

The Colorcon Position on Supplying Direct Food Contact Compliant Inks

NS30
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Colorcon has over four decades of experience in formulating, manufacturing, and servicing direct food contact compliant inks and coatings for all of the major printing disciplines. During this time period, we have instituted the following business practices and controls in order to supply consistent, regulatory compliant, consumer-safe No-Tox[®] products to all of our customers.

We formulate with only direct or indirect food additives, defined by the FDA, as components of our products.

- These materials are purchased only from approved vendors who are required to supply written guarantees of compliance, including any end-use or food-type restrictions.

Colorcon expends considerable time and resources to assure batch-to-batch performance and regulatory compliance of our finished products.

- We do not substitute raw materials or change sources of supply, unless absolutely necessary and only after notification to end-users so that they can determine the impact of such a change to their finished products.
- All incoming lots of raw materials are sampled and tested to confirm identity and purity. Retained samples of each lot of raw material are kept for approximately three years. Test results for each raw material lot are kept on site for seven years.
- We maintain complete traceability of our products back through the respective lots of raw materials used in any given batch (See Section 5.6 of our NS23 Technical Data Sheet regarding Colorcon's Current Good Manufacturing Practices (cGMP's)).

Our inks and coatings are produced in an environmentally-controlled, Kosher-inspected, customer audited, 21,000 square foot cGMP facility dedicated only to the manufacture of regulated products.

- Prior to batch manufacturing, all mixing and milling equipment is completely disassembled, cleaned and inspected.
- Airborne particulate matter is controlled to prevent contamination.
- Validated standard manufacturing procedures (SMP's) and standard operating procedures (SOP's) are utilized in the manufacture of our products.

By utilizing the above practices, we achieve a high degree of process control and maintain the integrity of our raw material supply, eliminating the risks to our customers associated from using contaminated or nonconforming inks and coatings. Additionally, this enables us to provide batch-specific, FDA compliance guarantee letters satisfying the regulatory requirements of our customers and their end-users.



For more information, contact your Colorcon representative or call 1-800-724-0624
You can also visit our website at <http://www.colorcon.com/notox>

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