**Application Form for New varieties Agent Declaration of Food Contact Materials**

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| **1. Information of Applicant** |
| Applicant (in Chinese) |  |
| Applicant (in English) |  |
| Address of applicant |  |
| Contact person |  | Mobile |  |
| Tel |  | E-mail |  |
| **2. Information of Materials to Be Declared** |
| Name |  |
| Type  | Pure substance;  mixture; polymer； |
| Type of application | □ New resin variety；□ Resin to expand the range of use；□ New variety of additives；□ Additives to expand the scope of use |
| The expected range of use | □ Plastic; □ Paper and paper board; □ Coating; □ Rubber; □ Silicone Rubber; □ Adhesive; □ Ink |
| Overseas permission conditions | Permitted, permitted country: ; not permitted; unknown.  |
| **3. Information required for declaration** ('■': required; '□': dispensable, tick if available. Otherwise, tests are required.) |
| **3.1 Application form** |
| * Application form (please register on the official website of Supervision Center of Health and Family Planning Commission, fill in and print out the application form)
 |
| **3.2 Physicochemical property (see attached table 1)** |
| * If the materials to be declared are monomers, please fill in the contents provided in table 1;
* If the declared substance is a polymer, in addition to the attached table 1, the products of monomers and initiators shall also be provided with the corresponding physical and chemical characteristics.

(can be provided as an attachment in case information is in quantity) |
| **3.3 Technical necessity, purpose and use conditions (see attached table 2,** can be provided as an attachment in case information is in quantity**)** |
| **3.4 Production process** (can be provided as an attachment) |
| * The data in this section shall include: raw and auxiliary materials, process flow chart and explanatory notes and technical parameters at each link.
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| **3.5 Quality specification requirements, test methods and test report** |
| Name of component | Content (%) | Molecular formula | CAS No. |
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| □ The quality specification requirements include the purity, impurity constituent, content and etc., and the relevant test method and test report. (The specific contents may be provided as an attachment.) |
| **3.6 Migration and/ or residue amount, estimated dietary exposure amount and the assessment method** (the specific contents may be provided as an attachment) |
| * As per the intended application and use conditions, please provide the food or food simulant migration test data

information, migration test method or test report;* Please provide the converted or unconverted component residue amount data, residue test method information or test report in the food container and packaging materials
* Please provide the information regarding the estimated assessment of dietary exposure in the mass and its assessment method.
 |
| **3.7 Toxicological safety assessment data** (the specific contents may be provided as an attachment) |
| * Structure-activity relationship analysis data;
* Acute oral toxicity test data;
* Test data of subchronic 90-day oral toxicity in rats;
* Chronic oral toxicity and carcinogenic test data;
* Three mutagenicity tests data (Ames test, Bone marrow cell micronucleus test and In-vitro mammalian cells chromosome aberration test or In-vitro mammalian cell gene mutation test);
* Reproductive and developmental toxicity test data (two-generation reproduction and teratogenicity test);
* Other safety research literature analysis information;

Note: If the material to be declared is a polymer with the average molecular weight exceeding 1000 Da, please provide the toxicological safety assessment data of each monomer. |
| **3.8 Domestic and overseas use permission information or supporting document** (the specific contents may be provided as an attachment) |
| * Please provide the supporting documents of use permission provided by the national governmental organization, trade association or international organization.

The following countries may be ticked: □European Union □United States □Germany □Switzerland □Holland □Japan □Canada □Others ; |

**Attached Table 1：**

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| **Physicochemical Property** |
| Basic information | Chemical name: |  |
| CAS No.: |  |
| Common name: |  |
| Molecular formula: |  |
| Molecular weight: |  |
| Physicochemical property | Melting point: |  |
| Boiling point: |  |
| Decomposition temperature: |  |
| Solubility (such as liposoluble, water soluble, acid soluble, alkali soluble and the solubility data): |  |
| Density: |  |
| Stability: |  |
| The products resulted from the decomposition or transformation during the production or use process: |  |
| Possible interaction with the food: |  |
| Whether the impurity is contained and the name of impurity: |  |
| Others | Appearance description (character, color and odour): |  |
| Declared materials molecular weight GPC test report (for polymers only): |  |
| Monomer material safety data sheet(GHS-SDS) (it is dispensable, but it is a plus): |  |
| **Note: Please provide any information regarding the above properties. Fill in "inapplicable" if the parameter is inapplicable. Please perfect the parameters that are applicable but missing.** **If the material to be declared is a polymer, please describe the physicochemical properties of all the monomers and initiators.** |

**Attached Table 2:**

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| **Technical Necessity, Application and Use Conditions** |
| Technical necessity and application (additive/ resin) | Technical necessity:[Please describe the necessity for the use of such material and whether it has the obvious enhancement or improvement function upon the product performance, environment, capacity or etc. (the description may be made from the principle and actual effect). When necessary, please provide the supporting documents, such as the design sketch.] |  |
| Intended use: |  |
| Range of application: |  |
| Maximum use limit (please fill in when the material to be declared is an additive): |  |
| Technical effect: |  |
| Use conditions (final product) | Type of foods that may contact (tick): | * All types of food (if ticked, the following options are not required to tick)
* Water-based foods (pH≥5.0)
* Acid foods (pH＜5.0)
* Fatty foods
* Alcoholic foods, alcohol content %
* Others
 |
| Time and temperature when contact with food: | Maximum use temperature: ℃ ( holding temperature ℃) Maximum single use time: min (holding temperature: min)  |
| Whether the material can be reused (tick) | □Yes □No |
| S/V upon the intended/ actual use | * S/V unknown;
* S/V known, dm2/ L;

or the mass or volume of the foods to be packaged: kg/L; S/V: it refers to the ratio of surface area of product foods contact to the volume or mass of the foods during the process of contact with foods; |
| **Note: Please provide any information regarding the above properties. Fill in "inapplicable" if the parameter is inapplicable. Please perfect the parameters that are applicable but missing.** |