

Product Information



RightSpot, RightSpot SmallBore and RightSpot Enfit are FDA class I (general controls) devices for the CLIA waived test of pH. These devices are not subject to pre-market notifications (510k) for FDA clearance, are non-patient contacting and are provided as non-sterile.

In regards to Material Safety Data Sheets (MSDS) related to our products, these products are considered to be exempt by the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) Hazard Communication Standard because the product meets the definition of an 'article' under 29 CFR 1910.1200(c). An 'article,' under 29 CFR 1910.1200(c), is defined as a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities (e.g., minute or trace amounts) of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

In addition, products regulated by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) are considered to be exempt by the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) Hazard Communication Standard 29 CFR 1910.1200(b)(5)(iii) for labeling requirements since these products are subject to the labeling requirements under that Act by the Food and Drug Administration (FDA).

For further information regarding these products please contact RightBio at:

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