**SENSITIVE APPLICATIONS SUPPLIER QUESTIONNAIRE**

**Medical & Food Contact Applications**

Suppliers are requested to provide the information below to ensure that the operations of Covestro comply with regulatory requirements and meet customer needs. Suppliers may also provide their own documents if those contain the requested information.

Please return the completed form in a pdf-format. Please also send a current regional Safety Data Sheet (SDS) and Technical Data Sheet (TDS) as well as further attachments, as appropriate, to the contact person at Covestro.

This questionnaire applies to the whole product including solvents, additives, by-products, and impurities.

1. **General information**

|  |  |
| --- | --- |
| Product Name(s) |  |
| Supplier Name |  |
| Supplier Address |  |
| Manufacturing Country/Countries/Region(s) |  |
| Composition:CAS Number(s) & concentration (%) (if applicable)including solvents, additives, by-products |  |
| Impurity profile:CAS Number(s) & concentration\* *Concentration of Carcinogenic, Mutagenic, Reprotoxic impurities present in your material above 1 ppm. Mention all non-CMR impurities above 1000 ppm* |  |

1. **Supplier Declaration**

We confirm that the information provided in this questionnaire is correct and complete. We agree to inform Covestro on any product modification that may affect the information provided in this document.

Prepared by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Department/Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email/Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature:**

For any questions, please contact:

|  |  |
| --- | --- |
| **Asia Pacific:****ProductSafetyAPAC@covestro.com**Covestro (Shanghai) Investment Company LimitedProduct Safety & Regulatory Affairs25/F, Building 5, Crystal PlazaNo.36 Pingjiaqiao Road, PudongShanghai, 200126, P.R. China, P.R. China | **Europe:****ProductSafetyEMLA@covestro.com**Covestro Deutschland AGProduct Safety & Regulatory AffairsB 211Kaiser-Wilhelm Allee 6051365 Leverkusen, Germany |

1. **General**

|  |  |  |  |
| --- | --- | --- | --- |
| **Questions on animal or plant origin** | **Yes** | **No** | **Remarks:** |
| 1.1 | Is product an animal derived material or does product contain any animal derived materials? | [ ]  | [ ]  | If No, please do not reply to questions 1.2 and 2.4 |
| 1.2 | Was product treated against Transmissible Spongiform Encephalopathies (TSE) like Bovine Spongiform Encephalopathy (BSE)?  | [ ]  | [ ]  |  |
| 1.3 | Is product a plant derived material or does product contain any plant derived materials? | [ ]  | [ ]  | If No, please do not reply to questions 1.4-1.5 |
| 1.4 | Does product contain palm, soybean and rapeseed oil or Jatropha plant materials? | [ ]  | [ ]  | Please specify which (if contained) |
| 1.5 | Does product contain Genetically Modified Organisms (GMO)? | [ ]  | [ ]  |  |

| **Questions on banned substances** | **Yes** | **No** | **Remarks:** |
| --- | --- | --- | --- |
| 1.6 | Can you confirm that **no substances** are present above 1 ppm which are classified as CMR 1A / 1B according to Regulation (EC) 1272/2008? | [ ]  | [ ]  | If No, please declare substances (CAS-No) with quantities |
| 1.7 | Can you confirm that **no substances** are present above 1 ppm which are classified as CMR 2 according to Regulation (EC) 1272/2008? | [ ]  | [ ]  | If No, please declare substances (CAS-No) with quantities |

1. **Medical**

| **Compliance with medical (device) regulations** | **Yes** | **No** | **Remarks:** |
| --- | --- | --- | --- |
| 2.1 | Have you carried out an assessment of the substance requirements regarding design and manufacture (Annex I, Chapter II, 10.4) and classification (Annex VIII, Chapter III) of medical devices under [Regulation (EU) 2017/745](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02017R0745-20200424&qid=1591782478076&from=DE)? | [ ]  | [ ]  |  |
| 2.2 | Can you confirm that **no substances** are present above 100 ppm which have endocrine disrupting properties according to [ECHA SVHC Candidate List](https://www.echa.europa.eu/web/guest/candidate-list-table)? | [ ]  | [ ]  | If No, please declare substances (CAS-No) with quantities |
| 2.3 | Can you confirm that **no substances** are present above 0.1% which have endocrine disrupting properties according to the [Biocidal Products Regulation (EU) 528/2012](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012R0528-20191120&qid=1591694590084&from=EN) and its [delegated Regulation (EU) 2017/2100](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R2100&from=DE)? | [ ]  | [ ]  | If No, please declare substances (CAS-No) with quantities |
| 2.4 | Was Animal Derived Content treated according to [Regulation (EU) 722/2012](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:212:0003:0012:EN:PDF)? | [ ]  | [ ]  | This question is only relevant if you have answered question 1.1 with Yes |

