil include the added regional background concentration ($PECregional_{add}$), according to the TGD equation $PEClocal_{add} = Clocal_{add} + PECregional_{add}$. The $PECregional_{add}$ for soil is 0.5 mg/kg wwt (calculated value). For STP effluent, the PEC_{add} is equal to the $Clocal_{add}$, as there is no regional PEC_{add} for STP effluent. For water and sediment, the $Clocal_{add}$ values (thus without the regional PEC_{add}) are listed in **Table 3.3**, as in the risk characterisation for water and sediment initially only the $Clocal_{add}$ values have been compared with the corresponding $PNEC_{add}$. See section 3.3.1 for further explanation of the local risk characterisation.
The $Clocal_{add}$s for air (atmosphere) have been left out of consideration in the environmental part of the Summary RAR, as no $PNEC_{add}$ could be derived for air (there are no useful data on the effects of airborne zinc on environmental organisms. The $Clocal_{add}$s for air have been used in the risk assessment of man indirectly exposed via the environment (see Human Health part).

3.1.4 Regional exposure assessment

A regional exposure assessment is described only in the RAR Zinc metal. The regional exposure assessment includes the industrial and diffuse emissions of all six current EU priority zinc compounds. In case of diffuse emissions it is not possible to distinguish between emissions from current EU priority zinc compounds and non-EU priority list zinc compounds. The diffuse emissions may thus also comprise emissions from other zinc compounds.

3.2 EFFECTS ASSESSMENT

3.2.1 Aquatic and terrestrial compartment

3.2.1.1 Zinc oxide

Ecotoxicity data on zinc oxide are limited. The aquatic toxicity data for zinc oxide, summarised below, were submitted by the industry as full test reports, with the exception of the study with amphibian *Bufo bufo japonicus.* The available data comprise (short-term) tests with bacteria, algae, crustaceans, fish and amphibians. The submitted ZnO IUCLID data sheet *(ECB-version of 28 March 1995)* contained no ecotoxicity data, with the exception of the study with amphibian *Bufo bufo japonicus* (see below) and a study in which fish were orally exposed (not included in the RAR).
The terrestrial toxicity data for zinc oxide are from the Risk Assessment Report Zinc metal.

Aquatic toxicity - microorganisms
In the two 16-h tests with the bacterium *Pseudomonas fluorescens*, in which two different grades of ZnO were tested ("Pharma A", purity 99.9%, and "Rotsiegel", purity 99.5%), no growth inhibition was observed up to the highest concentration tested, i.e. 100,000 mg ZnO/l, nominal concentration, equivalent to 80,000 mg Zn/l. No reliable NOEC values can be derived from these tests because all test concentrations strongly exceeded the water solubility limit and actual dissolved zinc concentrations were not measured.

An activated sludge respiration inhibition test (according to OECD 209) was carried out with ZnO powder. The test was performed with activated sludge from a domestic STP and ZnO loading rates between 1 and 100 mg ZnO/l. The maximum tested loading rate of 100.4 mg ZnO/l, corresponding to 0.954 mg/l dissolved zinc, resulted in 7.9% inhibition. The EC50 for ZnO powder is therefore >100 mg ZnO/l, nominal concentration, equivalent to >80 mg Zn/l.
In addition, an activated sludge respiration inhibition test (according to OECD 209) was done with tyre debris of cars (fraction < 100 µm). The maximum tested loading rate of 99.4 mg/l tyre debris, corresponding to only 0.029 mg/l dissolved zinc, resulted in negligible inhibition (4.2%).

Aquatic toxicity – algae
The two tests with the unicelllular alga *Pseudokierchneriella subcapitata* (formerly known as *Selenastrum capricornutum),* in which two different grades of ZnO were tested ("Red sea l-grade", purity 99.77%, and "EPM-grade", purity 99.37%), resulted in 72-h E_rC50 values for dissolved zinc of 135 and 136 µg Zn/l, respectively, for endpoint specific growth rate. The 72-h NOE_rC values for dissolved zinc were 8 and 24 µg/l, respectively.
Both tests were performed according to OECD 201 and under GLP.

It is noted that similar growth inhibition tests with the same algal species have been conducted with either a soluble zinc compound or with zinc metal powder (see Table 3.3.2.a and Table 3.3.2.d, respectively, in Annex 3.3.2.A of the RAR Zinc metal). These tests and the above tests with ZnO, all using soft to very soft artificial test media, resulted in comparable NOEC values if expressed as dissolved zinc, i.e. NOEC values in the range of 5-50 µg/l, regardless whether a soluble or "insoluble" test compound was used.

