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International Imaging Materials Inc.
310 Commerce Drive • Amherst, NY 14228-2396
p 716.691.6333 • f 716.691.1060 • www.iimak.com

Date: January 1, 2016

Re: FDA

Dear Customer:

IIMAK thermal transfer ribbons are formulated and manufactured for the use on a variety of printing application, including the use on food and pharmaceutical packaging. IIMAK has reviewed the raw materials used to formulate the ribbons.

IIMAK thermal transfer ribbons are considered acceptable for both direct and indirect food contact with food and pharmaceutical products in accordance with the appropriate chapters and section of Title 21 of the Code of Federal Regulations (21 CFR) as set forth below, subject to any restrictions and limitation listed:

1. All other ingredients are generally recognized as safe under the following 21 CFR regulations:

    a. 21 CFR Part 173 – Secondary Direct Food Additives Permitted in Food for Human Consumption
    b. 21 CFR Part 175 – Indirect Food Additive: Adhesives and Components of Coatings
    c. 21 CFR Part 176 – Indirect Food Additives: Paper and Paperboard Components
    d. 21 CFR Part 174 - 179 – Indirect Additives
    e. 21 CFR Part 181 – Prior-Sanctioned Food Ingredients
    f. 21 CFR Part 182 – Generally Recognized as Safe
    g. 21 CFR Part 184 – Direct Food Additives Generally Recognized as Safe
    h. 21 CRR Part 186 – Indirect Food Substances Generally Recognized as Safe

WAX	WAX/RESIN		RESIN
GP725	NET Mark	NET White	SP330
High Mark	IQ	NET Silver	SP575*
Fast Wax	NET Mark	NET	DC100
SW150	NET Flex	Premium	DC200
	Prime	NET Colors	DC300/305
	Mark	NETFlex+	
	PM308		

*Internal review. FDA review pending.

The Food and Drug Administration's ("FDA") sole concern is with materials that may become, either by default or design, food or pharmaceutical additives. While there is no intent on the substance to affect the food or pharmaceutical, it may be reasonable for it to migrate into the food and become a component of the food. Any printing ink or coating component that is converted in or on packaging materials may potentially become an indirect additive if migration occurs; therefore, would be regulated under 21 CFR Parts 170-189.

All products are manufactured under current Good Manufacturing Practices (cGMP) conditions based upon the guidelines established by the FDA in 21 CFR Part 110 and by the International Pharmaceutical Excipients Council (IPEC).

Please contact Mary Ellen Holvey, IIMAK Safety and Health Consultant, if you have any questions regarding this information at 1-888-464-4625, ext. 2514 or e-mail mary.ellen.holvey@iimak.com.

Best Regards,

Glenn Hopkins
Director, Manufacturing Engineering

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

This correspondence is in response to your March 22, 2010 request, on behalf of International Imaging Materials, Inc., for an opinion from the FDA on the regulatory status of the ingredients of an ink formulation to be used to print on the non food contact side of flexible films/bags manufactured from polyesters, polypropylene or polyethylene. This ink formulation would also be used to print on labels that would be attached to fresh fruit. The fresh fruit would then be placed in large bags where there is a possibility of incidental food contact between the printed label on one piece of fruit and that of another piece of fruit. Our correspondence on this matter, including the composition of the ink formulation, has been logged into our tracking system.

We have evaluated the composition of the ink formulation presented. All of the ingredients listed in this formulation are Generally Recognized as Safe as direct additives to food, prior sanctioned for the intended use, the subject or an applicable food additive regulation, or will not result in migration to food from the intended use (i.e., will not be considered a food additive). Therefore, as currently formulated, this ink is suitable for the intended use and will not need premarket authorization via the food contact notification process, the food additive petition process or the threshold of regulation exemption process. Please note that FDA does not approve or endorse products manufactured by specific companies. Rather, FDA is a regulatory agency which authorizes to use of chemical substances for food-contact applications under specific conditions.

If you have any further questions regarding this matter, please do not hesitate to contact us.

Sincerely,

Edward Machuga

Edward Machuga, Ph.D.
Supervisory Consumer Safety Officer
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

March 2, 2015

Mary Ellen Holvey, CIH International Imaging Materials, Inc.
310 Commerce Drive
Amherst, NY14228

Dear Ms. Holvey:

This correspondence is in response to your February 25, 2015 request, on behalf of International Imaging Materials, Inc., for an opinion from the FDA on the regulatory status of the ingredients of an ink formulation (Net Flex + Ribbon) to be used to print on the non food contact side of flexible films/bags manufactured from polyesters, polypropylene or polyethylene. This ink formulation would also be used to print on labels that would be attached to fresh fruit. The fresh fruit would then be placed in large bags where there is a possibility of incidental food contact between the printed label on one piece of fruit and that of another piece of fruit. Our correspondence on this matter, including the composition of the ink formulation, has been logged into our tracking system as PNC 1605.

We have evaluated the composition of the ink formulation presented in PNC 1605. All of the ingredients listed in this formulation are either Generally Recognized as Safe as direct additives to food, prior sanctioned for the intended use, the subject of an applicable food additive regulation, or will not result in migration to food from the intended use (i.e., will not be considered a food additive). Therefore, as currently formulated, this ink formulation (Net Flex + Ribbon) is suitable for the intended use and will not need premarket authorization via the food contact notification process, the food additive petition process or the threshold of regulation exemption process. Please note that FDA does not approve or endorse products manufactured by specific companies. Rather, FDA is a regulatory agency which authorizes the use of chemical substances for food-contact applications under specific conditions.

If you have any further questions regarding this matter, please do not hesitate to contact us.

Sincerely,

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