# ZINC DISTEARATE

CAS No: 557-05-1 & 91051-01-3

EINECS No: 209-151-9 & 293-049-4

# 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.

The scientific work on this report has been prepared by the Netherlands Organisation for Applied Scientific Research (TNO) and the National Institute for Public Health and the Environment (RIVM), by order of the rapporteur.

Contact point:

Bureau Reach
P.O. Box 1
3720 BA Bilthoven
The Netherlands

| | |
|---|---|
| **Date of Last Literature Search:** | **2003** |
| **Review of report by MS Technical Experts finalised:** | **2006** |
| **Final report:** | **May 2008** |



**NOTE:**

**Part II (Human Health) of the Summary Risk Report for zinc distearate 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 distearate 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

# CONTENTS



**TABLES**

# 1 GENERAL SUBSTANCE INFORMATION

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

## CLASSIFICATION AND LABELLING

In the EU, zinc distearate is not classified for physico-chemical properties, health effects or the environment.

# 2 GENERAL INFORMATION ON EXPOSURE

## 2.1 PRODUCTION

Zinc distearate is produced (>1000t/y) at thirteen known sites in the European Union.

For the years 1995, 1996 and 1997 the total production volume of zinc distearate in the EU was about 24,000, 26,080 and 30,675 tonnes, respectively. The exported volume of zinc distearate for the EU in 1995 was about 4700 tonnes, about 100 tonnes were imported.

## 2.2 USE PATTERN

**Table 2.1** shows the wide spectrum of industrial and use categories of zinc distearate. Zinc distearate is mainly used in the EU in the polymers industry as a stabiliser component (e.g. in PVC stabilisers), lubricant, mould release agent and dusting agent for rubber (±55 %). Zinc distearate is further used in the paints, lacquers and varnishing industry as a sanding and flatting agent (±18%), in the building industry as a waterproofing agent in concrete (±5%), in the paper, pulp, board and textile industry as a waterproofing agent (±2%), in the cosmetics and pharmaceutical industry (±1%), chemical industry (±1%), metal industry (±1%) and other applications. The main types of use categories of zinc distearate can be characterised as non dispersive and use resulting in inclusion into or onto matrix.

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

| **Industrial category** | **EC no.** | **Use category** | **EC no** |
|---|---|---|---|
| Basic industry: Basic chemicals | 2 | | |
| Chemical industry: used in synthesis | 3 | Intermediates<br>Others: not further specified | 33<br>55 |
| Personal/domestic | 5 | Cosmetics<br>Pharmaceuticals | 15<br>41 |
| Metal extraction, refining and processing industry | 8 | Lubricants and additives | 35 |
| Polymers industry | 11 | Anti-adhesive agent<br>Cleaning/washing agent<br>Lubricants and additives<br>Stabilisers<br>Others: dusting agent for rubber | 06<br>09<br>35<br>49<br>55 |
| Paper, pulp and board industry | 12 | Waterproofing agents (impregnation)<br>Slip agent preventing thermal paper from sticking to print head (impregnation) | 31<br>31 |
| Textile processing industry | 13 | Waterproofing agents (impregnation) | 31 |
| Paints, lacquers and varnishes industry | 14 | Others: flatting and sanding agents in lacquers | 55 |
| Engineering industry: civil and mechanical | 16 | Construction materials additives (concrete additive in building industry) | 13 |
| Others | 15 | Impregnation agents<br>Others | 31<br>55 |

# 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 distearate, 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 distearate that are presented in this RAR, the $PEC_{add}$ values (which are expressed as zinc, not as zinc distearate) are based on the local zinc emissions due to the production or use of zinc distearate.
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 distearate (which is a poorly soluble zinc compound, with a water solubility limit of 0.8-1.0 mg/l at 15-25 $^{0}$C), 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

Zinc distearate is poorly soluble in water. Once emitted into the environment, zinc distearate will partly dissociate into the zinc cation and the stearic [$CH_3(CH_2)_{16}COO^-$] and palmitic [$CH_3(CH_2)_{14}COO^-$] anions, especially in an acidic environment. The further speciation of zinc, which includes complexation, precipitation and sorption, and the environmental fate of the fatty acids depend on the environmental conditions. In the presence of other cations such as calcium and magnesium, zinc distearate will partly form other "insoluble" stearates.
Stearic and palmitic acid as such are readily biodegradable, although the degradability can be inhibited by the formation of insoluble salts (e.g. calcium, magnesium and zinc distearates), that are not readily biodegradable[2]. This is confirmed in a OECD 301D study. It is noted that the fatty acids as such are also poorly soluble in water.

