

Committee for Risk Assessment (RAC)

Opinion

on an Annex XV dossier proposing restrictions on
lead and lead compounds in jewellery

ECHA/RAC/ RES-O-0000001304-85-03/F

Chemicals concerned: **Lead and its compounds**

Adopted

10 March 2011

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**Opinion of the Committee for Risk Assessment
on an Annex XV dossier proposing restrictions of the manufacture, placing on the
market or use of a substance within the Community**

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation on the proposal for restriction of

Chemical name(s): *Lead and its compounds*
EC No.: *231-100-4*
CAS No.: *7439-92-1*

This document presents the opinion adopted by RAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions of RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINION

France has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The dossier conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at http://echa.europa.eu/consultations/restrictions/ongoing_consultations_en.asp on *21 June 2010*. Interested parties were invited to submit comments and contributions by *21 December 2010*.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: *Helmut GREIM*
Co-rapporteur, appointed by RAC: *Poul Bo LARSEN*

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health has been reached in accordance with Article 70 of the REACH Regulation on *10 March 2011*.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The RAC opinion was adopted *by consensus*.

OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and information submitted by interested parties as well as other available information as recorded in the Background Document.

RAC considers that the proposed restriction on *Lead and its compounds* in jewellery is the most appropriate Community wide measure to address the identified risks in terms of the effectiveness in reducing the risks provided that the conditions are modified.

RAC proposes that the conditions of the restriction should consider the following elements:

Lead (CAS No 7439-92-1, EC No 231-100-4) and its compounds shall not be used or placed on the market in

- i) Metallic and non-metallic parts of jewellery articles if the lead concentration is equal to or greater than 0.05% by weight of the part;
- ii) The paragraph above does not apply when it can be demonstrated that the rate of lead release from the jewellery article or any part thereof does not exceed 0.05 $\mu\text{g}/\text{cm}^2/\text{hr}$ (0.05 $\mu\text{g}/\text{g}$ per hr).

JUSTIFICATION FOR THE OPINION

Identified hazard and risk

The restriction proposal is targeted towards lead exposure from lead-containing jewellery. RAC finds that the targeting to jewellery items is justified by the data on lead content in jewellery and lead migration from jewellery presented in the dossier.

Lead content:

In a Danish survey (Danish EPA, 2008), 58% of 170 examined jewellery pieces contained lead in the concentration range from 0.01% to 70 % lead, and 42% of the pieces contained less than 0.01% lead. In a Swedish survey (KEMI, 2008) 23 of 50 examined jewellery pieces were found to contain lead with 4 pieces above 10% lead, 9 pieces in the range of 2-10% lead, and 10 pieces below 2% lead. A second Swedish survey (KEMI, 2008) was reported in which 36 of 50 pieces of jewellery contained lead with rather similar lead contents. In a German survey (BfR, 2008) on jewellery, 78 samples out of 87 contained lead with an average lead content of 6.3% and a maximum value of 90%. In a UK survey (the Sunday Times, 2008), 24 children's jewels were examined and 8 tested positive for a high content of lead. Six of the items exceeded a lead concentration of 80%. Based on these European surveys the lead content in jewellery articles is between very low and 90 %. Also Canadian and US surveys confirm this wide variation of lead content. Moreover, according to one independent testing laboratory (Anon, 2010), it is estimated that about 10 % of jewellery sold in EU contains an average of 6% of lead and that there is some indication that the trend of lead content in jewellery is increasing. The amount of tested items was above 12,000 articles.

Characterisation of risks

RAC agrees with the assessment from France that neurotoxicity, specifically neurobehavioral and neuro-developmental effects from repeated lead exposure, is the key effect that this restriction is aimed at protecting against. Children will be particularly sensitive to this hazard, given that their central nervous system is still under development. No threshold for the adverse effect has been identified in humans; therefore RAC considers that any exposure by released lead from jewellery will present a risk. In consideration of the mouthing behaviour of small children, and the possibility for lead migration, RAC concluded that lead exposure of children from jewellery may occur.

