



SAFE LUBRICANTS FOR ALL

Procurement
specifications for
lubricants used with male
and female condoms

Part I: UNFPA Technical Brief

This technical brief introduces key concepts and terms surrounding safe and effective personal lubricants. It provides background and context for the specifications for plain lubricants published by the World Health Organization and United Nations Population Fund, which are reprinted in full in Part II.

UNFPA takes a leading role in global efforts to produce, procure and distribute safe lubricants for all.

Procurement through UNFPA secures cost-effective, quality products to meet global needs, thanks to a robust quality assurance process and agreements with manufacturers. But what about lubes? Orders for lubricants have increased over the past decade, often along with orders for condoms. However, there were also complaints about products causing irritation or being too thin or too thick. It was time for a closer look. [The Global Consultation on Personal Lubricants](#) (Bangkok, 2016) was convened to (a) review the safety of personal lubricants, as research has shown users may experience irritation, burning and damaging effects to vaginal and rectal tissue, and (b) examine the ways to produce, procure and distribute safer products for all. The findings of the Consultation contributed significantly to the latest set of specifications, which were published in April 2020 and are reprinted in Part II for reference by professionals who manufacture and procure plain lubricants and plan for their use in sexual and reproductive health programming in developing countries.

1. Personal lubricants are a sexual health tool

Personal lubricants factor into sexual and reproductive health and rights and the efforts of countries to achieve the United Nations Sustainable Development Goals, implement the International Conference on Population and Development Programme of Action and meet targets to end the AIDS epidemic and eliminate HIV and other sexually transmitted infections (STIs) by 2030. As a global procurer of personal lubricants, UNFPA adheres to the recommendations and quality systems set by the World Health Organization and is committed to safeguarding public health. Manufacturers need to know our requirements for procurement and countries need to know they can count on UNFPA.

Personal lubricant – Any fluid, gel, cream or liquid used by health workers during the vaginal and rectal examinations or childbirth. Lubes may also be used to enhance the ease and comfort of intimate sexual activities.

Lubricants are widely used for sexual intercourse by men, women and transgender individuals around the world. A 2012 National Survey of Sexual Health and Behaviour in the United States of America found that 65.5 per cent of women and 70 per cent of men used lubricants to make sex more comfortable and pleasurable, while 74 per cent of men who have sex with men (MSM) used lubricant in at least 80 per cent of sexual encounters. Lubricants are also used by healthcare professionals for childbirth and to perform vaginal and rectal examinations.

Used in combination with condoms, personal lubricants help to reduce friction and improve comfort, and may help to reduce condom breakage in some situations. Water-based lubricants are the most commonly used commercial lubricants, although availability differs depending on the country.



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70%
of men and
65.5%
of women
use lubricants



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2. Concerns and challenges

Concerns about the safety and efficacy of personal lubricants, especially water-based ones, are significant. Research has shown that users are experiencing irritation, burning and damaging effects to vaginal and rectal tissue, which may increase susceptibility to HIV and other STIs. There is particular concern about personal lubricants used for rectal intercourse, as most available commercial products are designed for vaginal intercourse and pose greater risk of damage to rectal epithelium, which is more delicate and does not secrete lubricating fluids during intercourse.

“HIV infection is very high among sex workers. After 20 sex acts a day, natural lubrication is not possible and condoms are breaking. For sex workers, this is where the conversation starts.” – Daisy Nakato, WONETHA

✱ **For manufacturers,** lubricants pose two main challenges: maintaining good lubrication during use (not too runny or too thick, adequate absorption) and preventing irritation/allergic reactions.

✱ **For users,** lubricant can be messy, have an unpleasant smell, and cause irritation and pain, particularly for sex workers who may apply it multiple times a day.

✱ **Access is also an issue.** In many countries, condom-compatible lubricants are not available and people resort to using oil-based products that are not safe for the body and can cause condoms to break down.

Drawing on a process of research and review, UNFPA and the World Health Organization issued a set of specifications to guide those wishing to procure lubricants as well those engaged in its manufacture. This is of particular importance to UNFPA Country Offices when supporting the efforts of countries to implement their national programmes for sexual and reproductive health, including family planning, maternal health and prevention of HIV.

3. The first global consultation on personal lubrications played a pivotal role

In November 2016, UNFPA and partners convened the first [Global Consultation on Personal Lubricants](#). The purpose of the event was to hear the latest research on lubricant safety and develop general guidelines for non-toxic, long-lasting, condom-compatible lubricants that are safe and acceptable for all users and sexual practices. Eighty-six participants attended the consultation in Bangkok, including lubricant manufacturers, researchers and technical experts, sexual health advocates and educators, and international organizations that procure lubricants for governments or local organizations. It was hosted by the United Nations Population Fund (UNFPA), the United States Agency for International Development (USAID), the World Health Organization (WHO), and the International Planned Parenthood Federation (IPPF).