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 distearate. The $(PE)C_{add}$s are derived from either modelling or measured exposure data. All concentrations are expressed as zinc and not as zinc distearate. 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.

[2] For example, in a closed bottle test for biodegradation (OECD guideline 301 D), only 5% biodegradability of zinc distearate was found in 28 days. This value was calculated from the BOD, the biological oxygen demand, and the ThOD, the theoretical oxygen demand .

## 3.2 EFFECTS ASSESSMENT

### 3.2.1 Aquatic and terrestrial compartment

#### 3.2.1.1 Zinc distearate

Ecotoxicity data on zinc distearate seem to be very limited. The aquatic toxicity data for zinc distearate, summarised below, were submitted by the industry (zinc distearate IUCLID data sheet, *ECB-version of 2 March 1995).* One recent study with *Daphnia magna* was submitted in the framework of the environmental classification of zinc distearate. The available data comprise short-term tests with microorganisms (bacteria), invertebrates (*Daphnia magna)* and fish.
Terrestrial toxicity data were not submitted.

**Aquatic toxicity - microorganisms**
The two available tests with bacteria resulted in NOEC values of 1000 mg zinc distearate/L (*Pseudomonas putida*) and 1560 mg zinc distearate/L (Microtox-test according to DIN 38412, part 34). In the latter study an EC20 of 6250 mg zinc distearate/L was calculated, with the remark that an EC50 could not be derived because of the low effect response. These nominal concentrations are at least 3 orders of magnitude higher than the water solubility limit for zinc distearate (around 1 mg/L, see Chapter 1 in the RAR Zinc distearate).

**Aquatic toxicity - invertebrates**
The acute toxicity of zinc distearate to the waterflea *Daphnia magna* was determined according to OECD 202 in M7 medium at pH 6 and 8. Up to a loading rate of 100 mg zinc distearate/L the $EC_{50}$ was not reached. The zinc concentration (detected using ICP-MS) at the beginning of the test, was 1.2 mg Zn/L at pH 8 and 0.8 mg Zn/L at pH 6 at a loading rate of 100 mg zinc distearate/L.

**Aquatic toxicity - fish**
In the three available acute toxicity tests with fish (zebrafish *Brachydanio rerio,* bluegill *Lepomis macrochirus,* and an unspecified species), no effects were observed at nominal zinc distearate concentrations up to the water solubility limit or at nominal concentrations that were 3 to 4 orders of magnitude higher than the water solubility limit.

**Aquatic toxicity - conclusion**
From these data, although very limited, it is concluded that the toxicity of zinc distearate to bacteria and the acute toxicity of zinc distearate to *Daphnia magna* and fish is (far) above the water solubility limit of around 1 mg/L).

A comparison of the acute LC50 and EC50 values for zinc, zinc distearate, and sodium and potassium soaps with a similar ($C_{12}$-$C_{18}$) alkyl chain length indicate that the acute aquatic toxicity of zinc is in general considerably higher than that of these fatty acids and soaps. In addition, a comparison of the chronic NOEC values for zinc and soaps indicate that also the chronic aquatic toxicity of zinc is considerably higher than that of the fatty acids and soaps, although the number of chronic toxicity data on soaps are very limited. Thus, the risk characterisation can be based on zinc instead of zinc distearate.