Aquatic toxicity - invertebrates
A short-term *Daphnia magna* immobilisation test with "EPM-grade" ZnO (purity 99.37%) resulted in a 48-h EC50 for dissolved zinc of 1,760 µg/l and a 48-h NOEC for dissolved zinc of 280 µg/l. The test was performed according to OECD 202 and under GLP.

It is noted that the 48-h NOEC of 280 µg/l from this short-term test is within a factor of 2 of a number of NOEC values (endpoints: survival, reproduction and/or growth) derived in long-term *D. magna* tests in which a soluble zinc salt was used as test compound (see Table 3.3.2.a in Annex 3.3.2.A of the Risk Assessment Report on Zinc metal).

Aquatic toxicity - fish
In a 96-h acute toxicity test with fish *Brachydanio rerio* (test compound "EPM-grade" ZnO, purity 99.37%), no effect was found for dispersed ZnO at 100 mg ZnO/l (limit test), thus the 96-h EC50 is >100 mg ZnO/l, nominal concentration, equivalent to >80 mg Zn/l. The actual dissolved zinc concentration in this ZnO dispersion was 4,700 µg Zn/l.
The test was performed according to OECD 203 and under GLP.

Aquatic toxicity - amphibians
For tadpoles of the amphibian *Bufo bufo japonicus* exposed to ZnO, a 48-h EC50 for dissolved zinc of 3,200 µg Zn/l has been reported (static test, at pH 7.6); the toxicological endpoint was not reported.

Terrestrial toxicity
Table 3.3.3.a (toxicity of zinc to soil microbe-mediated processes) and Table 3.3.3.b (chronic toxicity of zinc to soil invertebrates) in Annex 3.3.3.A of the Risk Assessment Report on Zinc (Metal) include data on some tests in which ZnO was used as test compound, in addition to the majority of tests in which a soluble zinc salt was used as test compound. The results suggest that ZnO may be somewhat less toxic than soluble zinc, but the data for ZnO are much too limited for a firm conclusion. Based on differences in water solubility and, hence, most likely in bioavailability, it can be predicted that soluble zinc compounds will be more toxic to soil organisms than insoluble zinc compounds, at least shortly after the addition to soil. After a certain period of time, however, the toxicity will be less dependent on the zinc species that is added, because of transformations into other species. Ultimately, the resulting zinc speciation and bioavailability will mainly depend on the soil characteristics, and less on the original chemical form in which zinc was added to the soil.

Environmental risk assessment approach
Although zinc oxide is much less water soluble than zinc salts such as zinc sulphate and zinc chloride, zinc may be dissolved from zinc oxide solutions to a level that may result in toxic effects to aquatic and terrestrial organisms, see above. Once emitted into the environment, zinc oxide will (partly) be transformed into other zinc species. The further speciation of zinc, which includes complexation, precipitation and sorption, depends on the environmental conditions. Therefore, emitted zinc oxide and other emitted zinc species will contribute to the effect of the total amount of zinc in the environment, regardless of the original source or chemical form. For these reasons the risk characterisation for zinc oxide is based on zinc, not on zinc oxide as such, as explained also earlier in section 3.1 and in the RAR Zinc metal.

Because of the abovementioned approach, no effort has been made to retrieve additional ecotoxicity data on zinc oxide.

3.2.1.2 Zinc

For a comprehensive overview of the aquatic and terrestrial toxicity of (soluble) zinc, see the RAR Zinc metal and especially the Annexes of that report; the Annexes include detailed data on the ecotoxicity data bases for (soluble) zinc.

In the Risk Assessment Report on Zinc metal, $PNEC_{add}$ values have been derived for zinc, on the basis of tests with soluble zinc salts (especially zinc sulphate or zinc chloride), using the "added risk approach" (see also earlier in section 3.1 of the present report for an explanation of the added risk approach). These $PNEC_{add}$ values for zinc are listed in **Table 3.1** and used in the risk characterisation (see section 3.3).

Table 3.1 $PNEC_{add}$ values for zinc (from RAR Zinc metal)

Environmental compartment	**$PNEC_{add}$**	**$PNEC_{add}$ value, as Zn**	**Remark**
Freshwater (Hardness ≥ 24 mg/L) (1)	$PNEC_{add, aquatic}$	7.8 µg/l 21 µg /l	Dissolved zinc Total zinc (2)
Freshwater (Hardness <24 mg/L) (1)	$PNEC_{add, aquatic}$ softwater	3.1 µg/l	Dissolved zinc
Freshwater sediment	$PNEC_{add, sediment}$	49 mg/kg dwt 11 mg/kg wwt	Dry weight of sediment (3) Wet weight of sediment (3)
STP effluent	$PNEC_{add, microorganisms}$	52 µg/l	Dissolved zinc
Soil	$PNEC_{add, terrestrial}$	26 mg/kg dwt 23 mg/kg wwt	Dry weight of soil (4) Wet weight of soil (4)

(1) Total hardness (mg/l), as $CaCO_3$.