Researchers and technical experts presented the latest evidence on the safety, efficacy, and acceptability of personal lubricants, the science behind the products (osmolality, ingredients, and formulations) and the physiological effects of different types of lubricants. Manufacturers reported on how they have been applying the current WHO guidance on additional lubricants and what needs to be changed or added to make the specifications more detailed and robust. Members of civil society and international organizations described the experiences of MSM, sex workers, and transgender individuals

with personal lubricants, the availability and demand for personal lubricants in Eastern and Southern Africa, and the local challenges of accessing and distributing lubricant to high-risk populations.

The Global Consultation produced recommendations and action plans for manufacturing, procuring, and distributing quality-assured products that meet the needs of diverse users in a range of challenging environments. These recommendations informed revisions and updates to the 2011 WHO/UNFPA/FHI360 Advisory Note on personal lubricants. The status of the [WHO/UNFPA/FHI360 advisory note on Use and procurement of additional lubricants for male and female condoms](#) published in 2012 was also reviewed at the Global Consultation. It was agreed that the majority of the recommendations made in that note are still valid and they have been incorporated in the 2020 specifications.

Manufacturers, researchers and civil society have important and complementary roles to play in improving the safety, availability and use of personal lubricants. Together, they continue to work on establishing robust industry guidelines and clear public health messages.

Acknowledgements: The consultation was organized under the direction of Bidia Deperthes, Senior HIV Prevention Advisor, and Selo Mogatle, Technical Specialist, from UNFPA in close collaboration with Kent Klindera of USAID, Daniel McCarthy of International Planned Parenthood Federation (IPPF), and Mario Philip Festin of WHO/HRP. USAID supported attendance costs for members of civil society organizations and Bill Potter, Stapleford Scientific Services Limited provided invaluable assistance.

4. What have we learned since the 2011 guidance?

OSMOLALITY

Ideally, the osmolality of a personal lubricant should not exceed a certain level to minimize any risk of epithelial damage. Unfortunately, most currently available commercial lubricants significantly exceed this value. The World Health Organization recommends that procurers source lubricant with an osmolality less than 1,200 mOsm/kg.

pH

We now know it is not just the pH of a lubricant that is important, but also its buffering capacity. A lubricant with a low buffering capacity will have little effect on the pH of the vagina or rectum, whereas a lubricant with a high buffering capacity will cause a temporary shift in pH. The time it takes for the vagina or rectum to return to its natural pH will depend on the magnitude of the buffering capacity of the lubricant. Lubricants with low buffering capacity are therefore preferred.

POLYQUATERNIUM

The previous opinion on the safety of polyquaternium compounds has been revised and there is no longer any recommendation to avoid them. This note is not included in the updated April 2020 specifications.

5. What does the research say?

When it comes to the safety of lubricants, there are two main areas of concern: cytotoxicity and the impact on HIV and STI transmission. Although there are several categories of lubricants – water-based, silicone, natural oil and petroleum-based – the research has focused on water-based lubricants since only soluble types can be studied in vitro. Lubricant safety is an extremely difficult area to study. Studies are difficult to design and there are many confounding factors, such as condom use, frequency of sex, how lubricant use is reported, and many other issues. More research is needed. Studies to date have been small and need to be confirmed and conducted by others.

Bacterial vaginosis (BV) is a serious concern for women because it is very common, yet usually asymptomatic. The current research appears to show an association between lubricant use and increased incidence of BV and STIs. Based on the research, the main public health message should be that correct and consistent condom use is recommended to prevent exposure to pathogens.

“How do you know what the consumer wants? We ask them. In focus groups, feedback from consumer complaints about products already on market, etc. The types of lubricants are vast.”

– Global Consultation participant

6. Standard safety testing requirements

Most lubricant manufacturers carry out testing according to ISO 10993, a series of safety biocompatibility tests developed by international expert groups and used by all regulatory bodies to assess the safety of medical devices. Lubricants are classified as medical devices in the United States of America (Class II) and Europe (Class IIa). ISO 10993 is an extensive standard with 14 parts. Part 1 (10993-1) has a classification table that indicates which tests to conduct for a medical device depending on how it is used and the type and degree of exposure (i.e. where the lubricant goes and how long it stays there).

