TOXICOLOGICAL INVESTIGATIONS OF FERROUS SLAG IN THE CONTEXT OF THE REACH REGISTRATION

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INITIAL SITUATION

Based on extensive investigations, ferrous slag was registered in 2010. These former studies included testing for possible toxicological and ecotoxicological effects. As a result, it could be shown that ferrous slag behaves in a similar way to natural rocks. Therefore, there was no need to classify it as hazardous. However, at the time of registration in 2010 there were no investigations concerning the effect of inhaling respirable dust particles from ferrous slag [1]. Meanwhile, such very time-consuming tests (in vivo and in vitro) were performed by specialised institutes [2], supported by a consultant (IASON consulting). The in vivo tests were performed in Edinburgh with ground granulated blast furnace slag (GGBS) which had been ground to a fineness of 4230 cm^2/g according to Blaine. The in vitro tests were performed in Düsseldorf with every sort of registered ferrous slag, natural rocks and standard reference materials which served as positive or negative control, respectively. The most important results of the studies, which are summarised in so called „executive summaries" on the ECHA website, are presented below. More detailed descriptions will be published in a medical journal soon.

CHARACTERIZATION OF REGISTERED FERROUS SLAG

Ferrous slag is a solid UVCB substance (substance of Unknown or Variable composition, Complex reaction products or Biological materials) that resemble natural rocks - especially those of volcanic origin. The physicochemical properties are almost identical among all sorts of ferrous slag, and their benign toxicological and ecotoxicological profiles are very similar. Similarities comprise also the mineralogical composition of the ferrous slag. Importantly, all mineral components of ferrous slag are present in natural rocks; no new component is introduced during steel processing. Ferrous slag demonstrates low leachability in water as metals in slag are firmly bound in minerals which makes them generally resistant

to leaching. Ferrous slag is virtually free of hazardous fibres [3]. Overall, ferrous slag can be considered as artificial volcanic rock. The 'Ferrous Slag Category' comprises the following 5 slag types: (1) ABS/GBS i.e., Slag, ferrous metal, blast furnace (air cooled or granulated), (2) BOS i.e., Slag, steelmaking, converter (converter slag), (3) EAF C i.e., Slag, steelmaking, elec. furnace (carbon steel production), (4) EAF S i.e., Slag, steelmaking, elec. furnace (stainless/high alloy steel production), and (5) SMS i.e., Slag, steelmaking.

EXECUTION AND EVALUATION OF TOXICOLOGICAL STUDIES ON FERROUS SLAG

Several studies were conducted regarding potential pathways of exposure like inhalation of suspended airborne ferrous slag particulates, ingestion of ferrous slag, and dermal contact with ferrous slag.

From single-dose toxicity testing in animals via the oral, dermal and inhalation routes it can be concluded that ferrous slag is not acutely toxic. It does not need to be classified as oral, dermal and inhalation toxicant; neither a signal word nor hazard statement is required. Furthermore, ferrous slag exhibits no relevant irritant or sensitising potential, and does not show any mutagenic potential. Extensive testing in rat inhalation studies (in vivo tests) revealed that the biological responses to inhaled ferrous slag show no correlation to the course of pulmonary toxicity reported for amorphous silica (quartz); quartz dust served as positive control as it is well known to produce irreversible lung damage. Overall, ferrous slag in vivo data differ markedly from those reported for quartz in rats exposed at similar doses.

Supplemental in vitro testing also shows that ferrous slag, alike natural mineral samples, does not cause significant toxicity in cultured alveolar macrophages, nor does the slag induce major reactive oxygen species (ROS) formation and oxidative stress or trigger any inflammation in a biological system. On the contrary, the positive assay control quartz caused consistently evidence for an inflammation response in vitro associated with a significant secretion of the mature forms of pro-inflammatory cytokines from the cells, strong activation of the inflammasome pathway, and impaired phagocytosis functionality of alveolar macrophages.

Taken together the data generated in vivo and in vitro for ferrous slag it can be summarised that ferrous slag behaves like natural rock, representing an inert category of UVCB substances. Biokinetic investigations in rats suggest that the rat lung was able to get rid of the inhaled solid aerosol via physiological clearance mechanisms.

The toxicology programme for ferrous slag, as documented in the Chemical Safety Report (Chemical Safety Report, CSR) as part of the registration dossier of ferrous slag, can be considered to fulfil the information requirements for REACH (Registration, Evaluation,

Authorisation and Restriction of Chemical substances) registration at the European Chemicals Agency (ECHA). There is sufficient, adequate and reliable information on hazardous properties for classification and risk assessment of ferrous slag.

The registrants make use of Annex XI criteria regarding the scientific necessity of information, the technical possibility for testing, and exposure-based waiving to adapt the standard information requirements under REACH. Data waiving is justified for repeated oral dose toxicity testing and studies for toxicity to reproduction or developmental toxicity / teratogenicity in order to avoid unnecessary testing in vertebrate animals. These non-clinical studies are waived based on physicochemical properties of ferrous slag that resemble natural rocks, mimicking the natural concentration of an element in the environment, and the low solubility in water, low extractability of components from ferrous slag, and lack of toxicological bioavailable fraction / systemic bioavailability of metals. Ferrous slag has been utilised in road construction for more than two centuries, therefore long-standing experiences concerning possible effects on human health are available. Furthermore, ferrous slag has no PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative) properties. It is also of note that no toxicity effects of particular concern were observed in animal inhalation studies that is the likely route of human exposure, and results obtained from suitable in vitro studies demonstrate no certain dangerous property of ferrous slag. Finally, previous risk assessments of slag provides sufficient supporting evidence that toxicity can reliably be excluded.

There is no need to perform additional animal studies because ferrous slag behaves toxicologically similar as natural mineral samples; no further action is required.

In conclusion, the experimental data demonstrate that there is no likely hazard to humans due to ferrous slag.

LITERATURE

[1] Sokol, A.; Bialucha, R.: REACH-Registrierung von Eisenhüttenschlacken – aktueller Stand. Report des FEhS – Institut für Baustoff-Forschung e.V., 25 (2018) Nr. 2, pp. 21-23

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IUF - Leibniz Research Institute for Environmental Medicine, Auf´m Hennekamp 50, D-40225, Düsseldorf, Germany

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