



CCE COORDINATION BULLETIN 2005-3
Evaluation of Rubber, Rubber-Like, and Plastic Materials
Using 3-A Sanitary Standard for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces (18-nn),
and 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces (20-nn) for a 3-A Symbol

Purpose: This guideline applies to the evaluation of rubber, rubber-like and plastic materials for conformance with applicable 3-A Standard(s) for the purpose of authorizing a 3-A Symbol.

Application: The following guidance shall be used by the CCE when performing TPV evaluations of rubber, rubber-like and plastic materials requesting a 3-A Symbol for their material. This guidance is effective immediately upon receipt and shall be used until revoked or included in an up-date of the TPV Manual. This bulletin supercedes CCE Coordination Bulletin 2004-1, dated March 1, 2004.

1. Upon arrival at the Applicant's facilities, request a complete listing of the specific materials for which they are seeking Symbol authorization.
2. If the Applicant is only a supplier or distributor of rubber, rubber-like and plastic components and does not manufacture the rubber, rubber-like and plastic resins, they must be able to provide letters of documentation that the materials comply with the appropriate Standards.
3. The documentation shall be provided by the supplier, signed by a responsible official with that company, bear the trade name of the material as shown on specification sheets and purchase orders, and the appropriate declarations as shown below. Review of individual material test data is not necessary; however, verification of records for consistency shall be conducted.
 - a. For rubber and rubber-like materials, the documentation shall clearly indicate conformance with 21 CFR 177.2600 or the FDA Inventory of Effective Premarket Notifications for Food Contact Substances (<http://www.cfsan.fda.gov/~dms/opa-fcn.html>) and conformance to the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials

Used as Product Contact Surfaces, Number 18-nn and the material conforms to class (x) of the standard.

- b. For plastic materials, the documentation must clearly indicate conformance with the appropriate 21 CFR citation within parts 170-199 or the FDA Inventory of Effective Premarket Notifications for Food Contact Substances (<http://www.cfsan.fda.gov/~dms/opa-fcn.html>) and conformance to *3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces, Number 20-nn*. Verify against 21 CFR that the citations are correct and there are no disqualifying provisions.

Note: The CFR can be accessed at www.gpoaccess.gov/cfr/index.html.

4. If the Applicant is the manufacturer of the base rubber or plastic resins follow the guidance in Items 5 through 11 below.
5. For those Items, request a listing of the ingredients or formulations. Assure the Applicant that there will be no reference to proprietary information in the TPV Report.
6. Verify against Items 3a and 3b above that formulations and ingredients are in conformance. In addition,
 - a. Rubber and rubber-like materials shall conform to any restrictions for the type and levels of use of carbon black.
 - b. Plastic materials shall conform to one of the identified generic classes of plastics as listed in *3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces, Number 20-nn*.
7. Verify against the purchase order or material certification that the materials specified in the formulations are the materials that were purchased and that there have not been any substitutions. Purchase orders are to reference the ingredient names and for plastics the generic class of plastic. For carbon black, the purchase order shall specify the method of manufacture.
8. Request documentation for testing of the final materials to demonstrate conformance with the applicable Standard.
9. Verify against the appropriate Standard that test results are in conformance. Pay close attention to special limitations for the generic classes of plastics and to the declared class of rubber tested.
10. Request a copy of the Applicant's Quality Control Program to assure the proper formulations and ingredients were used.

11. During the on-site visit, tour the production facility to determine that the quality control program is effectively ensuring separation of the different materials and formulations being produced.

When all of these steps can be answered affirmatively, the materials can be determined to be in conformance and the TPV Report can be marked as satisfactory. If any of these steps cannot be answered in the affirmative, the TPV Report is to be marked unsatisfactory and the TPV evaluation fails.