

MATERIAL SAFETY DATA SHEET

Product Name:	Aware™ HIV-1/2 Oral (OTC) Test
Product Numbers:	98135 98157 98137 98159
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The Aware™ HIV-1/2 Oral OTC Test is comprised of 3 components, excluding packaging and product labeling:

- Pouched Assay Test Strip with Desiccant
- Tubes of Oral Fluid Sample Buffer
- Oral Fluid Sample Collection Swab

Materials and components in this product are not considered to be hazardous in their concentrated forms nor as they are currently formulated for the Aware™ HIV-1/2 Oral OTC product. This is based on evaluations made by Calypte Biomedical or the Manufacturer/Supplier of the subcomponent under the OSHA Hazard Communication Standard, 29 CFR 1910.1200. Material Safety Data Sheets are required only for products containing hazardous ingredients at a concentration equal or greater than 1% and/or carcinogens at a concentration equal or greater than 0.1% (OSHA, 29 CFR 1910.1200).

The Oral Fluid Sample Collection Swab has been evaluated for and complies with biocompatibility standards as per ISO 10993-1 (1997), "Biological evaluation of medical devices".

This device is intended for home use and not a clinical setting. The user assumes all responsibility for evaluating the risk of the specific use and application as well as any and all risks inherent in individual samples and situations.

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