“In some parts of the world there may be products on the market that are not yet subjected to full safety and toxicity testing. Where personal lubricants are classified as medical devices, their manufacture is controlled.”

-- Global Consultation participant



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There are three types of tests for lubricants:

- **Cytotoxicity testing** according to ISO 10993-5 (direct contact, elution, or indirect/overlay test. The elution test seems to be the most appropriate one to use.)
- **Irritation testing** according to ISO 10993-10 (Rabbit vaginal test and penile irritation test)
- **Sensitization testing** according to ISO 10993-10 (guinea pig maximization test)

Additional testing may be required depending on where the product will be registered.

Sustaining supplies of condoms and lubricants during COVID-19

UNFPA is working to ensure that the COVID-19 pandemic does not disrupt the supply of condoms or related efforts to generate demand. While access to male and female condoms has been critical in the global response to reduce HIV, sexually transmitted infections and unintended pregnancies over the past three decades, these gains can be lost if condoms are not included in the essential commodities that are freely available to populations during the lockdown of countries.

UNFPA supports actions to sustain supplies of male condoms, female condoms and lubricants, and to adjust approaches for condom promotion during the time of COVID-19. It is important to remain active in managing condom programmes within broader HIV and sexual and reproductive health and rights responses, and to explore linkages with other existing programmes as part of the COVID-19 response. For more information, see the brief [Condoms and lubricants in the time of COVID-19](#).



7. Personal lubricants: the basics

What are personal lubricants?

Personal lubricants, or lubes, are liquid gels packed in bottles or sachets and sold in pharmacies without a prescription.

What are lubes used for?

Lube is a moisturizer. Health workers use lube for childbirth and to perform vaginal and rectal examinations. Anyone who is sexually active may also use lube to improve comfort during vaginal or rectal intercourse, or for masturbation.

Condoms and lube

Lubes are sometimes used with condoms to reduce friction. But not all types of lube work with condoms. When condom-compatible lube is not widely available, people may resort to using substances that can cause condoms to break down. **Oil-based substances should never be used with condoms**, for example, cooking oils, body creams, massage oils, petroleum jelly, or slippery foods like avocados.

Are lubes safe?

Lubes are not all the same. There are no standard formulations, and certain lubes can cause irritation and burning. Research has shown that some lubricants can damage vaginal and rectal tissue, and this can increase susceptibility to HIV, STIs and bacterial vaginosis (BV).

What do people need to know?

Messages about safety and disease prevention must always be based on research and clarify common misconceptions. First, **no lubricant has ever been shown to protect against HIV and STIs**. The only way lubricant makes a difference is by preventing a condom from breaking. Lubricant is not a microbicide. Second, **lubricants must be condom compatible**. Items from the bathroom or kitchen should **never** come close to a latex condom because they are oil-based and will weaken latex condoms.

Where can I find the 2020 specifications on lubes?

Based on research, a group of experts evaluated the technical components of the safest products and created specifications and formulations for lube that will be safe and non-toxic for everyone.

World Health Organization/United Nations Population Fund specifications for plain lubricants

WHO Technical Report Series, no. 1025, Annex 11, 20 April 2020

Available from: www.who.int/publications/m/item/trs-1025-annex-11-who-unfpa-plain-lubricants

8. Common terminology

Additional lubricant – Any lubricant used in conjunction with a condom that is applied to either the condom or the vulva, anus, or inserted into the vagina or rectum.

Buffering capacity – A measure of the efficiency of a lubricant in resisting changes in pH. Conventionally, buffer capacity is expressed as the amount of strong acid or base, in gram-equivalents, that must be added to 1 liter of the solution to change its pH by one unit.

BV – Bacterial vaginosis is a common condition in which the balance of bacteria inside the vagina becomes disrupted.

Cytotoxicity – The degree to which an agent has specific destructive action on certain cells.

Cytotoxicity of lubricants can be assessed using a number of standard procedures specified in ISO 10993-5.

Epithelium/Epithelial – The thin tissue that forms the covering of most internal and external surfaces of the body and its organs.

Hyper-osmolality – A solution having an osmolality greater than the cells with which it is in contact.

Hypo-osmolality – A solution having an osmolality lower than the cells with which it is in contact.

Iso-osmolality – A solution having an osmolality that is equal to that for the cells with which it is in contact.

Key population – A specific population that is being considered, such as sex workers, men who have sex with men (MSM), transgender people (TG), people who inject drugs (PwD).

Microbicide – Substances that kill or reduce the infectivity of viruses or bacteria added to lubricants as preservatives or spermicides. Common microbicides are nonoxynol-9, carrageenan, cellulose sulfate, chlorhexidine gluconate, and sodium dodecyl sulfate.

