2 October, 2007

Revision of REACH Regulation Annex V:
Proposal for inclusion of Precious metal massive forms

Preamble

The exemptions from the obligation to register under Annex V refer to REACH Article 2:

"*7. The following shall be exempted from Titles II, V and IV:*
(b) substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this regulation."

Statements made in this document specifically relate to the characteristics and life cycle of precious metals in massive form.

Proposal

In the context of their existence in massive form[1], the precious metals as listed below should be included within Annex V.

Substance name	CAS-Nr.	EC-Nr.
Silver	7440-22-4	231-131-3
Gold	7440-57-5	231-165-9
Platinum	7440-06-4	231-116-1
Palladium	7440-05-3	231-115-6
Rhodium	7440-16-6	231-125-0
Iridium	7439-88-5	231-095-9

Summary of rationale

The properties of precious metals in such form are well known. Based on extensive accumulated experience, they do not pose a risk to man or to the environment. These substances are not classified as dangerous under Directive 67/548/EEC. In relation to the aims of REACH Article 1, a requirement to undertake full registration under Title II would confer no substantive advantage in terms of protection of human health or the environment.

[1] Precious Metals should be considered as massive, if their object size is >= 1 mm. Precious Metals in dispersible form (powder etc.) would still have to be registered under Title II.

~ *a member of Eurometaux* ~
Avenue de Broqueville, 12 – BE-1150 Brussels
Tel.: +32 2 775 63 23 **Fax:** +32 2 779 05 23 **Mobile:** +32 473 52 52 73
e-mail: braibant@epmf.be **website:** www.epmf.be

Commercially available massive forms of precious metals in scope of the proposal
These are predominantly ingots, coins, pucks, formed article types (including rods, wire, pipes, nets, and crafted decorative objects), and massives of irregular shape such as grains.

Uses of massive precious metals
These have the common feature of nearly always being non-dispersive in nature, and include use as a: catalyst, alloying agent, electrical equipment, jewellery, sterling ware, coinage, conductors, contacts, brazing, soldering, electrodes, and traded form of precious metal (e.g. ingot).

Human health effect potential, and environmental effects and classification
A robust dataset is available in the general literature (e.g. from effects studies, epidemiology, and human case reports). It provides no evidence that massive precious metals have appreciable mammalian toxicity via any route of exposure. Precious metals have been used in applications with direct and close human contact, such as in jewellery, for thousands of years without indications of significant adverse effects. Due to their highly inert state, these metals have also been used extensively in medical applications thus resulting in prolonged human tissue contact (e.g. as components of dental alloys) – very few adverse reactions have been documented even for these situations of exaggerated exposure. To support medical and dental applications, a number of precious metals have been fully tested according to the requirements of the EU Medical Devices Directive (93/42/EC), and have been deemed to have a satisfactory safety profile[2].

Precious Metals are basic elemental substances that also occur in nature in massive form. Their chemical reactivity ranges from inert to very inert, and their resistance to dissolution (in such form) precludes them from producing adverse environmental effects.

These substances are not classified as dangerous to human health or the environment within the scheme laid down by Directive 67/548/EEC. Furthermore, their intrinsic properties are quantitatively remote from any of thresholds for physical hazards or toxicity present within the Directive.

End-of-life / disposal / life cycle
Due to the high value of precious metals in massive form, they are nearly always subject to recycling and recovery into new use. Based on metrics for the recycling rates of precious metals, the industrial situation equates to a life cycle which takes the form of a closed loop. Within the EU the rework and processing of waste containing precious metals (e.g. scrap and sweeps) takes place in certified refineries, based on appropriate BREF[3]-conformance, and under conditions of significant containment and minimal emissions. These operations therefore represent minimal risk to human health or the environment.

[2] Additional information on these studies can be provided as a supplementary data submission upon request.
[3] IPPC Directive BAT Reference Documents (BREFs).

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e-mail: braibant@epmf.be **website:** www.epmf.be