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| --- | --- | --- | --- |
| **Does the product contain any of the following components or contains substances mentioned in the regulations below?** | **Yes** | **No** | **Remarks:** |
| 2.5 | Phthalates | [ ]  | [ ]  |  |
| 2.6 | Natural Rubber Latex | [ ]  | [ ]  |  |
| 2.7 | Nitrosamines | [ ]  | [ ]  |  |
| 2.8 | Nanomaterials according to the definition in [Recommendation 2011/696/EU](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011H0696&from=EN) or [Recommendation 2022/C 229/01](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022H0614(01)) | [ ]  | [ ]  |  |
| 2.9 | Hexachlorobenzene | [ ]  | [ ]  |  |
| 2.10 | Polyaromatic Hydrocarbons | [ ]  | [ ]  |  |
| 2.11 | Elemental impurities according to [ICH Q3D](https://www.ich.org/page/quality-guidelines) | [ ]  | [ ]  |  |
| 2.12 | Residual solvents according to [ICH Q3C](https://www.ich.org/page/quality-guidelines) | [ ]  | [ ]  |  |
| 2.13 | Substances listed in International Electrotechnical Commission Standard [IEC 62474](http://std.iec.ch/iec62474) | [ ]  | [ ]  |  |

1. **Food Contact**

| **Compliance with Food Contact Regulations** | **Yes** | **No** | **Remarks:** |
| --- | --- | --- | --- |
| 3.1 | EU | Can product be used in food contact applications according to [1935/2004/EC](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1590581415366&uri=CELEX:02004R1935-20210327)? | [ ]  | [ ]  | If No, please provide explanation |
| 3.2 | EU | Is your product manufactured at suitable purity for food contact applications according to [1935/2004/EC](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1590581415366&uri=CELEX:02004R1935-20210327)? | [ ]  | [ ]  |  |
| 3.3 | EU | Is product manufactured in accordance with [Regulation (EU) No 2023/2006](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1590581508211&uri=CELEX:02006R2023-20080417) Good Manufacturing Practices (GMP)? | [ ]  | [ ]  |  |
| 3.4 | EU | Are the components of the product (or product itself) listed in Annex I of [Regulation (EU) No 10/2011](https://eur-lex.europa.eu/search.html?DTN=0010&DTA=2011&qid=1590581477367&DTS_DOM=EU_LAW&type=advanced&lang=de&SUBDOM_INIT=CONSLEG&DTS_SUBDOM=CONSLEG) on plastic materials and articles intended to come into contact with food? | [ ]  | [ ]  | Please provide detailed information, including applicable restrictions |
| 3.5 | EU | Does the product contain substances listed in Annex II of [Regulation (EU) No 10/2011](https://eur-lex.europa.eu/search.html?DTN=0010&DTA=2011&qid=1590581477367&DTS_DOM=EU_LAW&type=advanced&lang=de&SUBDOM_INIT=CONSLEG&DTS_SUBDOM=CONSLEG) on plastic materials and articles intended to come into contact with food? | [ ]  | [ ]  | If Yes, please provide information on the identification and residual levels acc. to Annex IV (6) Reg. 10/2011 |
| 3.6 | CH | Are the components of the product (or product itself) listed in Annex 10 of [Swiss Consumer Goods Ordinance (SR 817.023.21)](https://www.blv.admin.ch/blv/en/home/gebrauchsgegenstaende/materialien-in-kontakt-mit-lebensmitteln.html)? | [ ]  | [ ]  | Please provide detailed information, including applicable restrictions |
| 3.7 | NL | Does the product comply with [Dutch Commodities Act chapter 1 and/or 10](https://www.nvgp.nl/wp-content/uploads/2016/07/Dutch-Packagings-and-Consumer-Articles-Regulation-March-2014-09072014.pdf)? | [ ]  | [ ]  |  |
| 3.8 | DE | Are the components of the product (or product itself) listed in [German BfR recommendations](https://www.bfr.bund.de/en/bfr_recommendations_on_food_contact_materials-308503.html)? | [ ]  | [ ]  | Please provide relevant recommendations |