Osmolality – A measure of the number of dissolved particles per kg of solvent (water).

Personal lubricant – Any fluid, gel, cream or liquid used by health workers during the vaginal and rectal examinations or childbirth. Lubes may also be used to enhance the ease and comfort of intimate sexual activities.

pH – The measure of a liquid's basicity or acidity on a scale from 0–14, 0 being most acidic and 14 being most basic (specifically the pH is the negative \log_{10} of the hydrogen ion concentration where the concentration is expressed in moles per litre).

9. An introduction to osmolality

What is osmolality?

In simple terms, osmolality is related to the concentration of dissolved chemicals in a water-based lubricant. In more technical terms, osmolality is the measure of the number of dissolved particles per kg of solvent (water), expressed as mOsm/kg (milliosmoles per kilogram of water).

Why is osmolality important?

Cells in the epithelial layer (the outermost layers of the vagina and rectum) need to maintain an equilibrium of water content. Osmolality determines whether or not water flows into or out of these cells.

Hypo-osmolality

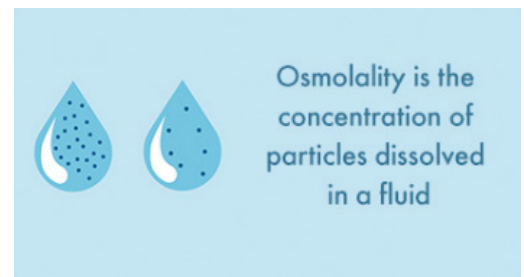
When a lubricant has **low osmolality** – lower than the inside of the cells – there is an imbalance in osmotic pressure and water is drawn into the cells, causing them to swell and even burst. This is called **hypo-osmolality**. Hypo-osmotic lubricants can damage epithelium cells and sperm, but there are not many of these types of lubricants on the market.

Hyper-osmolality

When a lubricant has **high osmolality**, it not only draws water out of epithelial cells, but also draws water into the lumen of the vagina or rectum. This is called **hyper-osmolality**. If osmolality is very high, it can cause cells to shrink, die and slough off, leaving the vagina or rectum irritated and more susceptible to infection. The shrunken cells also send out a danger signal to the immune system and initiate inflammation. Many lubricants on the market are hyper-osmolar. They may feel fine, but have toxic effects that do not cause most users any pain (silent toxicity).

Iso-osmolality

When a lubricant has an osmolality similar to that of the body's cells, little water flows into or out of the epithelial cells and everything remains in balance. This is called **iso-osmolality** and is ideal for a water-based lubricant.



Hypo-osmolality: swollen, ruptured cells



Hyper-osmolality: dried out, shrunken cells



Iso-osmolality: happy cells

Iso-osmolality

When a lubricant has an osmolality similar to that of the body's cells, little water flows into or out of the epithelial cells and everything remains in balance. This is called **iso-osmolality** and is ideal for a water-based lubricant.

What contributes to high osmolality in a lubricant?

Mainly **glycols**, which help prevent lubricants from “drying out” during use. Glycerol and propylene glycol are the most commonly used types. Glycols are relatively small molecules and may be found in quite high concentrations in lubricants. Since the osmolality of a lubricant is almost entirely dependent on small molecules, osmolality can be reduced by reducing the concentrations of glycol.

What is the recommended osmolality for personal lubricants?

To minimize the risk of epithelial damage, the osmolality of a lubricant should be in the same range as the osmolality of body fluids (see happy cells above). Vaginal secretions have osmolalities of 260–370 mOsm/kg and semen 250–380 mOsm/kg. Therefore, the osmolality of a personal lubricant should ideally not exceed 380 mOsm/kg. What is considered safe for vaginal use is also generally considered safe for rectal use.

However, the osmolality of most personal lubricants on the market is much higher: 2,000–6,000 mOsm/kg. Since manufacturers cannot change their formulations overnight, it is not practical to simply impose this limit. For now, the World Health Organization recommends that procurement agencies source lubricant with an osmolality less than 1,200 mOsm/kg. There are several products available that meet or only just exceed this recommended limit.

Part II: Specifications for plain lubricants as of April 2020

UNFPA is the lead agency within the United Nations system for the procurement of sexual and reproductive health supplies and the world's largest public-sector procurer of contraceptives including male and female condoms and additional personal lubricants. We leverage the significant volume of contraceptives procured annually to secure cost-effective, quality products to meet global needs. Among these products are personal lubricants.

