

Exemption Request Form

Date of submission: June 1st, 2017

1. Name and contact details

1) Name and contact details of applicant:

Company: Sciex Tel.: +1 289-982-2545
Name: Ali Ali E-Mail: ali.ali@sciex.com
Function: Compliance Analyst Address: 71 Four Valley Dr.,
Concord, ON. L4K 4V8 Canada

2) Name and contact details of responsible person for this application (if different from above):

Company: _____ Tel.: _____
Name: _____ E-Mail: _____
Function: _____ Address: _____

2. Reason for application:

Please indicate where relevant:

- Request for new exemption in: Category 8 & 9
 Request for amendment of existing exemption in
 Request for extension of existing exemption in
 Request for deletion of existing exemption in:
 Provision of information referring to an existing specific exemption in:
 Annex III Annex IV

No. of exemption in Annex III or IV where applicable: _____

Proposed or existing wording: Lead in solder and
Hexavalent Chromium in
parts used to make RF
detectors in Mass
Spectrometers.

Duration where applicable: 2 years

Other: _____

3. Summary of the exemption request / revocation request

This request is to exempt the use of lead in solder and the use of Hexavalent Chromium in parts used in the making of the RF detectors that are used in our mass spectrometers (MS). The RF detectors require certain thermal properties to operate accurately which is categorized as a company trade secret. The information that can be shared indicates that a RoHS compliant version was designed and built, but it did not pass failure analysis. A conversion plan has been developed to study the reliability of substitutes and conduct conversion to RoHS where feasible.

4. Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

Name of applications or products: Mass Spectrometers

- a. List of relevant categories: (mark more than one where applicable)

- | | |
|----------------------------|---------------------------------------|
| <input type="checkbox"/> 1 | <input type="checkbox"/> 7 |
| <input type="checkbox"/> 2 | <input checked="" type="checkbox"/> 8 |
| <input type="checkbox"/> 3 | <input checked="" type="checkbox"/> 9 |
| <input type="checkbox"/> 4 | <input type="checkbox"/> 10 |
| <input type="checkbox"/> 5 | <input type="checkbox"/> 11 |
| <input type="checkbox"/> 6 | |

- b. Please specify if application is in use in other categories to which the exemption request does not refer: No

- c. Please specify for equipment of category 8 and 9:

The requested exemption will be applied in

monitoring and control instruments in industry

in-vitro diagnostics

other medical devices or other monitoring and control instruments than those in industry

2. Which of the six substances is in use in the application/product?

(Indicate more than one where applicable)

Pb Cd Hg Cr-VI PBB PBDE

3. Function of the substance: Lead in Solder (Sn63Pb37) and Hexavalent Chromium coating.

4. Content of substance in homogeneous material (%weight): Lead is 37%, Hexavalent Chromium is between 0.1565 and 0.9065 µg/cm².
5. Amount of substance entering the EU market annually through application for which the exemption is requested: between 15 to 20g of Lead, 194mg of Hexavalent Chromium. Calculations and test report(s) can be provided as reference files.
Please supply information and calculations to support stated figure.
6. Name of material/component: Lead in Solder (Sn63Pb37) and Hexavalent Chromium in parts.
7. Environmental Assessment: _____
LCA: Yes
 No

(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

Material used in the RF detectors which is an essential part of the Mass Spectrometer. The RF detectors convert a high voltage RF input to a low voltage DC output signal. The DC output signal is used as the feedback for precision control of the high voltage RF applied to the quadrupole mass filter in our instruments. In order to meet our analytical mass stability and peak width stability requirements, the RF detector is required to be very stable, quite accurate, and highly linear over two orders of magnitude of input voltage. In order to meet these requirements, the RF detector uses special capacitors held within a temperature controlled oven.

(C) What are the particular characteristics and functions of the RoHS-regulated substance that require its use in this material or component?

A combination of lower soldering temperature and maintenance of shielding effectiveness of the detector capacitor case.

5. Information on Possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

- 1) Please indicate if a closed loop system exist for EEE waste of application exists and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)

Yes. Mass Spectrometers are used in laboratory settings and are disposed of in a controlled system.

