

6/7/2012

Re: Scotch-BriteTM and NiagaraTM Hand Pads and FDA/USDA Approval and/or Acceptance

Dear Customer,

Hand pads or scouring pads, including sponges and sponge laminates, are defined by the US Federal Food and Drug Administration (FDA) as a tool. The FDA and United States Department of Agriculture (USDA) have not required approval or acceptance of tools used for cleaning of food-contact surfaces.

Tools are not within scope of the current FDA approval process; FDA approval is typically used for ingredients of food, drugs, or cosmetics, and/or ingredients that are reasonably expected to become components of food, drugs, medical devices, or cosmetics. Hand pads or scouring pads are not typically intended to be used as ingredients in food, drugs, medical devices, or cosmetics, nor are they intended to be used as food packaging, or come into direct contact with food. Therefore "FDA approval" or "FDA acceptance" does not apply to these types of products.

Regarding "USDA approval" or "acceptance" historically, the Food Safety and Inspection Services (FSIS), a branch of the United States Department of Agriculture (USDA), used to require meat and poultry facilities to use only nonfood compounds and proprietary substances that had been approved under the USDA authorization program. However, two Federal Register notices, published August 25, 1997 and the final on February 13, 1998, announced the end of the USDA authorization program. The FSIS significantly altered their approach to facility inspections, eliminating the need for USDA product evaluation. This new approach was driven by the established system of Hazard Analysis and Critical Control Point (HACCP) facility operation. Under HACCP, all meat and poultry establishments must identify and manage critical control points for food processing. Control points are defined as those where chemical, physical, and microbial contamination may occur. Once these points are identified,

the processor must reduce contamination risk and maintain documentation describing the corrective actions taken. For nonfood compounds and proprietary substances, the facility operators must select the appropriate product to not only meet their operational needs, but also their HACCP requirements. ¹

Therefore, there is currently no requirement in place today that products like Hand Pads and Scouring Pads need FDA or USDA approval, or acceptance, in order to be used on food contact surfaces or in food processing facilities. The 2009 U.S. Food Code² (Section 4-603.14 Wet Cleaning and Section 4-603.16 Rinsing Procedures), maintained by the US Food and Drug Administration (FDA), and the US Department of Health and Human Services, states that:

"EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary such as the application of detergents containing wetting agents and emulsifiers; acid, alkaline, or abrasive cleaners; hot water; brushes; **scouring pads**; high-pressure sprays; or ultrasonic devices."

"Washed UTENSILS and EQUIPMENT shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent-sanitizer solution . . ."

Since there is no process for FDA or USDA approval for nonfood compounds, like hand pads, it becomes the responsibility of the manufacturer to ensure that the product they sell is safe in its intended application. For example, if a product like a hand pad is actually intended to come into direct contact with food, then the manufacturer would be required to ensure that the product meets the requirements of all food contact regulations that might apply to that particular application. This however would not be considered a formal "FDA approval" or "FDA acceptance". It simply means that to the best of the manufacturer's knowledge, the product and its materials meet the requirements of applicable food contact regulations, and that they do not believe it will create a hazard to food in its intended application. On the contrary, most hand pads or scouring pads are **not** intended to come into direct contact with food, and would also likely have a difficult time qualifying as a food contact surface.

Therefore FDA or USDA approval or acceptance does not currently apply to products like hand pads and scouring pads. These products are not currently in scope of FDA or USDA regulations.

Feel free to contact me if you have any additional questions or concerns.

Best Regards,

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 $\underline{http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/default.}\\ htm$

¹ http://nsf.org/business/nonfood_compounds/history.asp?program=NonFoodComReg