(2) Total-Zn concentration: calculated from the $PNEC_{add, aquatic}$ of 7.8 µg/l for dissolved zinc, a C_{susp} of 15 mg/l (according to the TGD, 2003) and a Kp_{susp} of 110,000 l/kg.

(3) For the dry to wet weight normalisation of the $PNEC_{add, sediment}$ it is assumed that wet sediment contains 10% solids (density 2500 kg/m^3) and 90% water (density 1000 kg/m^3) by volume, i.e. 22% solids by weight. These properties are set equal to those of suspended matter, thus the $PNEC_{add, suspended matter}$ equals the $PNEC_{add, sediment}$ (according to the TGD, 2003).

(4) For the dry to wet weight normalisation of the $PNEC_{add, terrestrial}$ it is assumed that wet soil contains 60% solids (density 2500 kg/m^3) and 20% water (density 1000 kg/m^3) by volume, i.e. 88% solids by weight.

3.2.2 Atmosphere

There are no data to derive an ecotoxicological $PNEC_{(add)}$ for zinc in the air compartment.

3.2.3 Secondary poisoning

Based on data on bioaccumulation of zinc in animals and on biomagnification (i.e. accumulation and transfer through the food chain), secondary poisoning is considered to be not relevant in the effect assessment of zinc, see further the RAR Zinc metal.

3.3 RISK CHARACTERISATION

3.3.1 Local risk characterisation

3.3.1.1 Local risk characterisation – methods

In the first step of the risk characterisation, the local added Predicted Environmental Concentrations ($PEClocal_{add}$s) in the various environmental compartments are compared with the corresponding added Predicted No Effect Concentrations ($PNEC_{add}$s). In case this yields a PEC_{add} / $PNEC_{add}$ ratio above 1, the risk characterisation includes (if possible) a second step in which a bioavailability correction is made, see **Table 3.2** for a summary of the bioavailability correction methods applied and see RAR Zinc metal sections 3.3.2.1.1 (water), 3.3.2.2.1 (sediment) and 3.3.3.1.1 (soil) for a comprehensive explanation of the derivation and application of these bioavailability correction methods[4]. In all cases the bioavailability correction is applied to the PEC_{add}, not to the generic $PNEC_{add}$, although for the resulting corrected PEC_{add} / $PNEC_{add}$ ratio it makes no difference whether the correction is applied to the PEC_{add} or to the $PNEC_{add}$.

- For water there is only a site-specific bioavailability correction, i.e. a bioavailability correction is only applied in case there are reliable site-specific data on the abiotic water characteristics that are needed to apply the BLM models. Bioavailability factors are being derived for two scenarios of abiotic conditions. One scenario refers to an average setting and the second one to a 'realistic worst case' setting. The highest bioavailability factor ($BioF_{water}$) is subsequently used in the risk characterisation by multiplying the original $(PE)C_{add}$ with this $BioF_{water}$. If a site has a discharge to seawater, no bioavailability correction is performed, as the BLM models were developed for freshwaters.
- For sediment the bioavailability correction is either site-specific (preference) or generic.
- For soil the bioavailability correction starts with the application of the generic lab-to-field correction factor (R_{L-F}) and if the corrected PEC_{add} / $PNEC_{add}$ ratio still is >1, then a further, site-specific bioavailability correction is applied.

Final conclusions of the risk assessment are based on the corresponding 'corrected' PEC_{add} / $PNEC_{add}$ ratios.

Table 3.2 Bioavailability corrections as applied in the EU RARs on zinc and zinc compounds

Compartment	***Added* Predicted Environmental Concentration (PEC_{add})**	
	Bioavailability correction (generic)	**Bioavailability correction (site-specific or region-specific)**
Water	None	Biotic Ligand Models (BLMs) for algae, Daphnia and fish (a)
Sediment	Factor of 2 (b)	Acid Volatile Sulphide (AVS) method (c)
Soil	Factor of 3 (d) (R_{L-F})	Regression lines for invertebrates, plants and microbial processes (e)

(a) Water – BLMs: Based on the relationship between toxicity of zinc and water characteristics, e.g. pH, dissolved organic carbon (DOC) and hardness (see RAR Zinc metal Section 3.3.2.1.1 for further explanation).
(b) The PEC_{add} (or measured concentration) for zinc in sediment is divided by a generic, AVS-related correction factor of 2 to obtain the bioavailable concentration of zinc (note that in the original description of this method in section 3.3.2.2.1 of the RAR Zinc metal it is stated that the PEC_{add} is multiplied with a factor of 0.5). The corrected PEC_{add} is subsequently used in the assessment of the PEC_{add} / $PNEC_{add}$ ratio.
(c) Sediment – AVS method: Based on the inverse relationship between toxicity of zinc and AVS content in sediment (see RAR Zinc metal Section 3.3.2.2.1 for further explanation).
This method is also described as the SEM/AVS-method, as also the toxicity of other metals, i.e. Cd, Cu, Ni, Hg and Pb, referred to as Simultaneously Extracted Metals (SEM) is reduced by AVS.
(d) The PEC_{add} (or measured concentration) for zinc in soil is divided by a generic, ageing-related lab-to-field correction factor (R_{L-F}) of 3 to obtain the bioavailable concentration of zinc. The corrected PEC_{add} is subsequently used in the assessment of the PEC_{add} / $PNEC_{add}$ ratio.
(e) Soil – Regression lines: Based on the relationship between toxicity of zinc and soil characteristics, e.g. pH and cation exchange capacity (CEC) (see RAR Zinc metal Section 3.3.3.1.1 for further explanation).

4 No bioavailability correction is done for the PEC_{add} in STP effluent. It is noted that in the main report (RAR Zinc oxide) the notation PEC_{STP} has been used as synonym for the PEC_{add} in STP effluent.

For STP effluent and soil, the PEC_{add}s are compared in the first step of the risk characterisation with the corresponding $PNEC_{add}$s, as stated above.

For water and sediment, initially only the $Clocal_{add}$ values (thus without the $PECregional_{add}$) are compared in the first step of the risk characterisation with the corresponding $PNEC_{add}$s. At first the local aquatic risk characterisation thus focuses on the contribution of point sources to the potential risks, thereby neglecting the contribution of diffuse sources. If the regional PEC_{add} would have been added for sediment, all local scenarios would have resulted in $PEC_{add}/PNEC_{add}$ ratios larger than 1. This because the regional PEC_{add} for sediment already exceeds the $PNEC_{add}$ of 11 mg/kg wwt. This holds for both calculated and measured sediment concentrations. For this reason for sediment for all scenarios with a $Clocal_{add}/PNEC_{add}$ ratio between 0 and 1 a **conclusion iii*** will be drawn, indicating that due to (possibly) high added regional background concentrations a risk for sediment at local scale cannot be excluded. It has to be noted that this conclusion would not be influenced by applying the generic sediment bioavailability correction factor (BioF) of 0.5 in the second step of the risk assessment.

The situation is somewhat less pronounced for the surface water compartment. With a $PNEC_{add}$ of 7.8 µg/l the regional PEC_{add} / $PNEC_{add}$ would lie between 0.8 (regional PEC_{add} of 6.7 µg/l) and 1.1 (regional PEC_{add} of 8.8 µg/l). When using an (arbitrary) average bioavailability correction factor (BioF) of 0.6[5] in the second step of the risk assessment, these ratios would become, respectively 0.5 and 0.7. As a result of this, it is decided that for $Clocal_{add}/PNEC_{add}$ ratios between 0.5[6] and 1 a **conclusion iii*** will be drawn, indicating that due to (possibly) high (added) regional background concentrations a local risk for water cannot be excluded. For scenarios with a surface water $Clocal_{add}$ / $PNEC_{add}$ ratio < 0.5 the local contribution to the (added) regional background is assumed to be negligible (**conclusion ii**).

For those scenarios in which the involved process type does intrinsically not result in water emissions a **conclusion ii)** is drawn for water and sediment.

It is important to note that the above-mentioned distinction between a (normal) conclusion iii) and a conclusion iii*) is not only made because of transparency, but also because the regional background is due to a variety of zinc compounds (and thus not only the zinc compound specifically addressed in the local risk characterisation).

In the RAR zinc metal a general reflection is given on the uncertainties in the zinc risk assessments.

3.3.1.2 Local risk characterisation - results

Table 3.3 shows the local C_{add} and PEC_{add} values ($(PE)C_{add}$ values) and the corresponding $(PE)C_{add}$ / $PNEC_{add}$ ratios for STP effluent, surface water, sediment and agricultural soil, based on the local exposure scenarios. It is emphasised that the $(PE)C_{add}$ values and thus the $(PE)C_{add}$ / $PNEC_{add}$ ratios in **Table 3.3** were not corrected for bioavailability. Subsequent

5 See data in RAR Zinc Metal. Average of realistic worst case and average BioF for average NL data.

6 A $Clocal_{add}$ / $PNEC_{add}$ of between 0.5 and 1 should theoretically also be corrected for bioavailability. This would give ratios between 0.3 and 0.6 when using the correction factor of 0.6. Such ratios could just raise the overall PEC_{add} / $PNEC_{add}$ ratio, thus including the regional background, to levels above one.

corrections for the bioavailability of zinc in water, sediment and soil (if allowed) were then applied on the (PE)C_{add} values in case the uncorrected (PE)C_{add} / PEC_{add} ratio is above 1.
No bioavailability correction is done for the PEC_{add} STP.
Table 3.4 presents the overall results of the local risk characterisation after the various bioavailability correction steps (if relevant). The conclusions of the risk assessment for the different local scenarios are based on the data in this table.

Aquatic compartment (including sediment)

STP-effluent
Production:
The PEC_{add} in STP effluent is below the $PNEC_{add}$ for microorganisms at all production sites of zinc oxide (**conclusion ii**).
Use categories:
The PEC_{add} in STP effluent of the processing sites of zinc oxide exceeds the $PNEC_{add}$ for microorganisms in a number of scenarios (‘glass industry (average and largest use)’, ‘varistor industry 3’, ‘catalysts processing’, ‘lubricants formulation (average and largest use)’, ‘paints processing (generic’ and ‘cosmetics formulation (average and largest use) (**conclusion iii**). The PEC_{added} / $PNEC_{add}$ ratio is <1 for the remaining scenarios **(conclusion ii).**

Surface water
Production:
The $Clocal_{add}$ water is below the $PNEC_{add}$ (ratio also <0.2) for surface water at all production sites of zinc oxide (**conclusion ii**).
Use categories:
The $Clocal_{add}$ in water for the processing sites of zinc oxide exceeds the $PNEC_{add}$ for surface water in a number of scenarios (‘glass industry (average and largest use)’, ‘varistor industry 3’, ‘catalysts processing’, ‘lubricants formulation (average and largest use)’, ‘paints processing (generic)’ and ‘cosmetics formulation (average and largest use). As relevant data are lacking to perform a correction for bioavailability for surface water (BLM), no additional correction can be carried out for these scenarios This implies that the original surface water risk characterisation ratios from **Table 3.3** remain unchanged (**conclusion iii**).
For the scenario ‘ferrites industry site 2’ the $Clocal_{add}$ / $PNEC_{add}$ ratio is between 0.5 and 1, indicating that due to (possibly) high regional background concentrations potential risk at local scale cannot be excluded (**conclusion iii***). The $Clocal_{add}$ / $PNEC_{add}$ ratio is <0.5 for the remaining scenarios **(conclusion ii).**

Sediment
Production:
For all production sites, except site no. 13, the $Clocal_{add}$ in sediment is below the $PNEC_{add}$ in sediment of 11 mg/kg wwt. The process type does not result in emissions to water and therefore a **conclusion ii)** is drawn for these sites (see also section 3.3.1.1.). For site 13 relevant data are lacking to perform a site-specific correction for bioavailability in sediment (SEM/AVS method). Therefore only the generic sediment bioavailability correction factor of 0.5 can be applied (multiplication of original $Clocal_{add}$ with 0.5). After this correction the $Clocal_{add}$ / $PNEC_{add}$ ratio remains above 1 for this scenario **(conclusion iii).**
Use categories:
The $Clocal_{add}$ in sediment for the processing sites of zinc oxide exceeds the $PNEC_{add}$ in a great number of scenarios (‘glass industry (average and largest use)’, ‘ferrites industry 2 and 3’, ‘varistor industry 3 and 4’, ‘catalysts processing’, ‘lubricants formulation (average and

largest use)', 'paints processing (generic)' and 'cosmetics formulation (average and largest use)' and 'cosmetics private use'. Relevant data are lacking to perform a site-specific correction for bioavailability in sediment (SEM/AVS method). Therefore only the generic sediment bioavailability correction factor of 0.5 can be applied for these scenarios. This implies that the original sediment $Clocal_{add}$ from **Table 3.3** are multiplied with a factor 0.5. After this correction the $Clocal_{add}$ / $PNEC_{add}$ ratio remains above 1 for these scenarios (**conclusion iii**). For the remaining scenarios the $Clocal_{add}$ / $PNEC_{add}$ ratio is below 1, but due to (possibly) high regional background concentrations a potential risk at local scale cannot be excluded (**conclusion iii***). However, for the use of ZnO in the tyre industry, the general rubber industry, the ceramic industry, paint industry (formulation and processing) and feedstuff additive formulation, it was stated that the process type does not result in water emissions. Therefore a **conclusion ii)** is drawn for these scenarios (see also section 33.1.1).

