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| J:\Design\Aerogen Rebranding\1. Brand Guidelines and Logos\Logos\Aerogen Logo.jpg | **Quality Form****Aerogen Ltd.** |

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| **Title** | **Materials Declaration Form** |
| **Document No.** | **QF146** |

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| --- | --- | --- |
| **Revision** | **DCR No.** | **Effectivity Date** |
| C | DCR21234 | 10 June 2021 |
| D | DCR23301 | 21 April 2023 |
| E | DCR23578 | 06 July 2023 |

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| --- | --- | --- |
| **Aerogen Item Number (s)** | **Supplier Part Number(s)** | **Description** |
| 21-083 | LP2981AIM5-5.0/NOPB | LP2981-N 100mA, Low-Dropout Regulator, 5 Lead SOT-23 |

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| --- | --- | --- |
| **Q 1** | **Presence of substances listed in REACH[[1]](#footnote-2) Annex XIV as amended or CLP[[2]](#footnote-3) Annex VI Part 3 as carcinogenic, mutagenic or toxic to reproduction of category 1A or category 1B ( ≥ 0.1% by weight)** | **Yes:** [ ]  **No:** [ ]  |
| **Q 2** | **Presence of substances having endocrine disrupting properties according to Article 59 of REACH1 as amended ( ≥ 0.1% by weight)** | **Yes:** [ ]  **No:** [ ]  |
| **Q 3** | **Presence of substances listed in REACH1 Annex XVII or candidate list ( ≥ 0.1% by weight)** | **Yes:** [ ]  **No:** [ ]  |
| **Q 4** | **Presence of RoHS 3 restricted substances[[3]](#footnote-4)?** | **Yes:** [ ]  **No:** [ ]  |
| **Q 5** | **Have you completed any SCIP[[4]](#footnote-5) notifications?** | **Yes:** [ ]  **No:** [ ]  |
| **Q 6** | **Presence of PROP65[[5]](#footnote-6) substances above the Safe Harbor Level?** | **Yes:** [ ]  **No:** [ ]  |
| **Q 7** | **Presence of substances with animal origin** | **Yes:** [ ]  **No:** [ ]  |
| **Q 8** | **Presence of Latex or natural rubber** | **Yes:** [ ]  **No:** [ ]  |
| **Q 9** | **Safety Data Sheets (SDS) and Test Data included confirming compliance to the information listed above** | **Yes:** [ ]  **No:** [ ]  |
| **Q 10** | **What is the status of the environment where you manufacture this component (General manufacturing, controlled environment, clean room)?** | **General:** [ ] **Controlled:** [ ] **Clean Room:** [ ]  |

**If Yes[[6]](#footnote-7):**

|  |  |  |  |
| --- | --- | --- | --- |
| **Location (In Product/Component)** | **If applicable, Substance Number** | **Concentration (%w/w)** | **Any Additional Information (e.g. SCIP number)** |
| **N/A** | **N/A** | **N/A** | **N/A** |

**Acknowledgement of Material Declaration**

We hereby confirm that the answers we have given are true and correct and that we oblige ourselves to comply with the below mentioned requirements and conditions:

1. Any new information and changes affecting already submitted replies regarding Aerogen Limited (Hereinafter referred to as ‘Aerogen’) requests relating to material declaration(s), to be forwarded to Aerogen immediately.
2. When updates of the REACH candidate list – see <http://echa.europa.eu> – affect substances that are part of any Aerogen product, it is mandatory to inform Aerogen at once. The same applies for substances restricted under the RoHS Directive.
3. Integral substances are pre-registered and registered when needed at the European Chemicals Agency’s website – <http://echa.europa.eu>.
4. In order to be able to make a correct REACH registration, suppliers at all levels of Aerogen’s supply chain have to be aware that the scope of use for Aerogen’s products is “Medical Technology.” It is also the duty of the suppliers to make sure that their sub-suppliers are made aware of this.

Table 1: Approvals

|  |  |  |
| --- | --- | --- |
|  |  | **Aerogen** |
|  | **Supplier** | **(R&D)** | **Design Assurance** |
| **Printed Name:** |  | Noel Porter | Rory Kenihan |
| **Position in Organization/Company:** |  | Principal Electronics Engineer | Design Assurance |
| **Date:** |  | Jun2025 | Jun2025 |
| **Signature:** |  |  |  |

