



## SAFETY DATA SHEET

### MAXI POUCH

#### IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND THE COMPANY

PRODUCT NAME: MAXI POUCH  
 PART No.: SUP200  
 SUPPLIER: Astral Chemical Solutions Ltd.  
 P.O. Box 250  
 Whitefield, Manchester  
 M45 8XQ.  
 TEL: 0161 767 8219  
 FAX: 0161 796 2003

The Maxi Pouch is a body liquid collection device intended to be used in such a way that return flow is unlikely, as the superabsorbent layer inside the pouch is to absorb body liquid.

It is not invasive, non sterile class 1 device, in accordance with annex 1X of Medical Device Directive.

Manufactured following good manufacturing procedures ISO 9002 and the design and testing carried out is to ISO 9001.

Component of Pouch	Biocompatibility / Safety Information
PE coated card (used on the top of the pouch)	This card is commonly used in milk cartons and therefore is to the food grade standard.
Outer layer of pouch (embossed PE Film)	Its based upon raw materials in accordance with food contact regulations and processed by ACE according to the same rules.
Super absorbent Laminate	Biocompatibility testing* has been carried out on the laminate and it was found to have a weak allergenic potential (sensitisation), a negligible irritant and to be non-cytotoxic and meets requirements of the elution test.
Inner non woven layer	Biocompatibility tested has been carried out on the inner non woven layer and it was found to be non-cytotoxic and non-irritating (skin irritation)

The disposal of the Liner should be according to local regulations and by laws. We use products which are to the best of our knowledge either non biodegradable or on breakdown do not release non-environmentally friendly by-products.

\*Testing conducted to ISO 10993.

Note: Contains **NO** latex