**ZnSO4**

**Section 8.1.4**

DNELS

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Workers | | | | General population | | | |
| Route of exposure | Acute effects local | Acute effects systemic | Chronic effects local | Chronic effects systemic | Acute effects local | Acute effects systemic | Chronic effects local | Chronic effects systemic |
| Oral | Not required | | | | | No hazard identified | Not required | No hazard identified |
| Inhalation | No hazard identified | No hazard identified | No hazard identified | No hazard identified | No hazard identified | No hazard identified | No hazard identified | No hazard identified |
| Dermal | No hazard identified | No hazard identified | No hazard identified | No hazard identified | No hazard identified | No hazard identified | No hazard identified | No hazard identified |
| Eyes | Local effects: Medium hazard (no threshold derived | | | | Local effects: Medium hazard (no threshold derived | | | |

PNECS relative to zinc ion

|  |  |
| --- | --- |
| Environmental protection target | PNECs |
| Freshwater | 14.4 µg/L |
| Freshwater sediments | 146.9 mg/kg sediment dw |
| Marine water | 7.2 µg/L |
| Marine sediments | 162.2 mg/kg sediment dw |
| Food chain | No potential for bioaccumulation |
| Microorganisms in sewage treatment | 100 µg/L |
| Soil (agricultural) | 83.1 mg/kg soil dw |
| Air | No hazard identified |

PNECS Zinc Sulphate

|  |  |
| --- | --- |
| Environmental protection target | PNECs |
| Freshwater | 35.6 µg/L |
| Freshwater sediments | 362.7 mg/kg sediment dw |
| Marine water | 17.8 µg/L |
| Marine sediments | 400.5 mg/kg sediment dw |
| Food chain | No potential for bioaccumulation |
| Microorganisms in sewage treatment | 246.9 µg/L |
| Soil (agricultural) | 205.2 mg/kg soil dw |
| Air | No hazard identified |

**Section 11: Toxicological information**

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

**a) Acute Toxicity –** **Acute Tox. oral Cat. 4; Acute Tox inhalation/dermal: classification criteria not met**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Effect dose/concentration** | **Species** | **Method** |
| **Acute oral toxicity** for ZnSO4 monohydrate  ZnSO4 Hexahydrate  ZnSO4 heptahydrate | LD50 574 mg/kg bw  LD50 862 mg/kg bw  LD50 920 mg/kg bw | Rat | OECD 401 & OECD 423 |
| **Acute inhalation toxicity** | Low acute inhalation toxicity | Rat, Hamster | No guideline followed (RA from ZnSO4 and ZnCl2) |
| **Acute dermal toxicity** | LD50 > 2,000 ZnSO4 mg/kg bw. | Rat | OECD 402 (RA from ZnSO4) |

**b) Skin corrosion / irritation - classification criteria not met**

|  |  |  |
| --- | --- | --- |
| Species | Method | Result |
| New Zealand white rabbits | OECD 404 | not irritant |

**c) Serious eye damage/irritation – Category 1 irritant**

|  |  |  |
| --- | --- | --- |
| Species | Method | Result |
| New Zealand white rabbits | OECD 405 | Category 1 irritant |

**d) Skin Sensitisation - classification criteria not met**

|  |  |  |
| --- | --- | --- |
| Species | Method | Result |
| Guinea pigs | OECD 406 | Not sensitizing |

**e) Germ cell mutagenicity – classification criteria not met**

Based on the weight of the evidence from the existing in vitro and in vivo genotoxicity assays available, it is concluded that the zinc category substances do not have biologically relevant genotoxic activity. Consequently, no classification for germ cell mutagenicity is applicable.

This conclusion is in line with those achieved by other regulatory reviews of the genotoxicity of zinc compounds (WHO, 2001; SCF, 2003; EU RAR, 2004, MAK, 2009). Hence, no classification and labelling for mutagenicity is required.

**f) Carcinogenicity**

No adequate experimental animal studies are available to evaluate the carcinogenicity of zinc compounds in humans.