RAC considers such chronic exposure as most relevant to justify a restriction. The very few reports on acute exposures due to swallowing parts of jewellery resulted in increased blood lead levels without reporting of acute symptoms in some of the cases. In other cases the reported symptoms may also have been the result of obstruction of the gastro-intestinal passage by the swallowed piece of jewellery. A focus of the restriction to chronic exposure due to children's mouthing behaviour would also cover acute risks from lead after swallowing.

RAC supports the risk assessment of EFSA (2010), in which a lower benchmark dose level (BMD(01)) of 0.5 µg Pb/kg bw/d was derived as a dose descriptor for the potential adverse effects of lead on children. This corresponded to a change in blood level of 12 µg Pb/L and an IQ loss of 1 point. EFSA observed that children in the age group of 1- 7 years have mean background lead exposures between 0.8 and 5.5 µg/kg bw per day (e.g. from the diet and background environmental exposure). Clearly, this already exceeds the BMDL(01) level of 0.5 µg Pb/kg bw/d, and therefore any additional lead exposure would on average be expected to further increase a typical child's exposure above the dose descriptor level.

In the original proposal submitted by France, a migration limit value of 0.09 µg /cm²/hr was proposed. This was associated with a DMEL which was based on analytical measurement error. In order to use a risk-based approach, RAC judged it more appropriate to consider the EFSA BMDL (01) value (0.5 µg Pb/kg bw/d) and to apply a MoE of 10, which according to EFSA (2010) is sufficiently low to ensure no appreciable risk. This exposure of 0.05 µg Pb/kg bw/d correlates with an IQ reduction in children of 0.1 points.

Considering an exposure scenario in which a child of 10 kg bw mouths a jewel for 1 hour with a surface of 10 cm² and a weight of 10 g a tolerable migration rate from the jewellery of 0.05 µg Pb/cm²/hr or 0.05 µg Pb/g/hr is estimated. The migration rate expressed in per surface unit is in principle applicable for all kind of surfaces (metallic as well as non metallic parts). With a general assumption that the ratio between surface (in cm²) and the weight (in g) of the jewel is 1 the migration rate would most practically be set to 0.05 µg Pb/g/hr.

For metallic parts of jewellery, the association between migration rates and content of 0.05% is based on the reassessment of the Danish EPA (2008) report. RAC recognises the uncertainty in this association as presented in BD supporting this opinion; however, RAC considers that this association is further supported by the direct consideration of the raw measurements reported in the Danish study, as migration was not detected in the three jewellery items containing less than 0.05% lead, while it was detected in two (out of three) items with lead content between 0.1 and 1%.

In the absence of specific data for the non-metallic parts of jewellery, RAC has considered the characteristics of the exposure scenario in order to assess if the value of 0.05% proposed for

the metallic parts may be sufficient for protecting children from the exposure from non-metallic parts and coating materials.

Since migration due to mouthing is expected to occur only from the surface area, a depth of 0.1 mm is considered as a conservative maximum for relevant migration within one hour mouthing. For a surface area of 10 cm² and a depth of 0.1mm (0.01 cm) a maximum mouthing total volume of 0.1 cm³ is estimated. Assuming a material density between 10 g/cm³ for heavy metals and crystals to 1 g/cm³ for plastics and woods the maximum amounts of lead in the relevant part of jewellery for the proposed limit of 0.05% would be 500 µg lead for the metallic parts of jewellery and crystals and 50 µg lead for plastics and woods. RAC considers that it is unlikely that these levels could exceed the tolerable daily exposure of 0.05 µg/kg bw/d, as the child would need on a daily basis to extract, by mouthing, more than 0.1% of the lead in crystals or more than 1% in the case of jewellery items made of plastics and woods. Thus, in absence of specific information, RAC considers that the 0.05% limit is also protective for the non-metallic parts of jewellery.

The concentration limit of 0.05% and the migration limit (0.05 µg Pb/g/hr) are based on a daily mouthing time of 1 hr. RAC notes that this is a worst-case estimate. For comparison, a daily mouthing time of 15 min would result in an exposure which is fourfold below the level to ensure no appreciable risk, a weekly mouthing time for 1 hr per week is about 7 times below this level. A detailed description of the impact of different lead exposures due to mouthing at different frequencies is given in Tables 35 and 36 of BD.

