

**Committee for Risk Assessment**  
**RAC**

**Annex II**

**Alternative outcomes regarding the relevance of  
particles > 1 mm generated from use of massive lead  
and the subsequent alternative classification  
outcomes**

to the **Opinion**  
**on the harmonised classification of lead  
(environment)**

Pursuant to Article 77(3)(c) of Regulation (EC) No  
1907/2006 of the European Parliament and of the Council of  
18 December 2006 concerning the Registration, Evaluation,  
Authorisation and Restriction of Chemicals

**EC Number: 231-100-4**  
**CAS Number: 7439-92-1**

A77-O-0000007042-85-01/F

**Adopted**  
**16 September 2021**

## Alternative classification outcomes following different options for the forms of lead

Conclusion 1, as presented in RAC’s opinion on the classification of lead, concludes that particles < 1 mm generated from the use of lead are relevant and that the powder is suitable for classifying massive lead. Following the options presented in section 4.13 that RAC has opted not to follow, classification conclusions 2 and 3 are presented below for completeness.

### Conclusion 2

RAC notes that while basing classification of the massive form on dissolution from generated particles < 1 mm is principally an option, no measured T/Dp data is available on any generated lead particles < 1 mm from any process. Attempts to model dissolution data with the existing information revealed a great deal of uncertainty due to the number of assumptions required in order to generate modelled data. As such, RAC considers the option to classify massive lead based on generated particle data as not currently viable. Fig. II.1 is included below to show how the decision scheme could principally be used under such circumstances.

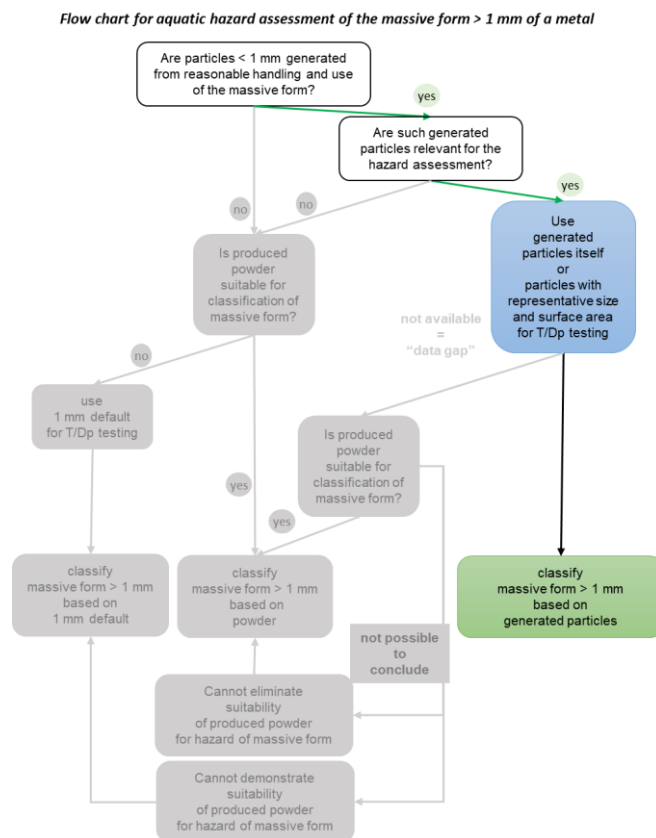


Figure AII.1: Interpretation of decision scheme for assessing basis for hazard assessment of massive metal where massive should be classified based T/Dp data from the generated particles themselves or equivalent surface area.

### Conclusion 3

This option would follow the conclusion that lead powder is not suitable for the classification of the massive form of lead and that T/Dp data for the default 1 mm should be used to classify lead. This is highlighted in the interpretation of the decision scheme in fig. II.2 below.

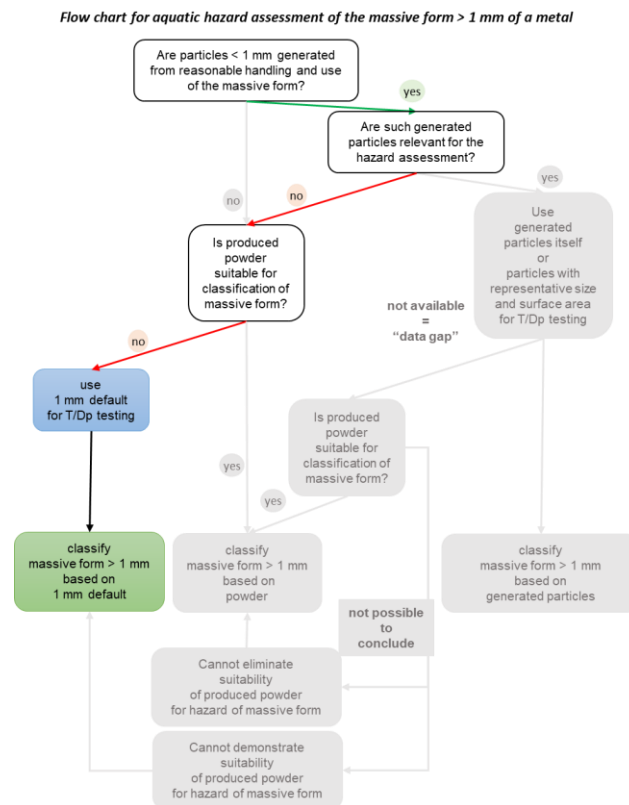


Figure AII.2: Interpretation of decision scheme for assessing basis for hazard assessment of massive metal where massive should be classified based on T/Dp data from 1 mm particles or equivalent specific surface area.

As a consequence, classification would be derived as follows:

#### *Massive lead*

- Dissolution of lead from default particle size 1 mm over 7 days at pH 6 and 1 mg/L loading (5.1 µg Pb/L) is smaller than the acute ERV (20.5 µg Pb/L) so no acute classification is warranted.
- Dissolution of lead from default particle size 1 mm over 28 days at pH 5.5 at 0.1 mg/L loading (5.21 µg/L) is larger than the chronic ERV (0.48 µg Pb/L) so classification as Aquatic Chronic 1 – H410 is warranted.
- The ratio between the chronic ERV and the T/Dp value over 28 days at pH 5.5 and 1 mg/L loading (52.1 µg Pb/L) is 108.5, so a chronic M-factor of 100 is warranted

#### *Lead powder*

- Dissolution of lead powder over 7 days at pH 6 and 1mg/L loading (390 µg Pb/L) is larger than the acute ERV (20.5 µg Pb/L) so classification as Aquatic Acute 1 –

H400 is warranted.

- The ratio between the acute ERV and the dissolution rate is 19, so an acute M-factor of 10 is warranted
- Dissolution of lead powder over 28 days at pH 5.5 at 0.1 mg/L loading (94.28 µg Pb/L) is larger than the chronic ERV (0.48 µg Pb/L) so classification as Aquatic Chronic 1 – H410 is warranted.
- The ratio between the chronic ERV and T/Dp value over 28 days at pH 5.5 at 1 mg/L loading (942.8 µg Pb/L) is 1964, so a chronic M-factor of 1000 is warranted

In conclusion, although powder and massive lead are not structurally different but lead powder is manufactured via distinct process and exhibits higher dissolution leading to a more stringent classification, lead warrants classification as:

*Lead Massive > 1 mm*

Aquatic Chronic 1 (H410), M=100

NB, Massive lead would warrant classification as Aquatic Chronic 1 (H410), M=10, following the approach using 28d loading data at 0.1 mg/L in section 8.1.

*Lead powder < 1 mm*

Aquatic Acute 1 (H400), M=10

Aquatic Chronic 1 (H410), M=1000

NB, lead powder would warrant classification as Aquatic Chronic 1 (H410), M=100, following the approach using 28d loading data at 0.1 mg/L in section 8.1.