2) Please indicate where relevant:

- Article is collected and sent without dismantling for recycling
- Article is collected and completely refurbished for reuse
- Article is collected and dismantled:
 - The following parts are refurbished for use as spare parts: _____
 - The following parts are subsequently recycled: _____
- Article cannot be recycled and is therefore:
 - Sent for energy return
 - Landfilled

3) Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum:

- In articles which are refurbished
- In articles which are recycled Lead: between 15 to 20g
Hexavalent Chromium: 194mg.
- In articles which are sent for energy return _____
- In articles which are landfilled _____

6. Analysis of possible alternative substances

- (A) Please provide information if possible alternative applications or alternatives for use of RoHS substances in application exist. Please elaborate analysis on a life-cycle basis, including where available information about independent research, peer-review studies development activities undertaken**

Alternative compliant materials will be used where such parts meet the required performance specifications of the equipment.

- (B) Please provide information and data to establish reliability of possible substitutes of application and of RoHS materials in application**

A three stage conversion plan has been developed to study the reliability of substitutes and conduct conversion to RoHS where feasible.

7. Proposed actions to develop possible substitutes

- (A) Please provide information if actions have been taken to develop further possible alternatives for the application or alternatives for RoHS substances in the application.**

A three stage conversion plan has been developed to study the reliability of substitutes and conduct conversion to RoHS where feasible with estimated duration of 24 months.

- (B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.**

A three stage conversion plan has been developed to study the reliability of substitutes and conduct conversion to RoHS where feasible with estimated duration of 24 months.

8. Justification according to Article 5(1)(a):

(A) Links to REACH: (substance + substitute)

- 1) Do any of the following provisions apply to the application described under (A) and (C)? No

Authorisation

SVHC

Candidate list

Proposal inclusion Annex XIV

Annex XIV

Restriction

Annex XVII

Registry of intentions

Registration

- 2) Provide REACH-relevant information received through the supply chain.

Name of document: N/A

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated?

Yes. Consequences? _____

No. Justification: A three stage conversion plan has been developed to study the reliability of substitutes and conduct conversion to RoHS where feasible.

2. Can the substance named under 4.(A)1 be substituted?

Yes.

Design changes:

Other materials:

Other substance:

No.

Justification:

A three stage conversion plan has been developed to study the reliability of substitutes and conduct conversion to RoHS where feasible.

3. Give details on the reliability of substitutes (technical data + information): A three stage conversion plan has been developed to study the reliability of substitutes and conduct conversion to RoHS where feasible.

4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to

1) Environmental impacts: None

2) Health impacts: None

3) Consumer safety impacts: None

⇒ Do impacts of substitution outweigh benefits thereof?

Please provide third-party verified assessment on this: _____

(C) Availability of substitutes:

a) Describe supply sources for substitutes: Standard supply chain sources

b) Have you encountered problems with the availability? Describe: No

c) Do you consider the price of the substitute to be a problem for the availability?

Yes No

d) What conditions need to be fulfilled to ensure the availability? Standard supply chain conditions

(D) Socio-economic impact of substitution:

⇒ What kind of economic effects do you consider related to substitution?

Increase in direct production costs

Increase in fixed costs

Increase in overhead

Possible social impacts within the EU

Possible social impacts external to the EU

Other: Mass spectrometers have a significant positive social and economic impact to society. Mass spectrometers are analytical devices that are used to detect and quantify analytes in samples. Examples of applications that employ mass spectrometric techniques include:

- help scientists make confident decisions faster, enabling them to move candidates through the pipeline, resulting in more efficacious, safer therapeutics in pharma- and biopharmaceutical research;
- identify key genes, proteins, lipids and metabolites in complex systems biology and then integrate the findings to gain a comprehensive insight to further understand health and disease in life sciences research;
- detect and quantify chemical contaminants and residues in food substances to meet regulatory demand and ensure food safety;
- detect and quantify environmental contaminants in drinking water, waste water and soil;
- assist in the diagnosis and treatment of disease states.

Removal of mass spectrometers from industry would have far reaching effects upon the economy and society.

⇒ Provide sufficient evidence (third-party verified) to support your statement: _____

9. Other relevant information

Please provide additional relevant information to further establish the necessity of your request:

10. Information that should be regarded as proprietary

Please state clearly whether any of the above information should be regarded to as proprietary information. If so, please provide verifiable justification:
