LUBRICANT, WATER BASED, NON-IRRITANT, FOR USE DURING INTERCOURSE

QUANTITIES REQUIRED:20 000 000 UNITS PER YEAR
(60 000 000 UNITS FOR 3 YEARS)

PACKAGING: INDIVIDUALLY PACKED SATCHETS CONTAINING FIVE MILLILITRES (5ML) OF LUBRICANT

SAMPLES TO BE SUBMITTED TO SABS, IN QUANTITIES REQIURED AS PER SABS SPECIFICATIONS

COST MUST INCLUDE DELIVERY COST.

1. GENERAL REQUIREMENTS

Manufacturers and suppliers shall follow an appropriate code of quality management, including good manufacturing practices (GMP) and statistical process control, in the manufacture and packaging of lubricants.
The methods used to test for compliance are:

- use of statistical samples; and
- subjective inspection;
- documentary evidence, such as comprehensive reports of stability tests, certificate of analysis (COA), certificates of purity from material suppliers, or certification by regulatory agency or an independent body, certificate of analysis, Material Safety Data Sheet (MSDS), Formulation of the lubricant).

The product must be tested by an independent laboratory for condom compatibility, and biocompatibility. Final results from these tests must demonstrate that the device meets established acceptance criteria in accordance with the identified industry standards.

Requirements marked with a star* will be confirmed and/or tested on each lot and will be seen as critical to the fulfilment of the tender agreement. The remaining requirements will be tested on a random basis. Should any of the lubricants not meet the requirements when tested that particular lot will be considered to be unfit for delivery.

1.1. Product Indication

1.1.1. The product is principally intended as a personal lubricant to moisturise and supplement the body's natural lubricating fluids, and to enhance the ease and comfort of sexual activity.

1.1.2. The lubricant must be suitable for both vaginal and anal intercourse.

1.1.3. The lubricant must be compatible with natural rubber latex, polyurethane and synthetic material as evidenced by condom compatibility tests.

1.1.4. The lubricant is not intended as a contraceptive or spermicide and should not contain any such components.

1.2. Constituent Materials

1.2.1. The lubricant must be water-based gel-like liquid and have the following properties: *

- sugar free; colourless; fragrance free; tasteless; dermosensitive glide; moisturising; non-irritating; non-staining; non-greasy; non-sticky;
- pH balanced (5.5–7.0PH)*, at room temperature
- alcohol free

1.2.2. The lubricant must be compatible with natural rubber latex as defined by ASTM D7661–10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*

1.2.3. Lubricant must be safe for use with polyurethane and synthetic condoms

1.2.4. The use of preservatives, viscosity modifiers, moisturisers, humectants and other components used to modify the texture, rate of water evaporation and lubricating properties of lubricants should be stated.

1.2.5. The osmolality of the lubricant must be suitable for both vaginal and anal use.

1.2.6. The lubricant formulation should not contain polyquaternium compounds, specifically polyquaternium 15.

These requirements may be verified through COA and/or MSDS

Note: Verification of the results of the following tests may be conducted through a COA or MSDS

Characteristic **Specification**

- Appearance: clear medium viscous gel, free of impurities
- pH: 5.5–7.0
- Colour: clear
- Odour: odourless
- Specific gravity: 1.055–1.085
- Viscosity at 25C: 8000–20000 (viscous)
- Solubility in water: soluble
- bio-burden:
    - total aerobic microbial count cfu/g: 100 maximum
    - total combined yeasts and moulds count cfu/g: 20 maximum

These requirements will be verified by documentary evidence.

1.3. Shelf-life

2. These requirements may be verified by documentary evidence (COA and/or MSDS).

2.1.1. *The shelf-life must be at least 3 years from date of manufacture.

2.1.2. The lubricant must comply with the performance requirements of this specification throughout the stated shelf life.

2.1.3. *The lubricant must retain its properties when exposed in individual packages to an average temperature of 35^0C for the stated shelf-life.

2.1.4. *The manufacturer shall stipulate a shelf-life, measured from the month of manufacture, during which the packed products will be stable in properties, and will continue to meet these requirements.

2.1.5. *At the time of delivery, at least 80% of the shelf-life must still be available to the procurer.

2.1.6. The manufacturer shall make available to the purchaser on request, data to support the stated shelf-life. This data may take the form of:

- Real time stability studies conducted over the stated shelf-life at 35^oC.
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- Updated documentation on 35^{o}C post-market trials must be made available to the purchaser on request.
- Validated expiry dates up to 3 years will be allowed.

