Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (1) involves the data reporting, priority setting, risk evaluation and, where necessary, development of strategies for limiting the risks of existing substances.

In the framework of Regulation (EEC) No 793/93 the following substances have been identified as priority substances for evaluation in accordance with Commission Regulation (EC) No 2268/95 (2) concerning the second list of priority substances as foreseen under Regulation (EEC) No 793/93:

— zinc,
— zinc chloride,
— zinc distearate.

The rapporteur Member State designated pursuant to this Regulation has completed the risk evaluation activities with regard to man and the environment for those substances in accordance with Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances (3) and has suggested a strategy for limiting the risks in accordance with Regulation (EEC) No 793/93.

The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) and the Scientific Committee on Health and Environmental Risks (SCHER) have been consulted and have issued an opinion with respect to the risk evaluations carried out by the rapporteur. These opinions can be found on the website of the Scientific Committees.

Article 11(2) of Regulation (EEC) No 793/93 stipulates that the results of the risk evaluation and the recommended strategy for limiting the risks shall be adopted at Community level and published by the Commission. This Communication, together with the corresponding Commission Recommendation 2008/464/EC (4), provides the results of risk evaluations (5) and strategies for limiting the risks for the above mentioned substances.

The results of the risk evaluation and strategies for limiting the risks provided for in this communication are in accordance with the opinion of the Committee set up pursuant to Article 15(1) of Regulation (EEC) No 793/93.

(5) The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the Internet site of the European Chemicals Bureau:
http://ecb.jrc.it/existing-substances/
ANNEX

PART 1

<table>
<thead>
<tr>
<th>CAS No: 7440-66-6</th>
<th>Einecs No: 231-175-3</th>
</tr>
</thead>
</table>

Structural formula: Zn
Einecs name: Zinc
IUPAC name: Zinc
Rapporteur: The Netherlands
Classification (1): F; R15-17 (zinc powder — zinc dust (pyrophoric))
N; R50-53 (zinc powder — zinc dust (pyrophoric))
N; R50-53 (zinc powder — zinc dust (stabilised))

The risk assessment is based on practices related to the life-cycle of the substance produced in or imported into the European Community as described in the risk assessment forwarded to the Commission by the Member State Rapporteur. The risk assessment has been conducted in accordance with the methodology for metals applicable at the time and in line with the Technical Guidance Document on Risk Assessment in support of Commission Regulation (EC) No 1488/94 on risk assessment for existing substances.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used for galvanising and in brass. Other uses are in die casting alloys, rolled/wrought zinc, pigments and chemicals and for the production of other zinc compounds. Uses of zinc and certain zinc compounds as nanomaterials have not been assessed.

The Predicted No-Effect Concentrations (PNECs) for zinc metal included in the risk assessment have been derived solely for the purposes of this risk assessment. They must not be used for other purposes, such as setting environmental quality standards or sanitation levels, without further in-depth consideration as to whether they are fit for that purpose. In every case an appropriate bioavailability correction should be incorporated as an essential part of the process.

RISK ASSESSMENT

A. Human health

The conclusions of the assessment of the risks to WORKERS is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:
— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusions of the assessment of the risks to CONSUMERS is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:
— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusions of the assessment of the risks to

**HUMANS EXPOSED VIA THE ENVIRONMENT**

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusions of the assessment of the risks to

**HUMAN HEALTH (physicochemical properties)**

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

### B. Environment

The conclusions of the assessment of the risks to

**ATMOSPHERE**

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusions of the assessment of the risks to the

**AQUATIC ECOSYSTEM INCLUDING SEDIMENT**

1.1. is that there is a need for specific measures to limit the risks for the specific scenarios listed below. This conclusion is reached because of:

— concerns for effects on the local aquatic (including sediment) environment as a consequence of exposure arising from the production of zinc metal and from the use in continuous hot dip galvanising, electro galvanising, in brass, as die casting alloy, as rolled/wrought zinc and as zinc powder/dust. For a number of production sites of zinc metal and processing scenarios of zinc metal no immediate concern has been identified but a potential risk at local scale cannot be excluded due to possible existence of high regional background concentrations of zinc,

— concerns for effects on the regional aquatic (including sediment) environment due to elevated regional zinc levels in some, but not all, regional surface waters and sediments.

