

Exemption Request Form

Date of submission:

1. Name and contact details

1) Name and Contact details of applicant

Company	AB Sciex	Telephone	
Name		E-mail	
Function		Address	
2) Name and Contact details of responsible person for this application (if different from above)			
Company	Claigan Environmental	Telephone	613-599-4444
Name	Bruce Calder	E-mail	Bruce.calder@claigan.com
Function	VP Consulting Services	Address	4043 Carling Av. Suite 120 Ottawa

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: <input type="checkbox"/> Annex III <input type="checkbox"/> Annex IV	
No of exemption in Annex III or IV where applicable:	
Proposed of existing wording:	Lead in solder used to make electrical connections to vacuum boards used in Laboratory Analytical Instruments. Boards designed to be used periodically under low pressure.
Duration where applicable:	5 years.
Other:	

3. Summary of the exemption request/ revocation request

This request is to exempt use of lead in solder used to make electrical connections (connectors to PCB) at interface between internal vacuum chamber and detection section of Laboratory Analytical Instrument. Solder joint does not meet technical criteria for leaks and reliability. **Ref Files**

4. Technical description of the exemption request/revocation request

A) Description of the concerned application:

An analytical tool that is used to detect elements in a chemical compound. The atoms in the sample compound can be identified by correlating known elements to the identified elements. The technique is widely used in pharmaceutical, medical, agriculture, food and other industries.

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

Name of applications or products:	Laboratory Analytical Instruments
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a. List of relevant categories: (mark more than one where applicable)			
1		7	
2		8	Medical Devices
3		9	Industrial Monitoring and Control Instruments
4		10	
5		11	
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:			
<ul style="list-style-type: none"> • monitoring and control instruments in industry 			
<ul style="list-style-type: none"> • in-vitro diagnostics 			
<ul style="list-style-type: none"> • other medical devices or other monitoring and control instruments than those in industry. 		Laboratory Analytical Instruments	
2. Which of the six substances is in use in the application/product? (indicate more than one where applicable)		<input checked="" type="checkbox"/> Pb	<input type="checkbox"/> Cr-VI
		<input type="checkbox"/> Cd	<input type="checkbox"/> PBB
		<input type="checkbox"/> Hg	<input type="checkbox"/> PBDE
3. Function of the substance.		Lead in Solder (Sn63Pb37)	
4. Content of substance in homogenous material (% weight)		37%	
5. Amount of substance entering the EU market annually through application for which the exemption is requested.		The estimated total amount of Lead (Pb) entering the EU market annually (in all instruments) vary between 1,342gm to 2,684gm (1.342Kg to 2.684Kg) depending on the instrument and the number of contact per PCB for which the exemption is requested	
Please supply information and calculations to support stated figures		Quantity estimated based on actual PCB and connector type. Ref File	
6. Name of material/component		Lead in tin –lead solder. (63wt% Sn / 37wt% Pb)	
7. Environmental assessment			
A) LCA – Life Cycle Assessment		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 manufacturing the Laboratory Analytical Instruments. These instruments are used in wide range of applications in medical and none medical fields. Simplified, it is a tool that is used to detect elements in a chemical compound in multiple fields: pharmaceutical, food, water supply, medical for research and/or commercial use.	