**Environmental risk assessment**

Once emitted into the environment, zinc distearate will dissociate into the zinc cation and the stearic and palmitic anions, especially in an acidic environment. The further speciation of zinc, which includes complexation, precipitation and sorption, depends on the environmental conditions. Therefore, emitted zinc distearate as well as other emitted zinc species (e.g. zinc chloride) will contribute to the effect of the total amount of zinc in the environment, regardless of the original source or chemical form. For this reason the risk characterisation for zinc distearate is based on zinc, not on zinc distearate as such, as explained earlier in section 3.1 and in the RAR Zinc metal.

Based on the above, the derogation statements with respect to the missing ecotoxicity data were accepted (i.e., exemptions were given for the required *Daphnia* acute toxicity test and algal growth inhibition test missing in the base set for zinc distearate) and no effort has been made to retrieve additional ecotoxicity data on zinc distearate. Note that a *Daphnia magna* acute toxicity study was submitted more recently in the framework of the environmental classification of zinc distearate.

### 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<br>(Hardness ≥ 24 mg/L) (1) | $PNEC_{add, aquatic}$ | 7.8 µg/l<br>21 µg /l | Dissolved zinc<br>Total zinc (2) |
| Freshwater<br>(Hardness <24 mg/L) (1) | $PNEC_{add, aquatic}$<br>softwater | 3.1 µg/l | Dissolved zinc |
| Freshwater sediment | $PNEC_{add, sediment}$ | 49 mg/kg dwt<br>11 mg/kg wwt | Dry weight of sediment (3)<br>Wet weight of sediment (3) |
| STP effluent | $PNEC_{add, microorganisms}$ | 52 µg/l | Dissolved zinc |
| Soil | $PNEC_{add, terrestrial}$ | 26 mg/kg dwt<br>23 mg/kg wwt | Dry weight of soil (4)<br>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[3]. 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 ($R_{L\text{-}F}$) 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.

---

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

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).

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[4] 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[5] and 1 a **conclusion iii*** will be drawn, indicating that

4 See data in RAR Zinc Metal. Average of realistic worst case and average BioF for average NL data.
5 A $Clocal_{add}$ / $PNEC_{add}$ of between 0.5 and 1 should theoretically also be corrected for bioavailability. This

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 <u>not</u> corrected for bioavailability. Subsequent 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)**

<u>STP-effluent</u>
*<u>Production</u>:*
The calculated $PEC_{add}$ in STP effluent for all production sites of zinc distearate is lower than the $PNEC_{add}$ for microorganisms **(conclusion ii).** The same conclusion holds for $PEC_{add}$ / $PNEC_{add}$ ratios based on measured effluent concentrations.
*<u>Use categories</u>:*
The $PEC_{add}$ in STP effluent for the processing sites of zinc distearate exceeds the PNEC for microorganisms in six scenarios (**conclusion iii**). In contrast with the production scenarios (see above), mainly generic scenarios have been used for the processing of zinc distearate. This is due to a lack of (sufficient) site-specific data for most use categories.
The $PEC_{add}$ / $PNEC_{add}$ ratio is <1 for the use categories 'processing rubber industry', 'processing building industry', 'formulation and industrial use coating industry', 'processing textile industry', ‘processing in the paper and pulp industry’, ‘personal/domestic formulation and private use’ and ‘formulation in metal extraction’**(conclusion ii).** The same conclusion holds for the use of zinc distearate in the polymer industry.

---

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.

Surface water

*Production:*

The surface water $Clocal_{add}$ / $PNEC_{add}$ ratio for all plants is <1 (and also <0.2) **(conclusion ii)**.

*Use categories:*

The $Clocal_{add}$ in water for the processing sites of zinc distearate exceeds the $PNEC_{add}$ for surface water in five scenarios. 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 $Clocal_{add}$ / $PNEC_{add}$ ratios (from **Table 3.3**) remain unchanged (**conclusion iii**). The $Clocal_{add}$ / $PNEC_{add}$ ratio is between 0.5 and 1 for the use categories ‘coating industry formulation (solvent borne)’, ‘textile industry processing’ and ‘processing in the paper and pulp industry’, indicating that due to (possibly) high regional background concentrations a potential risk at local scale cannot be excluded (**conclusion iii***). For the scenarios 'processing rubber industry', 'processing building industry', 'industrial use coating industry (solvent borne)', 'formulation and industrial use coating industry (water borne)', ‘processing chemical industry’, ‘personal/domestic formulation and private use’ and ‘formulation in metal extraction’ the $Clocal_{add}$ / $PNEC_{add}$ is below 0.5 (**conclusion ii**). The same conclusion holds for the use of zinc distearate in the polymer industry.

