



Risk Management Option Analysis Conclusion Document

Substance Name: Mercury in dental restorative materials (dental amalgam)

EC Number: 231-106-7

CAS Number: 7439-97-6

Authority: Swedish Chemicals Agency (Kemi)

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020¹.

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

¹ For more information on the SVHC Roadmap: <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation>

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Mercury and mercury compounds are widespread hazardous substances with well-known adverse effects on environment and on human health. Hence, mercury and its compounds are regulated in several regulations in the EU and in global conventions. Among those processes and international regulations are;

- EU regulation 1907/2006 (Reach) Annex XVII on restrictions (entries 18 and 18a for mercury compounds and mercury, respectively) and appendix 6 (entry 30, — Toxic to reproduction: category 1B, Table 3.1/category 2, Table 3.2 (for mercury)).
- EC regulation 1272/2008 (CLP) Annex VI, Part 3, table 3.1 (mercury index no. 080-001-00-0).
- EU regulation 649/2012 (PIC) Part 1, Part 2 and Part 3 (for mercury compounds).
- Seveso III Directive 2012/18/EU.
- Water Framework Directive 2000/60/EC Annex X on list of priority substances (entry 21 for mercury and its compounds).
- The Mercury Discharges Directive (82/176/EEC).
- The Mercury Directive (84/156/EEC).
- Community Strategy Concerning Mercury (the Communication from the Commission to the European Parliament and the Council, 2005).
- The Minamata Convention on Mercury (adopted in October 2013 but entered into force on 16 August 2017).
- The Convention on Long-range Transboundary Air Pollution (CLRTAP).
- The Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR).
- The Convention on the Protection of the Marine Environment of the Baltic Sea Area (Helsinki Convention, HELCOM).
- The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal.
- The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.
- **Regulation (EU) 2017/852 concerning mercury.**

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	Tick box
Need for follow-up regulatory action at EU level:	
<i>Harmonised classification and labelling</i>	
<i>Identification as SVHC (authorisation)</i>	
<i>Restriction under REACH</i>	
<i>Other EU-wide regulatory measures</i>	
Need for action other than EU regulatory action	
No action needed at this time	X

3. NO ACTION NEEDED AT THIS TIME

As it stands now, the Regulation (EU) 2017/852, which enters into force 1st of January 2018, takes into account risk management measures for dental amalgam in the most sensitive groups of the population, i.e. children as well as pregnant and breastfeeding women. It also considers the use of amalgam separators in dental facilities to better handle mercury-containing waste and diminish the environmental exposure.

However, in order to protect the environment and human health, the use of dental amalgam should be phased out to the furthest extent possible by including all adults. This requires that all European dentists are fully trained and skilled in conducting Hg-free restorations. Further, national dental health insurance schemes ought to promote mercury-free alternatives. This would contribute to the long-term goal to reduce emissions and exposure of mercury to the environment.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Sweden will await the outcome of Regulation (EU) 2017/852 and an assessment of a follow-up of the risk management measures by the European Commission. Hence, Sweden considers that there is no need for any further measures on top of those already specified for mercury in the regulation at the moment. However, this conclusion may be revised should the outcome of the regulation not be satisfactory with regard to the risks of mercury use in dental restorative materials.