**g) Reproductive toxicity – classification criteria not met**

Neither the impairment of fertility nor the developmental toxicity of the zinc category substances are considered endpoints of concern for humans. Based on the available information in experimental animals as well as in humans, there is no reason to classify any of the zinc category substances for reproductive toxicity in accordance with regulation (EC) 1272/2008.

**h) Specific Target Organ Toxicity – STOT-single exposure**

No data available – not classifiable due to data lacking

**i) Specific Target Organ Toxicity- STOT-repeated exposure- Animal data – classification criteria not met**

No animal or human sufficient evidence for specific target organ toxicity (repeated oral/inhalation exposure). In accordance with the criteria of regulation (EC) 1272/2008, none of the zinc category substances is classified for Specific target organ toxicity by repeated exposure (STOT-RE).

**j) Aspiration hazard**

No data available – not classifiable due to data lacking

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties: Substance is not classified as an endocrine disruptor. Zinc is essential and has no known endocrine disruption properties.

**Section 12: Ecological Information**

For the zinc substances, Ecotoxicity Reference Values (ERVs) are based on the soluble ion, Zn2+, and are determined from the extensive datasets on acute and chronic ecotoxicity testing of soluble zinc salts.

12.1. Toxicity

*a) Aquatic toxicity*

The available high-quality data were normalized towards two sets of physico-chemical conditions, reflecting the required range of pH. Such normalization is possible because for zinc, well-established bioavailability models (so called “Biotic Ligand Models” or BLMs) exist for algae, invertebrates, and fish, that enable the prediction of **acute** and **chronic** zinc ecotoxicity as a function of physicochemical test conditions. The Acute aquatic toxicity database on zinc contains data on 59 species (5 algae, 29 invertebrates, 21 fish species, 3 amphibians and 1 aquatic plant). The chronic aquatic toxicity database on zinc contains high quality data on 41 species (17 taxonomic groups).

Zinc Ecotoxicity Reference Values for aquatic toxicity

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Endpoint |  | Zn++ ion concentration | Species |
| Acute ecotoxicity | NOEC | pH 6 | 154 µg Zn/l | Daphnia magna |
| NOEC | pH 8 | 41 µg Zn/l | Pseudokirchneriella subcapitata |
| Chronic ecotoxicity | NOEC | pH 6 | 99 µg Zn/l | Pseudokirchneriella subcapitata |
| NOEC | pH 8 | 11 µg Zn/l | Pseudokirchneriella subcapitata |

*b) Sediment toxicity*

|  |  |  |  |
| --- | --- | --- | --- |
| Endpoint | Value range | Data source | PNEC extrapolation method |
| NOEC/ EC10 | 218 to 1101 µg Zn/l | 7 benthic species | Species Sensitivity Distribution |

*c) Soil toxicity*

|  |  |  |  |
| --- | --- | --- | --- |
| Endpoint | Value range | Data source | PNEC extrapolation method |
| NOEC/ EC10 | 31.2 and 8003.5 mg Zn/kg dry weight (dw) | 12 terrestrial plants, 10 invertebrates and 13 microbial endpoints | Species Sensitivity Distribution |

*d) Toxicity to micro-organisms in STP*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Endpoint | Value | Test method | Data source | PNEC extrapolation method |
| NOEC | 100 µg Zn/l | Nitrification inhibition test | Juliastuti et al. 2003 | Assessment factor  AF = 1 |

12.2. Persistence and biodegradability

Biodegradation is not applicable to metals/inorganic substances. An analysis on the removal of zinc from the water column has been presented as a surrogate for persistence.

12.3. Bioaccumulative potential

Due to homeostatic control mechanisms, bioaccumulation is not relevant to essential elements in general and to zinc in particular.

12.4. Mobility in soils

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Distribution | Transport type | parameter | Result | Method |
| Soil - water | Adsorption | Log Kp | 3.24 (0.30 – 4.31) | OECD 106 |

12.5. Results of PBT and vPvB assessment

PBT and vPvB criteria are not applicable to inorganic substances.

12.6. Endocrine disruptive properties

Substance is not classified as an endocrine disruptor. Zinc is essential and has no known endocrine disruption properties.