Justification that action is required on a Community-wide basis

Placing on the market of lead-containing jewellery occurs across the EU. Generally, there are no risk management measures to avoid lead exposure from jewellery, and so adequate measures to minimise such exposures should be implemented on a community-wide basis. In particular, this should protect children from lead exposure and the possibility of adverse effects on the central nervous system. As no threshold has been found for the harmful effect of lead on the central nervous system, and with a view to background exposure from diet and other environmental sources, any relevant lead exposure should in principle be avoided.

Justification that the suggested restriction is the most appropriate Community-wide measure

Risk Reduction Capacity

Several restriction options are discussed in BD. RAC concluded that the most appropriate option would be to set a limit for the migration of lead under the conditions found when children might place lead-containing jewellery in their mouths. A targeted restriction option linked directly to lead migration from a given surface area or a given weight of jewellery would cover the potential for exposure.

However, RAC recognised practical as well as methodological problems with this restriction option, including that it would be more costly to monitor enforcement and compliance than an alternative option based on the content of lead in jewellery. For the metallic part of the jewellery alone, given that RAC found an association (although rather uncertain) between migration rate and overall lead content, a limit value of 0.05% is proposed. In the absence of migration rate information on non-metallic parts, RAC has assessed the applicability of the same limit value proposed for the metallic parts as explained in the section of characterisation

of risks, and concluded that the limit of 0.05 % is also protective for non-metallic parts of jewellery.

Practicality (including enforceability) and monitorability

For metallic parts, the analysis of lead content can usually be made in a non-destructive way using X-ray fluorescence (XRF) devices; only occasionally would a destructive standard wet chemical analysis need to be performed. Many items can be tested in a short time; only the jewellery containing lead above the limit value would require migration testing.

As low migration rates may occur at higher lead contents in jewellery, RAC considers that the restriction may allow industry to market jewellery items exceeding the limit of 0.05% lead provided that the actual migration does not exceed the proposed migration rate.

However, RAC recognises that further work has to be done in order to specify how the testing for content as well as for migration should be performed. RAC emphasises that reliable methods to determine migration rates from jewellery especially at lead concentrations below 1% need to be established.

Based on the received comments, RAC considers that a migration limit based on weight instead of surface is preferable in terms of practicality and implementability, and therefore suggests the use of 0.05 µg Pb/g/hr as the best measure for migration, provided that adequate analytical methods are available.

During the public consultation conducted by ECHA, it was proposed to differentiate between fashion and precious jewellery and also jewellery intended for use by children. However, RAC did not find any basis for such differentiation.

Conclusion

Based on a thorough evaluation of the available information, RAC proposes to limit the lead content in jewellery. Specifically the proposal is to restrict the lead content in jewellery articles and any parts thereof to 0.05%, unless it is demonstrated that the migration rate of lead release from jewellery articles does not exceed 0.05 µg/cm²/hr (0.05 µg/g per hr) for both the metallic and the non-metallic parts.

The reasoning behind the proposed restriction by RAC is the following:

The restriction conditions should ensure that the migration of lead from jewellery articles or any parts thereof placed on the market does not exceed 0.05 µg/cm²/hr if measured by surface or 0.05 µg/g per/hr if measured by weight.

Due to lack of validated methods for measuring migration which mimics mouthing RAC considers that a restriction based on content is more practicable for implementation and enforcement. From the assessment of the data available on metallic parts, RAC considers that a content of 0.05% lead in metallic parts of jewellery is appropriate for ensuring the protection level presented above.

Although there is no information on migration versus content for non-metallic parts, RAC considers that the concentration value of 0.05% is also protective for the non-metallic parts.

BASIS FOR THE OPINION

BD provided as a supportive document gives the detailed grounds for the opinion.

The opinion in principle supports the dossier submitter's proposal for having such a restriction; however, the conditions of the opinion of RAC diverge significantly from the originally proposed restriction.