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C) What are the particular characteristics and functions of the ROHS-regulated substance that required its use in this material or components?	Low temperature melting point that attributes to the reliability and integrity of the interconnect joints.
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 exists for EEE waste of application exists and provide information of its characteristics (method of collection to ensure closed loop, method of treatment etc.)	Yes. Laboratory Analytical Instruments are used in laboratory settings and are disposed in a controlled system.
2) Please indicate where relevant: <ul style="list-style-type: none"> ○ Article is collected and sent without dismantling for recycling. ○ Article is collected and completely refurbished for reuse. ○ Article is collected and dismantled: <ul style="list-style-type: none"> ● The following parts are refurbished for use as spare parts: ● The following parts are subsequently recycled. ○ Article cannot be recycled and is therefore: <ul style="list-style-type: none"> ● Sent for energy return ● Land filled. 	Yes
3) Please provide information concerning the amount (weight) of ROHS substance present in EEE waste accumulated per annum: <ul style="list-style-type: none"> ● In articles which are refurbished ● In articles which are recycled ● In articles which are sent for energy return ● In articles which are land filled 	1,342gm to 2,684gm (1.342Kg to 2.684Kg) of lead (Pb) depending on the instrument and the number of contact per PCB for which the exemption is requested.
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 solutions are currently under investigation. <ul style="list-style-type: none"> a) Surface mount interconnect. Surface mount interconnect solution looks promising. Additional testing (functional and reliability) still required to establish the validity of this solution. b) Low temperature Bi based solder. Bi Based solder still under evaluation and it will require additional testing to establish reliability under low pressure environment. This solution may prove to be higher cost than surface mount approach. Also full characterization of Bi based solder may not be available until 2021/2022.

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B) Please provide information and data to establish reliability of possible substitutes of application and of ROHS material application.	There is no research or data available related to lead free solder reliability under vacuum.
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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.	<ul style="list-style-type: none"> PCB designs under review for interconnect change to surface mount Board level testing for functional verification System level verification and reliability testing. Work complete in 2021/2022.
B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stage.	<ul style="list-style-type: none"> Identify reliable and cost effective interconnect surface mount parts. Identify reliable lead free solder that is suitable for vacuum use. Verify that functionality is not compromised. Verify that proposed solution(s) will work in vacuum for long time interval. Successful solutions: examine contact integrity after testing, perform reliability estimation to determine life cycle of interconnect joints. Prototype builds for verification and validation and full system reliability test. Production release.

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)					
○ Authorization					
○ SVHC	No				
○ Candidate List	No				
○ Proposal inclusion Annex XIV	No				
○ Annex XIV	No				
○ Restriction					
○ Annex XVII	No				
○ Registry of instructions	No				
○ Registration	N/A				
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?	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 2px;"><input type="checkbox"/> Yes. Consequences?</td> <td style="width: 50%;"></td> </tr> <tr> <td style="padding: 2px;"><input checked="" type="checkbox"/> No. Justification</td> <td style="padding: 2px;">Plan in progress</td> </tr> </table>	<input type="checkbox"/> Yes. Consequences?		<input checked="" type="checkbox"/> No. Justification	Plan in progress
<input type="checkbox"/> Yes. Consequences?					
<input checked="" type="checkbox"/> No. Justification	Plan in progress				

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2. Can the substance named under 4(A)1 be substituted?	<input type="checkbox"/> Yes. Design changes:
	Other materials:
	Other substance:
	<input checked="" type="checkbox"/> No. Justification
3. Give details on the reliability of substitutes(technical data +information)	Surface mount solution expected to meet design expectations. (Details same as Item 6)
4. Describe environmental assessment of substance from 4(A)1 and possible substitutes with regard to: 1) Environmental impacts: 2) Health impacts: 3) Consumer safety impacts: Do impacts of substitution outweigh benefits thereof?	None None None
5. Please provide third party verified assessment on this:	
C) Availability of substitutes:	
a) Describe supply sources for substitutes: b) Have you encountered problems with the availability? Describe: c) Do you consider the price of the substitute to be a problem for the availability? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No d) What conditions need to be fulfilled to ensure the availability?	No current substitutes, however alternative solutions are currently under investigation.
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 Provide sufficient evidence (third-party verified) to support your statement.	Laboratory Analytical Instruments are used to detect elements in a chemical compound. Examples of applications that employ those analytical techniques include: <ul style="list-style-type: none"> • 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 your 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

	<p>contaminants in drinking water, waste water and soil</p> <ul style="list-style-type: none"> • assist in the diagnosis and treatment of disease states
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:	