Terrestrial compartment

Production:
All production sites have a PEC_{add} / $PNEC_{add}$ ratio <1 for the terrestrial compartment **(conclusion ii).**

Use categories:
The PEC_{add} in soil for the processing sites of zinc oxide exceeds the $PNEC_{add}$ in a number of scenarios ('ferrites industry 3', 'lubricants formulation (average and largest use)', 'paints processing (generic)', 'glass industry (average and largest use)' and 'cosmetics formulation (average and largest use)'. As relevant data are lacking to perform a site-specific correction for bioavailability in soil (soil type characteristics), only the generic soil correction factor of 3 (R_{L-F}: ageing aspects) can be applied for these scenarios. This implies that the original terrestrial PEC_{add}s from **Table 3.3 a**re divided by a factor 3. After this correction the PEC_{add} / $PNEC_{add}$ for soil remains above 1 for most of these scenarios (**conclusion iii**). For all other scenarios the (corrected) PEC_{add} / $PNEC_{add}$ ratio is <1 (**conclusion ii**).

Atmosphere
Not applicable, as no ecotoxicological $PNEC_{(add)}$ for the air compartment could be derived.

3.3.2 Regional risk characterisation

See RAR Zinc metal.

3.3.3 Secondary poisoning

Not relevant (see section 3.2.3).

Table 3.3 Local exposure assessment – (PE)C_{add}s and (PE)C_{add}/$PNEC_{add}$ ratios for the different scenarios (no correction for bioavailability)

Company	**PEC_{add} effluent STP (dissolved)**	**C_{add} water (dissolved)**	**C_{add} sediment**	**PEC_{add} agricultural soil**	**PEC_{add} / $PNEC_{add}$ STP**	**C_{add} / $PNEC_{add}$ water**	**C_{add} / $PNEC_{add}$ sediment**	**PEC_{add} / $PNEC_{add}$ agr. soil**
	(µg/l)	**(µg/l)**	**(mg/kgwwt)**	**(mg/kgwwt)**				
Production companies:[1)]								
Company 1	0	0	0	5.46	0	0	0	0.23
Company 2	0	0	0	0.694	0	0	0	0.03
Company 3	0	0	0	0.63	0	0	0	0.03
Company 4	0	0	0	0.579	0	0	0	0.02
Company 5	0	0	0	0.593	0	0	0	0.02
Company 6	0	0	0	0.812	0	0	0	0.03
Company 7	0	0	0	1.34	0	0	0	0.06
Company 8	0	0	0	0.575	0	0	0	0.02
Company 10	0	0	0	0.739	0	0	0	0.03
Company 11	0	0	0	0.903	0	0	0	0.04
Company 12	0	0	0	1.25	0	0	0	0.05
Company 13	7.8	1.26	30.1	1.29	0.15	0.16	2.9	0.05
Company 16	0	0	0	3.38	0	0	0	0.14
Company 17	0	0	0	0.871	0	0	0	0.04
Company 18	0	0	0	0.691	0	0	0	0.03
Company 20	0	0	0	1.18	0	0	0	0.05
Company 22	0	0	0	0.819	0	0	0	0.03
Company 23	0	0	0	0.64	0	0	0	0.03
Company 24	0	0	0	1.04	0	0	0	0.04
Company 25	0	0	0	0.552	0	0	0	0.02
Company 26	0	0	0	0.536	0	0	0	0.02
Company 27	0	0	0	0.52	0	0	0	0.02
Company 28	0	0	0	0.603	0	0	0	0.03
Company 29	0	0	0	1.16	0	0	0	0.05
Companies 30-34	0	0	0	0.931	0	0	0	0.04