Sediment

*Production:*

For three production sites (no. 8, 10 and 16) the $Clocal_{add}$ in sediment exceeds the $PNEC_{add}$ in sediment of 11 mg/kg wwt. As relevant data are lacking to perform a site-specific correction for bioavailability in sediment (SEM/AVS method), 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 sites 8 and 10 (**conclusion iii**). The corrected $Clocal_{add}$ / $PNEC_{add}$ ratio for site 16 and the (uncorrected) $Clocal_{add}$ / $PNEC_{add}$ ratio for all remaining production sites are < 1. Owing to (possibly) high regional background concentrations in sediment a potential risk at local scale cannot be excluded (**conclusion iii***). However, for production sites 4, 7, 9, 12 and 14, it was stated that the process type intrinsically does not include emissions to water. Therefore a **conclusion ii)** is drawn for these sites.

*Use categories:*

For sediment the $Clocal_{add}$ / $PNEC_{add}$ ratio is larger than 1 for all scenarios, except for 'chemical industry processing', ‘personal/domestic private use’ and 'metal extraction formulation'. As relevant data are lacking to perform a site-specific correction for bioavailability in sediment (SEM/AVS method), only the generic sediment bioavailability correction factor of 0.5 can be applied for these scenarios. This implies that the original sediment $Clocal_{add}$s 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, except for the scenarios 'rubber industry processing', 'building industry processing’ and 'industrial use coating industry (water borne)' (**conclusion iii**). For the scenario with a $Clocal_{add}$ / $PNEC_{add}$ < 1 a **conclusion iii*)** is drawn, because it cannot be excluded that potential risks may occur at a local scale due to the (possibly) high regional background concentration. The same conclusion holds for the use of zinc distearate in the polymer industry.

**Terrestrial compartment**

*Production:*
For all production sites, the $PEC_{add}$ / $PNEC_{add}$ ratios for soil are <1 **(conclusion ii)**.
*Use categories:*
For a great number of use scenarios the $PEC_{add}$ / $PNEC_{add}$ ratio is above 1. 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** are divided by a factor 3. After this correction the $PEC_{add}$ / $PNEC_{add}$ ratio for soil remains above 1 for two scenarios, 'çhemical industry processing' and 'other industries processing' (**conclusion iii**). For all other scenarios the (corrected) $PEC_{add}$ / $PNEC_{add}$ is < 1 (**conclusion ii**). The same conclusion holds for the use of zinc distearate in the polymer industry.