**Instructions for completion of Material Declaration form QF146**

1. Check if any carcinogenic, mutagenic or toxic to reproduction (CMR) substances listed as category 1A or category 1B in EC Regulation 1907/2006 Annex XIV as amended (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210215&qid=1621871973368&from=en>), or,
EU Regulation 1272/2008 Annex VI Table 3.1 (<https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF>) is present in the part / component.
	1. If none of the CMR substances in the list are present in the part, then put a cross in the ***No*** box in QF146.
	2. If any of the substances in the list is present in the part, then put a cross in the ***Yes*** box and specify in the table below where the substance/substances are to be found in the part and details of the concentration if greater than 0.1%w/w.
	3. If **Yes**, and the concentration is greater than 0.1%w/w please provide the justification according to EU Regulation 2017/745 Annex I Chapter II 10.4.2.
2. Check if any substances with endocrine disrupting properties according to Article 59 of EC Regulation 1907/2006 as amended (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210215&qid=1621871973368&from=en>) is present in the part / component.
	1. If there are no endocrine disrupting substances present in the part, then put a cross in the ***No*** box in QF146.
	2. If any of the substances is present in the part, then put a cross in the ***Yes*** box and specify in the table below where the substance/substances are to be found in the part and details of the concentration if greater than 0.1%w/w.
	3. If **Yes**, and the concentration is greater than 0.1%w/w please provide the justification according to EU Regulation 2017/745 Annex I Chapter II 10.4.2.
3. Check if any substance listed in the REACH Candidate List is present in the part / component, see <https://echa.europa.eu/candidate-list-table>
	1. If none of the substances in the list are present in the part, then put a cross in the ***No*** box in QF146.
	2. If any of the substances in the list is present in the part, then put a cross in the ***Yes*** box and specify in the table below where the substance/substances are to be found in the part and details of the concentration if greater than 0.1%w/w.
	3. If **Yes**, then please provide the relevant SCIP number per the Waste Framework Directive.
4. Check if any RoHS substance is present in the homogeneous material of each part / component at a concentration greater than 0.1%w/w (and 0.01% w/w in the case of cadmium).
	1. If none of the substances in the list are present in the part, then put a cross in the ***No*** box in QF146.
	2. If any of the substances in the list is present in the part, then put a cross in the ***Yes*** box and specify in the table below where the substance/substances are to be found in the part and the relevant concentration.
	3. If any of the substances that are present fall under any given exemption, then this exemption should be detailed.
5. If any SCIP[[7]](#footnote-8) notifications have been completed, then please provide the relevant SCIP number per the Waste Framework Directive.
6. Check if any substance listed in the PROP65 List above the Safe Harbor Level is present in the part/component, see <https://oehha.ca.gov/media/downloads/proposition-65/p65chemicalslistsinglelisttable2021p.pdf>
	1. If none of the substances in the list are present in the part, then put a cross in the **No** box in QF146.
	2. If any of the substances in the list are present in the part (above the Safe Harbor Level), then put a cross in the Yes box and specify in the table below where the substance/substances are to be found in the part and the relevant concentrations.
7. Check if any substance with animal origin is present in the part/component.
	1. If no substances of animal origin are present in the part, then put a cross in the ***No*** box in QF146.
	2. If any substance with animal origin is present in the part, then put a cross in the ***Yes*** box and specify in the table below where the substance/substances are to be found in the part.
8. Check if any latex or natural rubber is present in the part/component.
	1. If no substances with latex or natural rubber in the list are present in the part, then put a cross in the ***No*** box in QF146.
	2. If any substance with latex or natural rubber is present in the part, then put a cross in the ***Yes*** box and specify in the table below where the substance/substances are to be found in the part.
9. Provide Safety Data Sheets (SDS) and Test Data which confirm compliance to the Regulations and Directive listed above.
10. If manufactured in a cleanroom, please indicate the class of cleanroom.

**RE: Compliance with REACH, and RoHS 3 Regulations**

Dear Valued Supplier,

Aerogen are working to achieve compliance with EU REACH, WEEE, RoHS, Waste Framework Directive and the Californian PROP65 requirements. Aerogen request a Declaration from you regarding the presence of banned or restricted substances in the materials/components supplied to us for use in the manufacture of our Medical Devices.

To accommodate this request, we ask that you please complete this form QF146 for each material/component which you supply to Aerogen, and return the signed completed form in electronic format to Aerogen.

Details of the specific substances / categories for which a ‘*Declaration*’ is required are listed in attached form - QF146.

Instructions for completion of this Material Declaration form are included in the document.

We look forward to your cooperation in this important matter.

Yours sincerely,

|  |  |
| --- | --- |
| **Printed Name:** |  John Herrity  |
| **Position in Organization/Company:** | Manager of Design Assurance |
| **Signature:** |  |

Aerogen Limited, Galway Business Park, Dangan, Galway, Ireland **Tel:** +353 91540400 **Fax:** +353 91584639 **Web:** www.aerogen.com

1. EC Regulation 1907/2006. [↑](#footnote-ref-2)
2. EC Regulation 1272/2008 - classification, labelling and packaging of substances and mixtures (CLP) [↑](#footnote-ref-3)
3. Directives 2011/65/EU and 2015/863/EU. [↑](#footnote-ref-4)
4. Directive 2008/98/EC on Waste [↑](#footnote-ref-5)
5. Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986) (PROP 65) [↑](#footnote-ref-6)
6. Please expand Table on next page if required. [↑](#footnote-ref-7)
7. [↑](#footnote-ref-8)