In regions where these waters (including sediment) are found, it is strongly recommended that the available information on known and potential sources of zinc emissions, and region-specific natural background concentration are carefully taken into account before taking decisions about risk reduction measures.

The findings of the risk assessment report are that the current uses of zinc and zinc compounds do not per se lead to the elevated regional levels found in surface water and sediment.

The elevated zinc levels in those waters and sediments, where they are found, may be caused by a combination of zinc and zinc compounds. The elevated levels come from various emission sources, including local industrial point sources, historical contamination, mining activities, geology and diffuse sources. The contribution of each of these sources may vary between regions.

Local industrial point sources may include industrial processes that use and emit zinc and zinc compounds, as well as other processes that are unintentional sources and are not directly connected with the zinc producing or using industries. These were not examined in the risk assessment report, but may nevertheless have emissions of zinc to the aquatic environment.
1.2. is that there is a need for further information and/or testing. This conclusion is reached because of:

— concerns for effects on the aquatic (including sediment) environment alongside motorways in the European Union. Due to a number of uncertainties additional information is needed to refine this part of the risk assessment.

1.3. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied for all local and regional scenarios, including concerning secondary poisoning, except for those listed under point 1.1 and 1.2 above. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the TERRESTRIAL ECOSYSTEM

2.1. is that there is a need for specific measures to limit the risks for the specific scenarios listed below. This conclusion is reached because of:

— concerns for the local terrestrial environment as a consequence of exposure arising from use in continuous hot dip galvanising and electro galvanising.

2.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied, for all local and regional (line sources at terrestrial road borders and zinc accumulation in regional soils) scenarios, including concerning secondary poisoning, except for those listed under point 2.1 above. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

3.1. is that there is a need for limiting the risks for some, but not all, local scenarios. This conclusion is reached because of:

— concerns for micro-organisms in the sewage treatment plant as a consequence of exposure arising from some of the production sites of zinc metal and from some of the processing sites of continuous hot dip galvanising, electro galvanising, as brass and as die casting alloy.

3.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied for all local scenarios, except for those listed under point 3.1 above. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

For the ENVIRONMENT

It is recommended:

— to consider under Directive 2008/1/EC (1) and Directive 2000/60/EC (2) if additional risk management is needed for other sources of zinc emissions than those from the produced and imported chemical (for instance natural sources, mining activities, historical pollution and the use of other zinc compounds), which the risk reduction strategy has identified as contributing significantly to the emissions of zinc to the aquatic compartment,

— to facilitate permitting and monitoring under Directive 2008/1/EC, zinc should be included in the ongoing work to develop guidance on ‘Best Available Techniques’ (BAT).

PART 2

<table>
<thead>
<tr>
<th>CAS No: 7646-85-7</th>
<th>Einecs No: 231-592-0</th>
</tr>
</thead>
</table>

Structural formula: ZnCl$_2$

Einecs name: Zinc chloride

IUPAC name: Zinc chloride

Rapporteur: The Netherlands

Classification (1): Xn; R22

C; R34

N; R50-53

The risk assessment is based on practices related to the life-cycle of the substance produced in or imported into the European Community as described in the risk assessment forwarded to the Commission by the Member State Rapporteur. The risk assessment has been conducted in accordance with the methodology for metals applicable at the time and in line with the Technical Guidance Document on Risk Assessment in support of Regulation (EC) No 1488/94 on risk assessment for existing substances.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used in the chemical industry, galvanising industry, battery industry and agrochemical industry (fungicides). Other uses are in the printing and dye industry. Uses as nanomaterials have not been assessed.

RISK ASSESSMENT

A. Human health

The conclusion of the assessment of the risks to WORKERS is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

— concerns for acute respiratory tract irritation as a consequence of inhalation exposure arising during the production of zinc chloride.

The conclusion of the assessment of the risks to CONSUMERS is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to HUMANS EXPOSED VIA THE ENVIRONMENT is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

**HUMAN HEALTH (physicochemical properties)**

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

**8. Environment**

Conclusions are given on local scenarios only. The conclusions regarding the regional risks to the environment as described in the risk assessment for zinc metal (EINECS No 231-175-3) apply as well.

The conclusions of the assessment of the risks to

**ATMOSPHERE**

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusions of the assessment of the risks to the

**AQUATIC ECOSYSTEM INCLUDING SEDIMENT**

1.1. is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

— concerns for effects on the local aquatic environment as a consequence of exposure arising from production at one site and exposure arising from the use by the dyes and inks industry (formulation and processing). For one production site no immediate concern has been identified but a potential risk at local scale cannot be excluded due to possible existence of high regional background concentrations of zinc,

— concerns for effects on sediment dwelling organisms as a consequence of local exposure arising from production at three sites and local exposure arising from the use in the chemical industry (processing), battery industry (processing) and dyes and inks industry (formulation and processing). For a number of production sites and processing scenarios no immediate concern has been identified but a potential risk at local scale cannot be excluded due to possible existence of high regional background concentrations of zinc.

1.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied for all local scenarios, including concerning secondary poisoning, except for those listed under point 1.1 above. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the

**TERRESTRIAL ECOSYSTEM**

2.1. is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

— concerns for the local terrestrial environment as a consequence of exposure arising from the use in the chemical industry (processing) and dyes and inks industry (formulation and processing).

2.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied, for all local scenarios, including concerning secondary poisoning, except for those listed under point 2.1 above. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.
The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

3.1. is that there is a need for limiting the risks. This conclusion is reached because of:

— concerns for micro-organisms in the sewage treatment plant as a consequence of exposure arising from production at three sites and exposure arising from the use in the chemical industry (processing) and dyes and inks industry (formulation and processing).

3.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied for all local scenarios, except for those listed under point 3.1 above. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

For WORKERS

The legislation for workers’ protection currently into force at Community level is generally considered to give an adequate framework to limit the risks of zinc chloride to the extent needed and shall apply.

For ENVIRONMENT

It is recommended:

— to consider under Directive 2008/1/EC (1) and Directive 2000/60/EC (2) if additional risk management is needed for other sources of zinc emissions than those from the produced and imported chemical (for instance natural sources, mining activities, historical pollution and the use of other zinc compounds), which the risk reduction strategy has identified as contributing significantly to the emissions of zinc to the aquatic compartment,

— to facilitate permitting and monitoring under Directive 2008/1/EC, zinc chloride should be included in the ongoing work to develop guidance on ‘Best Available Techniques’ (BAT).

PART 3

<table>
<thead>
<tr>
<th>CAS No: 557-05-1 and 91051-01-3 (3)</th>
<th>Einecs No: 209-151-9 and 293-049-4</th>
</tr>
</thead>
</table>

Structural formula: 

\[
\text{Zn} \quad \begin{array}{c}
\text{O} \\
\text{C}_{17} \text{H}_{35}
\end{array} \\
\begin{array}{c}
\text{O} \\
\text{C}_{18} \text{H}_{36}
\end{array}
\]

Einecs name: Zinc distearate

IUPAC name: Zinc dioctadecanoate

Rapporteur: The Netherlands

Classification: No classification

The risk assessment is based on practices related to the life-cycle of the substance produced in or imported into the European Community as described in the risk assessment forwarded to the Commission by the Member State Rapporteur. The risk assessment has been conducted in accordance with the methodology for metals applicable at the time and in line with the Technical Guidance Document on Risk Assessment in support of Regulation (EC) No 1488/94 on risk assessment for existing substances.

(3) Commercially produced stearic acid is always a mixture of what chemically was called stearic acid (C<sub>18</sub>) and palmitic acid (C<sub>16</sub>). In practice, the description ‘Fatty acids, C<sub>16-18</sub>, zinc salts’ registered under CAS No 91051-01-3 is a more exact fit with commercial zinc stearate, but it is only listed on EINECS and Chemical Abstracts have never indexed a single article to this number. Based on these considerations, the CAS No 91051-01-3 was added.
The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used in the polymers industry as a stabiliser component, lubricant, mould release agent and dusting agent for rubber.

Other uses are in the paints, lacquers and varnishing industry as a sanding and flattening agent, in the building industry as a waterproofing agent in concrete, in the paper, pulp, board and textile industry as a waterproofing agent, in the cosmetics and pharmaceutical industry, chemical and metal industries and other applications. Uses as nanomaterials have not been assessed.

RISK ASSESSMENT

A. Human health

The conclusion of the assessment of the risks to WORKERS is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to CONSUMERS is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to HUMANS EXPOSED VIA THE ENVIRONMENT is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to HUMAN HEALTH (physico-chemical properties) is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

Conclusions are given on local scenarios only. The conclusions regarding the regional risks to the environment as described in the risk assessment for zinc metal (EINECS No 231-175-3) apply as well.

The conclusions of the assessment of the risks to ATMOSPHERE is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.
The conclusions of the assessment of the risks to the

AQUATIC ECOSYSTEM INCLUDING SEDIMENT

1.1. is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

— concerns for effects on the local aquatic environment as a consequence of exposure arising from the use in the textile industry (formulation), paper, pulp and board industry (formulation), metal extraction, refining and processing industry (processing) and formulation and processing by other industries. For a number of production sites and processing scenarios no immediate concern has been identified but a potential risk at local scale cannot be excluded due to possible existence of high regional background concentrations of zinc,

— concerns for effects on sediment dwelling organisms as a consequence of local exposure arising from the production at two sites and local exposure arising from the use in the coating industry (formulation and industrial use), in the textile industry (formulation and processing), paper, pulp and board industry (formulation and processing), metal extraction, refining and processing industry (processing) and formulation and processing by other industries and personal and domestic use (formulation). For a number of production sites and processing scenarios no immediate concern has been identified but a potential risk at local scale cannot be excluded due to possible existence of high regional background concentrations of zinc.

1.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied for all local scenarios, including concerning secondary poisoning, except for those listed under point 1.1 above. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

2.1. is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

— concerns for the local terrestrial environment as a consequence of exposure arising from processing in the chemical industry and ‘other’ industries.

2.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied, for all local scenarios, including concerning secondary poisoning, except for those listed under point 2.1 above. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

3.1. is that there is a need for limiting the risks. This conclusion is reached because of:

— concerns for micro-organisms in the sewage treatment plant as a consequence of exposure arising from the use in the chemical industry (processing), textile industry (formulation), paper, pulp and board industry (formulation), metal extraction, refining and processing industry (processing) and formulation and processing by other industries.

3.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied for all local scenarios, except for those listed under point 3.1 above. This conclusion is reached because:

— the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.
STRATEGY FOR LIMITING RISKS

For ENVIRONMENT

It is recommended:

— to consider under Directive 2008/1/EC (1) and Directive 2000/60/EC (2) if additional risk management is needed for other sources of zinc emissions than those from the produced and imported chemical (for instance natural sources, mining activities, historical pollution and the use of other zinc compounds), which the risk reduction strategy has identified as contributing significantly to the emissions of zinc to the aquatic compartment,

— to facilitate permitting and monitoring under Directive 2008/1/EC, zinc distearate should be included in the ongoing work to develop guidance on ‘Best Available Techniques’ (BAT).