Risk Assessments-executive summary

Substance Group: Alkali Silicates

The use of soluble silicates is manifold. Approximately 50 % of produced soluble silicates are further processed to derivatives; the remaining 50 % are used directly with detergents and pulp and paper as the predominate application areas.
Soluble silicates are solid inorganic compounds used in a large variety of household cleaning products. Soluble silicates are widely used in regular and compact laundry detergents (powder, tablets), automatic dishwashing detergents (powder, liquid, gel, tablets), toilet cleaners, and surface cleaners. Thus, soluble silicates provide a number of functions including sequestration of ⌧water hardness enabling surfactants to function effectively, bleaching, pH buffering and corrosion prevention. In Europe, in the year 2000, the total use of soluble silicates in these applications were estimated to be approximately 188 000 tonnes.

Environmental risk assessment
Due to the physico-chemical properties of soluble silicates a release into the atmosphere during its use as household product is not to be expected. Direct emissions from soluble silicates used as detergents to the terrestrial compartment are considered negligible. Consequently, no environmental risk assessment related to the use of soluble silicates in detergents for the compartments soil and air has been performed.
As ingredients of household cleaning products, soluble silicates present in domestic waste waters are mainly discharged to the aquatic compartment, directly, via waste water treatment plants, via septic tanks, infiltration or other autonomous waste water systems.
As soluble silicates are inorganic substances, biodegradation studies are not applicable. However, the removal of silica in several sewage treatment plants was measured and an average removal of 10 % was determined. In addition, it was found that silica is continuously removed from water by biochemical processes: diatoms, radiolarians, silicoflagellates, and certain sponges serve as a sink for silica by incorporating it into their shells and skeletons as amorphous biogenic silica, frequently referred to as opal ($SiO_2 \cdot nH_2O$).
The primary hazard of commercially used soluble silicates is their moderate-to-strong alkalinity. Soluble silicates with a low molar ratio ($SiO_2:M_2O < 2$; M = Na or K) like sodium metasilicate and its hydrates with a molar ratio (MR) of 1.0 exhibit a higher alkalinity than the soluble silicates of higher molar ratio. However, most of natural aquatic ecosystems are slightly acid or alkaline and usually their pH values fall within the range of 6 ⌧ 9, and due to the high buffer capacity of these ecosystems pH effects of released soluble silicates to aquatic organisms are very unlikely. Consequently, the PNEC derived from artificial laboratory test systems overestimate the effects of soluble silicates to aquatic organisms in realistic natural ecosystems. Therefore, the PNEC was derived from the ubiquitous SiO_2 background concentration in the environment (mean of 7.5 mg SiO_2/L in European rivers). This conservative PNEC of 7.5 mg SiO_2/L was used for the final risk characterisation. Based on the EUSES HERA detergent scenario the PECregional.added and PEClocal.added of SiO_2 were calculated to be 0.536 and 1.75 mg/L, respectively. The resulting PEC/PNEC ratio was found to be 0.07 and 0.23 for the regional and local compartment, respectively. These ratios are far below 1, indicating that there is no risk to aquatic organisms after an input of silicates due to the use in detergent household products.
In addition, the amount of soluble silicates introduced into the environment must be seen in the context of the background level due to geochemical weathering processes of silicate minerals. The overall anthropogenic contribution to this total flux is only about 4 % and even lower for the use of soluble silicates in household detergents indicating that the natural background concentration/fluctuation is of much higher significance for the silica content of aquatic ecosystems than the use of silicates in detergents. For this reason it can be concluded that the SiO_2, which originates from the use of soluble silicates in household cleaning products has a negligible effect on the aquatic ecosystems.
The measured concentrations in the influent of domestic sewage treatment plants as well as the calculated PECs with the EUSES HERA detergent scenario showed that the expected concentrations of silica in sewage treatment plants will not have adverse effects on the functions of the sewage treatment plants, i.e. the degradation or the reduction of organic carbon (COD/BOD), phosphorus and nitrogen.
An eutrophication of surface waters due to nutrient enrichment as a result of the use of silica in household detergent products is not expected. The growth of diatoms and their seasonal fluctuation

(blooms) is not influenced significantly by the additional anthropogenic silica input, taking into account that the input of silica from the use of commercial silicates is negligible as compared to geochemical weathering processes. Such effects are dependent on many factors varying spatially and temporally (temperature, light, concentrations of phosphates and of other nutrients, activity of grazer population, etc.).
Based on the available data, the use of soluble silicates in household cleaning products is not expected to have adverse effects on the aquatic ecosystem.

Human Health risk assessment
Consumers can be exposed to silicates from household cleaning products by the routes, skin contact, eye contact, oral ingestion or by inhalation. Using exposure scenarios relevant for consumer uses, the total potential exposure was estimated to be 12.4 µg SiO2/kg/day.
Experimental data showed that soluble silicates have a low acute toxicity by the oral route. No data are available on dermal toxicity of soluble silicates. However, due to moderate to high water solubility, very low lipophilicity and the molecule size of soluble silicates, the dermal bioavailability for such ionic substances is assumed to be rather limited. Soluble silicates can be irritating to corrosive to the skin and eyes, depending on their molar ratio and concentration. Skin sensitising properties of soluble silicates are highly unlikely. In several repeated dose studies the NOAELs of soluble silicates ranged from 159 mg/kg bw/d (180 days) to 284 mg/kg bw/d (90 days). Because of severe limitations in a poorly conducted 4-generation study, no firm conclusions could be drawn on potential reproductive effects. The noted effects in the daughter generations cannot be evaluated from the limited data given in the study and due to the generally low surveillance rate noted in all groups including the controls. No teratogenic effects were observed in a mouse developmental toxicity study. No genotoxic effects are reported in in vitro or in vivo studies for silicates or very similar compounds like magnesium silicates. Consequently, there is no risk for developmental or reproductive toxicity or genotoxicity. The only critical endpoint for soluble silicates seems to be local irritation or even corrosive properties on skin or eye. It should be noted that the primary hazard of commercially used soluble silicates is their moderate-to-strong alkalinity causing the observed local irritations/corrosive properties. Soluble silicates with a low molar ratio like sodium metasilicate and its hydrates (MR 1.0) exhibit a higher alkalinity than the soluble silicates of higher molar ratio.
Consumers may be exposed to soluble silicates due to direct skin contact with solutions containing silica. These can be laundry hand washing or the use of products containing soluble silicates for surface and toilet cleaning. However, the estimated concentrations of soluble silicates (0.22 to 2.5 mg/mL) and contact time in these solutions are generally too low to cause local skin irritation.
Accidental acute overexposure to soluble silicates may occur via the oral route, via exposure of the eyes (e.g. due to splashing) or via inhalation. Due to the particle size, formulation and bad taste of the products an accidental overexposure to soluble silicates is rather unlikely to occur. In addition, the available data do not indicate severe adverse effects when accidental overexposure to soluble silicates occurs.
Comparison of the total estimated systemic exposure to silica through the use of detergents (5.1 µg SiO2/kg/day) to the No Effect Level estimated in animals (159 mg SiO2/kg/day, 180d) results in a margin of safety of approximately 31 000. Consequently, soluble silicates are of low concern for the consumer use in household detergents. In addition, the average daily intake of silica background exposure via drinking water and diet is in the range of 43 - 107 mg SiO2/d and therefore, an exposure of silica due the use of household products is negligible in comparison of the average daily intake via drinking water and diet.

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