Company	**PEC_{add} effluent STP (dissolved)**	**C_{add} water (dissolved)**	**C_{add} sediment**	**PEC_{add} agricultural soil**	**PEC_{add} / $PNEC_{add}$ STP**	**C_{add} / $PNEC_{add}$ water**	**C_{add} / $PNEC_{add}$ sediment**	**PEC_{add} / $PNEC_{add}$ agr. soil**
	(µg/l)	**(µg/l)**	**(mg/kgwwt)**	**(mg/kgwwt)**				
Use categories:								
Tyre industry: processing	0	0	0	3.64	0	0	0	0.15
General rubber industry: processing	0	0	0	2.01	0	0	0	0.08
Glass industry: processing (average use)	121	19.6	469	68.3	2.3	2.5	45	2.8
Glass industry: processing (largest use)	302	49.1	1173	171	5.8	6.3	113	7.1
Ceramic industry: processing (average)	0	0	0	3.44	0	0	0	0.14
Ceramic industry: processing (range)	0	0	0	1.37-9.16	0	0	0	0.06-0.38
Ferrites industry: site 1	2.02	0.327	7.82	3.96	0.04	0.04	0.75	0.17
Ferrites industry: site 2	30.9	5.05	121	5.04	0.59	0.65	11.6	0.21
Ferrites industry: site 3	18.8	3.05	73	25.2	0.36	0.39	7	1.1
Ferrites industry: site 4	0.55	0.0892	2.13	1.49	0.01	0.01	0.21	0.06
Varistor industry: site 1	5.81	0.943	22.6	3.76	0.11	0.12	2.2	0.16
Varistor industry: site 2	0	0.0453	1.08	0.567	0.01	0.01	0.1	0.02
Varistor industry: site 3	372	60.4	1444	0.509	7.2	7.7	139	0.02
Varistor industry: representative for site 4	17.5	2.83	67.8	3.15	0.34	0.36	6.5	0.13
Catalysts: processing	≤ 233	≤ 38	≤ 926	0.540	<4.5	<4.9	<89	0.02
Feedstuff additive: formulation (site specific)	0	0	0	0.501	0	0	0	0.02
Feedstuff additive: formulation (generic average use)	0	0	0	0.62	0	0	0	0.03
Feedstuff additive: formulation (generic largest use)	0	0	0	1.15	0	0	0	0.05
Lubricants: formulation (average use)	360	58.4	1395	204	6.9	7.5	134	8
Lubricants: formulation (largest use)	630	102	2444	356	12	13	235	15
Lubricants: private use	0.083	0.0238	0.569	0.549	0.0016	0.0031	0.05	0.02
Paints: formulation	0	0	0	0.5	0	0	0	0.02
Paints: processing (industry data)	0	0	0	0.5	0	0	0	0.02
Paints: processing (generic data)	75.6	12.3	293	42	1.5	1.6	28	1.8
Cosmetics pharmaceuticals: formulation (average use)	121	19.6	469	68.3	2.3	2.5	45	2.8
Cosmetics pharmaceuticals: formulation (largest use)	1,008	164	3910	566	19	21	376	24

Company	**PEC_{add} effluent STP (dissolved)**	**C_{add} water (dissolved)**	**C_{add} sediment**	**PEC_{add} agricultural soil**	**PEC_{add} / $PNEC_{add}$ STP**	**C_{add} / $PNEC_{add}$ water**	**C_{add} / $PNEC_{add}$ sediment**	**PEC_{add} / $PNEC_{add}$ agr. soil**
	(μg/l)	**(μg/l)**	**(mg/kgwwt)**	**(mg/kgwwt)**				
Cosmetics pharmaceuticals: private use	20.7	3.36	80.3	12.1	0.40	0.43	7.7	0.50

1) Some companies (numbers 9, 14, 15, 19, 21) proved to be not a zinc oxide producer and therefore no information is presented for these companies.

Table 3.4 Local exposure assessment –uncorrected and corrected (PE)C_{add} / $PNEC_{add}$ ratios for the different scenarios

	Uncorrected				Corrected	
Company	**PEC_{add} / $PNEC_{add}$ STP**	**C_{add} / $PNEC_{add}$ water**	**C_{add} / $PNEC_{add}$ sediment**	**PEC_{add} / $PNEC_{add}$ agr. soil**	**C_{add} / $PNEC_{add}$ sediment**	**PEC_{add} / $PNEC_{add}$ agr. soil**
Production companies						
Company 1	0	0	0	0.23		
Company 2	0	0	0	0.03		
Company 3	0	0	0	0.03		
Company 4	0	0	0	0.02		
Company 5	0	0	0	0.02		
Company 6	0	0	0	0.03		
Company 7	0	0	0	0.06		
Company 8	0	0	0	0.02		
Company 10	0	0	0	0.03		
Company 11	0	0	0	0.04		
Company 12	0	0	0	0.05		
Company 13	0.15	0.16	2.9	0.05	**1.5**	
Company 16	0	0	0	0.14		
Company 17	0	0	0	0.04		
Company 18	0	0	0	0.03		
Company 20	0	0	0	0.05		
Company 22	0	0	0	0.03		
Company 23	0	0	0	0.03		
Company 24	0	0	0	0.04		
Company 25	0	0	0	0.02		
Company 26	0	0	0	0.02		
Company 27	0	0	0	0.02		
Company 28	0	0	0	0.03		
Company 29	0	0	0	0.05		