**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 3 | 1.17 | 0.196 | 4.69 | 0.503 | 0.02 | 0.03 | 0.59 | 0.02 |
| Company 4 | 0 | 0 | 0 | 0.53 | 0 | 0 | 0 | 0.02 |
| Company 6 | 0.951 | $3.22.10^{-4}$ | $7.69.10^{-3}$ | 1.47 | 0.02 | $4.13.10^{-5}$ | 0.001 | 0.06 |
| Company 7 | 0 | 0 | 0 | 0.500 | 0 | 0 | 0 | 0.02 |
| Company 8 | 7.47 | 1.21 | 29 | 0.530 | 0.14 | 0.16 | 3.6 | 0.02 |
| Company 9 | 0 | 0 | 0 | 0.529 | 0 | 0 | 0 | 0.02 |
| COMPANY 10 | 12.1 | 1.96 | 46.9 | 0.512 | 0.23 | 0.25 | 5.9 | 0.02 |
| COMPANY 11 | 0.388 | $6.29.10^{-2}$ | 1.5 | 0.811 | 0.007 | 0.008 | 0.19 | 0.03 |
| Company 12 | 0 | 0 | 0 | 0.529 | 0 | 0 | 0 | 0.02 |
| Company 14 | 0 | 0 | 0 | 0.504 | 0 | 0 | 0 | 0.02 |
| Company 15 | 0.0183 | $2.97.10^{-3}$ | $7.10.10^{-2}$ | 0.79 | 0.0004 | 0.0004 | 0.0089 | 0.03 |
| Company 16 | 3.63 | 0.589 | 14.1 | 1.103 | 0.07 | 0.08 | 1.8 | 0.05 |
| Company 17 | 0.0293 | $1.30.10^{-4}$ | $3.12.10^{-3}$ | 0.516 | 0.0006 | 0.00002 | 0.0004 | 0.02 |
| ***Use categories:*** | | | | | | | | |
| **Rubber industry**: formulation | - | - | - | 0.625 | - | - | - | 0.026 |
| **Rubber industry**: processing | 3.90 | 0.63 | 15.1 | 2.80 | 0.075 | 0.081 | 1.4 | 0.12 |
| **Building industry**: formulation | - | - | - | 0.51 | - | - | - | 0.021 |
| **Building industry**: processing | 4.59 | 0.75 | 17.8 | 3.08 | 0.088 | 0.096 | 1.7 | 0.13 |
| **Coating industry**: formulation (solvent borne) | 40.1 | 6.51 | 155 | 23.0 | 0.771 | 0.83 | 14.6 | 0.96 |
| **Coating industry**: formulation (water borne) | 11.2 | 1.82 | 43.4 | 6.77 | 0.215 | 0.23 | 4.1 | 0.28 |
| **Coating industry**: industrial use (solvent borne) | 15 | 2.44 | 58.3 | 8.92 | 0.289 | 0.31 | 5.5 | 0.37 |
| **Coating industry**: industrial use (water borne) | 4.2 | 0.678 | 16.2 | 2.84 | 0.08 | 0.087 | 1.52 | 0.12 |
| **Chemical industry**: processing | 156 | 0.0978 | 2.34 | 88.2 | 3.0 | 0.013 | 0.22 | 3.7 |

| 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) | | | | |
| **Textile industry**: formulation | 77.8 | 12.6 | 302 | 44.1 | 1.5 | 1.6 | 28 | 1.8 |
| **Textile industry**: processing | 31.3 | 5.08 | 121 | 18.5 | 0.60 | 0.65 | 11 | 0.77 |
| **Paper, pulp, board industry**: formulation | 56.5 | 9.17 | 219 | 32.2 | 1.1 | 1.2 | 21 | 1.3 |
| **Paper, pulp, board industry**: processing | 28.2 | 4.58 | 109 | 16.3 | 0.54 | 0.59 | 10 | 0.68 |
| **Personal / domestic**: formulation | 7.38 | 1.20 | 28.6 | 4.64 | 0.14 | 0.15 | 2.7 | 0.19 |
| **Personal / domestic**: private use | 0.152 | 0.0246 | 0.589 | 0.585 | 0.003 | 0.0032 | 0.055 | 0.024 |
| **Metal extraction, refining and processing industry**: formulation | 0.375 | 0.0609 | 1.46 | 0.71 | 0.007 | 0.008 | 0.14 | 0.03 |
| **Metal extraction, refining and processing industry**: processing | 59.3 | 9.62 | 230 | 33.7 | 1.1 | 1.2 | 22 | 1.4 |
| **Other industries**: formulation | 119 | 19.3 | 462 | 67.5 | 2.3 | 2.5 | 43 | 2.8 |
| **Other industries**: processing | 3,127 | 507 | $1.21.10^{4}$ | $1.75.10^{3}$ | 60 | 65 | 1,139 | 73 |

1) Company 1 appeared to be a trader and no producer; no production anymore at company 2, 5 and 13

