



Statement of Hazardous substances

Product Code	Product description	Product description
1115		Lemon flavour glycerine swabsticks
1116		Blackcurrent flavour glycerine swabsticks

Optimum Medical hereby confirm that the above listed products, including all raw materials, processing aids and packaging used during the manufacturer and packing of the products do not contain the following:

- Substances which are carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 in a concentration above 0.1% weight by weight (w/w)
- Substances having endocrine-disrupting properties in a concentration above 0.1% weight by weight (w/w), including the following Phthalates: Dibutyl phthalate (DBP) CAS 84-74-2: Diisobutyl phthalate (DIBP) CAS 84-69-5: Butyl benzyl phthalate (BBP) CAS 85-68-7: Di-n-pentyl phthalate (DnPP) CAS 131-18-0: Di(2-ethylhexyl) phthalate (DEHP) CAS 117-81-7: Di-n-octyl phthalate (DnOP) CAS 117-84-0: Diisononyl phthalate (DINP) CAS 28553-12-0: Diisodecyl phthalate (DIDP) CAS 26761-40-0
- Bisphenol A (BPA) CAS 80-05-7
- Derivatives of tissue or cells of human origin which are non-viable or are rendered non-viable
- Tissue cells of animal origin or their derivatives which are non-viable or are rendered non-viable
- Substances utilising non-viable biological substances
- Natural rubber latex or materials which contain natural rubber latex
- Substances considered to be medicinal products
- Substances which are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body
- Heavy metals: lead (0.1% by mass or 1000ppm) Mercury (0.1% by mass or 1000PPM) Cadmium (0.01% by mass or 1000PPM) Hexavalent chromium (0.1% by mass or 1000PPM)

Signed on behalf of Optimum Medical,

Claire Sykes

Senior Quality Associate

29-Jul-2021