| 3.9 | DE | Does the product comply with German Consumer Goods Regulation for printed food contact materials? | [ ]  | [ ]  |  |
| 3.10 | EU | Does the product comply with the [Council of Europe resolution AP(2004)1](https://rm.coe.int/09000016809293e5)? | [ ]  | [ ]  |  |
| 3.11 | EU | Does the product comply with the [Council of Europe resolution AP(89)1](https://rm.coe.int/16804f8648)? | [ ]  | [ ]  | Relevant for colourants or colourant containing products, only |
| 3.12 | CN | Does the product comply with GB9685 (current version)? | [ ]  | [ ]  | If Yes, please provide detailed information, including allowed food-contact application(s) and restrictions |
| 3.13 | CN | Does the product comply with GB4806.7-2023? Are the resins listed in Annex A?  | [ ]  | [ ]  | If Yes, please provide detailed information, including applicable restrictions |
| 3.14 | CN | Does the product comply with GB4806.8-2022? | [ ]  | [ ]  | If Yes, please provide detailed information, including applicable restrictions |
| 3.15 | CN | Does the product comply with GB4806.10 (current version)? Are the resins listed in Annex A?  | [ ]  | [ ]  | If Yes, please provide detailed information, including applicable restrictions |
| 3.16 | CN | Does the product comply with GB4806.14-2023? | [ ]  | [ ]  | If Yes, please provide detailed information, including direct/indirect contact and applicable restrictions |
| 3.17 | CN | Does the product comply with NHC circulates of approval on food contact materials? | [ ]  | [ ]  | If Yes, please provide detailed information, including applicable restrictions |
| 3.18 | CN | Do you intend to submit a dossier to the National Health Commission? | [ ]  | [ ]  | If Yes, please provide detailed information, including applicable restrictions |
| 3.19 | CN | Is product manufactured in accordance with GB 31603-2015? | [ ]  | [ ]  |  |
| 3.20 | JP | Does your product comply with draft Japan Positive List (revised on Oct.12, 2023)? | [ ]  | [ ]  | If Yes, please provide detailed information, including applicable restrictions |
| 3.21 | JP | Does your product contain catalysts, processing aids, etc. with permitted maximum concentrations (wt%), according to the draft Positive List (revised on Oct.12, 2023)? | [ ]  | [ ]  | If Yes, please specify identification and applicable restrictions |
| 3.22 | JP | Does your product contain pigments? | [ ]  | [ ]  | If Yes, please provide detailed information |
| 3.23 | LA | Does your product comply with Mercosur GMC resolution No. 3/92? | [ ]  | [ ]  |  |
| 3.24 | LA | Does your product comply with Mercosur 39/19? | [ ]  | [ ]  |  |
| 3.25 | LA | Does your product comply with Mercosur 02/12? | [ ]  | [ ]  |  |

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| --- | --- | --- | --- |
| **Does the product contain any of the following components?** | **Yes** | **No** | **Remarks:** |
| 3.26 | EU | Dual use additives(food additives and flavourings according to [Regulation (EC) No 1333/2008](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1333-20200325&qid=1591696099519&from=DE) and [(EC) No 1334/2008](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1334-20190521&qid=1591696464544&from=DE)) | [ ]  | [ ]  |  |
| 3.27 | EU | Food allergens (according to Annex II of [Regulation (EU) No 1169/2011](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011R1169-20180101&qid=1591695877974&from=DE)) | [ ]  | [ ]  |  |
| 3.28 | EU | Substances for which genotoxicity has not been ruled out | [ ]  | [ ]  | If Yes, please provide information on the identification and residual levels acc. to Annex IV (6) Reg. 10/2011 |
| 3.29 | EU | NIAS (not-intentionally added substances) that need to be observed by downstream users | [ ]  | [ ]  | If Yes, please specify. |