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 3 | 0.02 | 0.03 | 0.59 | 0.02 | | |
| Company 4 | 0 | 0 | 0 | 0.02 | | |
| Company 6 | 0.02 | $4.13.10^{-5}$ | 0.001 | 0.06 | | |
| Company 7 | 0 | 0 | 0 | 0.02 | | |
| Company 8 | 0.14 | 0.16 | 3.6 | 0.02 | **1.8** | |
| Company 9 | 0 | 0 | 0 | 0.02 | | |
| COMPANY 10 | 0.23 | 0.25 | 5.9 | 0.02 | **3.0** | |
| COMPANY 11 | 0.007 | 0.008 | 0.19 | 0.03 | | |
| Company 12 | 0 | 0 | 0 | 0.02 | | |
| Company 14 | 0 | 0 | 0 | 0.02 | | |
| Company 15 | 0.0004 | 0.0004 | 0.0089 | 0.03 | | |
| Company 16 | 0.07 | 0.08 | 1.8 | 0.05 | 0.9 | |
| Company 17 | 0.0006 | 0.00002 | 0.0004 | 0.02 | | |
| ***Use categories:*** | | | | | | |
| **Rubber industry**: formulation | - | - | - | 0.026 | - | |
| **Rubber industry**: processing | 0.075 | 0.081 | **1.4** | 0.12 | 0.7 | |
| **Building industry**: formulation | - | - | - | 0.021 | - | |
| **Building industry**: processing | 0.088 | 0.096 | **1.7** | 0.13 | 0.8 | |
| **Coating industry**: formulation (solvent borne) | 0.771 | 0.83 | **14.6** | 0.96 | **7.3** | |
| **Coating industry**: formulation (water borne) | 0.215 | 0.23 | **4.1** | 0.28 | **2** | |
| **Coating industry**: industrial use (solvent borne) | 0.289 | 0.31 | **5.5** | 0.37 | **2.7** | |

| | 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** |
| **Coating industry**: industrial use (water borne) | 0.08 | 0.087 | **1.52** | 0.12 | 0.76 | |
| **Chemical industry**: processing | **3.0** | 0.013 | 0.22 | **3.7** | | **1.2** |
| **Textile industry**: formulation | **1.5** | **1.6** | **28** | **1.8** | **14** | 0.6 |
| **Textile industry**: processing | 0.60 | 0.65 | **11** | 0.77 | **5.7** | |
| **Paper, pulp, board industry**: formulation | **1.1** | **1.2** | **21** | **1.3** | **10.3** | 0.4 |
| **Paper, pulp, board industry**: processing | 0.54 | 0.59 | **10** | 0.68 | **5** | |
| **Personal / domestic**: formulation | 0.14 | 0.15 | **2.7** | 0.19 | **1.3** | |
| **Personal / domestic**: private use | 0.003 | 0.0032 | 0.055 | 0.024 | | |
| **Metal extraction, refining and processing industry**: formulation | 0.007 | 0.008 | 0.14 | 0.03 | | |
| **Metal extraction, refining and processing industry**: processing | **1.1** | **1.2** | **22** | **1.4** | **10.8** | 0.5 |
| **Other industries**: formulation | **2.3** | **2.5** | **43** | **2.8** | **21.7** | 0.9 |
| **Other industries**: processing | **60** | **65** | **1,139** | **73** | **570** | **24** |

# 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**). The $Clocal_{add}$ / $PNEC_{add}$ ratio is between 0.5 and 1 for three processing scenarios listed in **Table 3.4,** indicating that a potential risk at local scale cannot be excluded due to the possible existence of high regional background concentrations (**conclusion iii***).

*Sediment*

- for two production sites and a number of processing scenarios listed in **Table 3.4** the $Clocal_{add}$ in sediment exceeds the $PNEC_{add}$ (**conclusion iii**). For all remaining sites and scenarios listed in **Table 3.4** the $Clocal_{add}$ / $PNEC_{add}$ is < 1. However, a potential risk at local scale cannot be excluded due to possible high regional background concentrations (**conclusion iii***).

*Soil*

- for two processing scenarios listed in **Table 3.4** the $PEC_{add}$ / $PNEC_{add}$ is above 1 (**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**