

ANSELL LTD  
Form 6-K  
September 16, 2005

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**FORM 6-K**

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**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**Report of Foreign Issuer**

**Pursuant to Rule 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934**

For the month of September 2005 (September 16, 2005)

Commission File Number: 0-15850

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**ANSELL LIMITED**

(Translation of registrant's name into English)

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Level 3, 678 Victoria Street, Richmond, Victoria 3121, Australia

(Address of principal executive offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

This Form 6-K contains forward-looking statements within the meaning of the Securities Exchange Act of 1934 as amended, and information that is based on management's beliefs as well as assumptions made by and information currently available to management. When used in this Form 6-K, the words anticipate, approach, begin, believe, continue, expect, forecast, going forward, improved, likely, look forward, outlook, plans, potential, proposal, should and would and similar expressions are intended to identify forward-looking statements. These forward-looking statements necessarily make assumptions, some of which are inherently subject to uncertainties and contingencies that are beyond the Company's control. Should one or more of these uncertainties materialize, or should

underlying assumptions prove incorrect, actual results may vary materially from those anticipated, expected, estimated or projected. Specifically, the ability of the Company to realize its ongoing commitment to increasing shareholder value through its ongoing restructuring, asset dispositions, strategic review and implementation, and cost cutting initiatives, may be affected by many factors including: uncertainties and contingencies such as economic conditions both in the world and in those areas where the Company has or will have substantial operations; foreign currency exchange rates; pricing pressures on products produced by its subsidiaries; growth prospects; positioning of its business segments; future productions output capacity; and the success of the Company's business strategies, including further structural and operational changes, business dispositions, internal reorganizations, cost cutting, and consolidations.

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**NEWS RELEASE**

**Ansell Limited**

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16 September 2005

**UNITED STATES FOOD & DRUG ADMINISTRATION THAILAND CONDOM DETENTION**

Ansell has been advised that the United States Food & Drug Administration (FDA) has, following routine random inspection of shipments of condoms manufactured at Ansell's Surat Thani, Thailand facility, determined that all future shipments from that facility for import to the United States will need to be tested as two lots recently tested failed to meet the FDA's defined standards. This level of inspection is referred to by the FDA as Level 2 detention.

All medical devices imported into the U.S. are subject to lot testing by the FDA and condoms are rated a class II medical device. If the sample selected for inspection does not meet the defined standard then the supplying plant is put on detention, which requires that all future shipments be tested until the plant is removed from detention status.

Ansell made about 140 condom shipments (over 2000 lots) to the U.S. in F 05 without any problems. The two lots that did not meet the standards were tested within the last seven weeks. For the Surat Thani plant to be released from detention, at least ten successive incoming shipments will have to pass testing by the FDA prior to release into the U.S. market.

Should future shipments during the testing or probationary period not meet standard, this could result in escalation to a Level 3 detention, which would require the plant to be recertified, necessitating alternative supplies to the U.S. Consumer business which represents a mid single-digit part of Ansell's total sales.

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Ansell is expediting shipments to the U.S from this facility so that product can be submitted to the FDA for testing and approval. Ansell maintains inventories within the U.S. and also has two other plants supplying this market. While there will be some modest additional costs, the current Level 2 detention is not expected to materially impact the Company's financial results.

All Ansell condoms currently available in the U.S. and other markets are designed and manufactured to meet the highest standards of product safety. Ansell is concerned by this recent turn of events after an extended period of meeting or exceeding standards and a cross functional team is working to ensure that Surat Thani swiftly resolves any issues.

For further information:

### **Media**

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Ansell Ltd is a global leader in healthcare barrier protective products and in 2005 celebrates 100 years in its field. With operations in the Americas, Europe and Asia, Ansell employs more than 11,000 people worldwide and holds leading positions in the natural latex and synthetic polymer glove and condom markets. Ansell operates in three main business segments: Occupational Healthcare, supplying hand protection to the industrial market; Professional Healthcare, supplying surgical and examination gloves to healthcare professionals; and Consumer Healthcare, supplying sexual health products and consumer hand protection. Information on Ansell and its products can be found at <http://www.ansell.com>.

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ANSELL LIMITED  
(Registrant)

By: /s/ DAVID M. GRAHAM

Name: DAVID M. GRAHAM  
Title: GENERAL MANAGER FINANCE & TREASURY

Date: September 16, 2005