Company	Uncorrected				Corrected	
	PEC_{add} / $PNEC_{add}$ STP	**C_{add} / $PNEC_{add}$ water**	**C_{add} / $PNEC_{add}$ sediment**	**PEC_{add} / $PNEC_{add}$ agr. soil**	**C_{add} / $PNEC_{add}$ sediment**	**PEC_{add} / $PNEC_{add}$ agr. soil**
Companies 30-34	0	0	0	0.04		
Use categories:						
Tyre industry: processing	0	0	0	0.15		
General rubber industry: processing	0	0	0	0.08		
Glass industry: processing (average use)	**2.3**	**2.5**	45	2.8	**23**	0.93
Glass industry: processing (largest use)	**5.8**	**6.3**	113	7.1	**57**	**2.4**
Ceramic industry: processing (average)	0	0	0	0.14		
Ceramic industry: processing (range)	0	0	0	0.06-0.38		
Ferrites industry: site 1	0.04	0.04	0.75	0.17		
Ferrites industry: site 2	0.59	0.65	11.6	0.21	**5.8**	
Ferrites industry: site 3	0.36	0.39	7	1.1	**3.5**	0.37
Ferrites industry: site 4	0.01	0.01	0.21	0.06		
Varistor industry: site 1	0.11	0.12	2.2	0.16	**1.1**	
Varistor industry: site 2	0.01	0.01	0.1	0.02		
Varistor industry: site 3	**7.2**	**7.7**	139	0.02	**70**	
Varistor industry: representative for site 4	0.34	0.36	6.5	0.13	**2.3**	
Catalysts: processing	**<4.5**	**<4.9**	<89	0.02	**< 45**	
Feedstuff additive: formulation (site specific)	0	0	0	0.02		
Feedstuff additive: formulation (generic average use)	0	0	0	0.03		
Feedstuff additive: formulation (generic largest use)	0	0	0	0.05		
Lubricants: formulation (average use)	**6.9**	**7.5**	134	8	**67**	**2.7**
Lubricants: formulation (largest use)	**12**	**13**	235	15	**118**	**5**
Lubricants: private use	0.0016	0.0031	0.05	0.02		
Paints: formulation	0	0	0	0.02		
Paints: processing (industry data)	0	0	0	0.02		
Paints: processing (generic data)	**1.5**	**1.6**	28	1.8	**14**	0.6
Cosmetics pharmaceuticals: formulation (average use)	**2.3**	**2.5**	45	2.8	**23**	0.93

	Uncorrected				Corrected	
Company	**PEC_{add} / $PNEC_{add}$ STP**	**C_{add} / $PNEC_{add}$ water**	**C_{add} / $PNEC_{add}$ sediment**	**PEC_{add} / $PNEC_{add}$ agr. soil**	**C_{add} / $PNEC_{add}$ sediment**	**PEC_{add} / $PNEC_{add}$ agr. soil**
Cosmetics pharmaceuticals: formulation (largest use)	**19**	**21**	376	24	**188**	**8**
Cosmetics pharmaceuticals: private use	0.40	0.43	7.7	0.50	**3.8**	

4 HUMAN HEALTH

See Part II – Human Health

5 RESULTS

5.1 ENVIRONMENT

(X) ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already

(X) iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account

(X) iii*) A conclusion applied to local scenarios in which the local scenario merits conclusion (ii) but where (possibly) due to high regional background concentrations a local risk cannot be excluded.

5.1.1 Local

Conclusion (ii) is drawn for all local scenarios, including secondary poisoning, except those listed below.

Conclusion (iii) or (iii*) is drawn for the specified scenarios, because:

STP

- the PEC_{add} in STP effluent exceeds the $PNEC_{add}$ for microorganisms in a number of processing scenarios listed in **Table 3.4** (**conclusion iii**).

Surface water

- the $Clocal_{add}$ in water exceeds the $PNEC_{add}$ for surface water in a number of processing scenarios listed in **Table 3.4** (**conclusion iii**). For one other processing scenario listed in **Table 3.4** the $Clocal_{add}$ / $PNEC_{add}$ ratio is between 0.5 and 1, indicating that a potential risk at local scale cannot be excluded due to the possibly existence of high regional background concentrations (**conclusion iii***).

Sediment

- the $Clocal_{add}$ in sediment exceeds the $PNEC_{add}$ at one production site and in a number of processing scenarios listed in **Table 3.4** (**conclusion iii**). For the remaining processing scenarios and production sites listed in **Table 3.4** (and having emissions to water) the $Clocal_{add}$ / $PNEC_{add}$ ratio is below 1, but a potential risk at local scale cannot be excluded due to the possible existence of high regional background concentrations (**conclusion iii***).

Soil

- the PEC_{add} in soil exceeds the $PNEC_{add}$ in a number of processing scenarios listed in **Table 3.4 (conclusion iii**).

5.1.2 Regional

The regional risk characterisation is discussed in the RAR on Zinc Metal.

5.2 HUMAN HEALTH

See Part II – Human Health