These requirements will be verified by documentary evidence.

3. DESIGN REQUIREMENTS

The purchaser, as part of the purchase agreement or before delivery of the product, must approve any variances in these requirements.

- The methods used to test these requirements for compliance will be:
  - visual inspection;
  - use of statistical samples; and/or
  - prescribed test protocols.
- Tests or verifications in this section will generally be:
  - at the pre-qualification stage;
  - compliance of lot by lot testing carried out by an independent laboratory prior to delivery;
  - periodic audits other than the mandatory lot by lot testing if the quality of the product is in doubt once it has been purchased.

3.1. Colour and Clarity*

3.1.1. The lubricant must be translucent (clear) and without added colouring.

3.2. Odour and Taste*

3.2.1. The lubricant must be odourless.

3.2.2. The lubricant must be tasteless**.**

3.3. Individual package materials, integrity and markings*

3.3.1. ISO 2859-1 Special Inspection Level S-3.

3.3.2. Sachet volume: 5 mL

3.3.3. Size: 65mmX53mm approx

3.3.4. Material: Foil

3.3.5. Pack size: 500 sachets per pack

3.3.6. Compliance with Package Integrity Test Method in *ISO 4074* Annex M

3.3.7. **Any lot numbers on packages must *be printed at the time of packaging* and not pre-printed.**

3.3.8. In addition, the following shall apply:

- There shall be no evidence of leakage.
- The outside surface of the package shall be clean.
- There shall be no separation of the layers of laminate.
- The individual packages are separated by perforations or other means which allow the packages to be separated by hand without interfering with the seals.
- The package must be easy to open and will have a notch or serration to assist in opening.
- The packages shall have the following ***indelible*** markings:
    - Lot number or lot identification code (printed at the time of packaging, not pre-printed);
    - Not for sale
    - Distributed for the Department of Health, South Africa
    - Manufacture date and expiry date
    - Store away from direct sun light in a cool dry place
- *Expiry Date: month and year of expiry labelled **in full** or **Exp Date abbreviated*** in English (the year shall be written as a four digit number, and the month as a two digit number)

Compliance will be verified by visual inspection

4. PERFORMANCE REQUIREMENTS

The product must be tested by independent laboratories for condom compatibility, biocompatibility and preservative effectiveness. Final results from these tests must demonstrate that the product meets established acceptance criteria in accordance with the identified industry standards (These may be verified through COA and/or MSDS).

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- Performance requirements will be tested for compliance by the use of statistical samples and prescribed test protocols.
- Verifications in this section will be undertaken at the pre-qualification stage, and by lot-by-lot compliance testing carried out by an independent laboratory prior to delivery.

4.1. *Biocompatibility Testing (Please provide declaration for compliance)

4.1.1. Testing for cytotoxicity, vaginal irritation, sensitisation, and systemic toxicity must be in accordance with 1S0 10993 and must indicate lubricant biocompatibility.

4.1.2. Biocompatibility testing performed on the lubricant must confirm it is safe for its proposed indication.

4.1.3. Cytotoxicity testing must be evaluated using the Direct Contact Method according to ISO 10993-5:2009

4.1.4. Sensitisation testing must be evaluated using the Maximisation Test for Delayed Type Hypersensitivity test according to ISO 10993-10:2010

4.1.5. Vaginal irritation must be evaluated using the Vaginal Irritation Test according to ISO 10993-10:2010

4.1.6. Systemic toxicity must be evaluated using the Acute System Toxicity Test according to ISO 10993-11:2006

These requirements may be verified by documentary evidence.

4.2. Condom Compatibility Testing

4.2.1. *Condom compatibility testing as defined by ASTM D7661-10 Standard Test Method must demonstrate that the lubricant formulation is compatible with natural rubber latex condoms as well as polyurethane and synthetic condoms.

This requirement may be verified by documentary evidence (COA and/or MSDS)

4.3. Stability Testing*

4.3.1. Stability data, using real-time and accelerated ageing tests, must confirm a shelf life of at least 3 years for the lubricant.

This requirement may be verified by documentary evidence (COA and/or MSDS)

4.4. Quality Control Release Testing*

4.4.1. Lot release testing of the lubricant must include evaluation of appearance/colour, odour, viscosity, specific gravity, pH, water activity and microbiological safety (bio-burden).

This requirement may be verified by documentary evidence (COA and/or MSDS).