The UNFPA Product Catalogue contains a variety of quality-assured commodities related to sexual and reproductive health and humanitarian response. As an example, UNFPA provides a [Quick Reference Guide: Lubricants](#) (February 2021) that is helpful for identifying different options when procuring lubricants.

Guidelines for the procurement of plain lubricants were updated following the UNFPA Global Consultation on Lubricants and then adopted at the Fifty-fourth meeting of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) in Geneva, Switzerland, 14 to 18 October 2019. The complete guidelines were published in April 2020, and efforts continue to share them widely.

The World Health Organization/United Nations Population Fund specifications for plain lubricants are available from:
www.who.int/publications/m/item/trs-1025-annex-11-who-unfpa-plain-lubricants

WHO/UNFPA specifications for plain lubricants

WHO Technical Report Series, Annex 11, no. 1025

Background

The report of the Fifty-third meeting of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations (ECSP) in 2018 (1) stated the following:

Ms Seloi Mogatle and Dr William Potter from the United Nations Population Fund (UNFPA) gave an update on the prequalification guidance for contraceptive devices and condoms. The UNFPA had contacted WHO to inquire how best to start a process to update the relevant texts that we adopted by the ECSP and published in 2008 (2, 3). The Expert Committee agreed to the importance of updating these materials in view of the changes in the contraceptive field globally over the previous decade. The two organizations committed to work together to bring the documents up to date. It was suggested by UNFPA to separate out the current existing procedure for condoms to include the following aspects:

- 1. prequalification guidance for contraceptive devices;*
- 2. prequalification programme for male latex condom and annexes;*
- 3. technical specification for male latex condom and annexes;*
- 4. male latex condom prequalification inspection aide memoire;*
- 5. condom quality assurance and annexes;*
- 6. guidance on testing male latex condoms;*
- 7. condom storage and transportation;*
- 8. post-market surveillance of condoms;*
- 9. public assessment reports for contraceptive devices – condoms and intrauterine devices.*

UNFPA also raised the issue of specifications for lubricants (both water-based and silicon-based), which needs to be considered when developing the new guidelines.

The Expert Committee supported the development of the relevant documents for prequalification of condoms in consultation with the WHO Secretariat and their preparation for public consultation and took note that they will be reported back to the Expert Committee.

As agreed at the ECSPP meeting in October 2018, UNFPA and WHO have separated out different aspects of the current procedure for contraceptive devices and condoms.

All related documents were restructured and revised in the first half of 2019, then sent out for public consultation in July 2019. Comments received were reviewed by a group of specialists in October 2019, before being presented to the ECSPP. This is one of the three adopted by the Fifty-fourth ECSPP meeting to replace the previous guidance document.

1. Introduction

The following guidelines give the specifications for procurement of additional lubricants to be used with male and female condoms in reproductive health programmes.

These guidelines have been updated following a detailed technical review conducted at the United Nations Population Fund (UNFPA) Global Consultation on Lubricants in November 2016 in Bangkok, Thailand, and a follow-up meeting, primarily with lubricant manufacturers, held in conjunction the Thirty-fourth ISO/TC 157 (International Organization for Standardization, Technical Committee 157 for Non-Systemic Contraceptives and STI Barrier Prophylactics) meeting in George Town, Penang, Malaysia in September 2017.

The Global Consultation on Personal Lubricants was convened to review the safety of personal lubricants, as research has shown users may experience irritation, burning and damaging effects to vaginal and rectal tissue, and to examine the ways to produce, procure and distribute safer products for all. Hosted by UNFPA, the United States Agency for International Development (USAID), the World Health Organization (WHO) and the International Planned Parenthood Federation (IPPF), the meeting brought together more than 80 manufacturers, researchers and technical experts, sexual health advocates and educators, as well as international organizations that procure lubricants for governments or local organizations.

The status of the WHO/UNFPA/FHI360 (Family Health International) advisory note on *Use and procurement of additional lubricants for male and female condoms* published in 2012 (4), was also reviewed at the Global Consultation. It was agreed that the majority of the recommendations made in that note are still valid and they have been incorporated in this specification. The recommendation that polyquaternary compounds should be avoided was found to be no longer supportable and has not been included in this specification.

2. Requirements

Manufacturers shall include in their product dossier evidence to confirm that the lubricant complies with the requirements listed in Table A11.1. Verification of conformance to these requirements is assessed by review of the product dossier.

Table A11.1
Generic requirements

Requirements	Description
Definition and general properties	<p>Description</p> <p>Water-based lubricants shall be clear, translucent or white gels or viscous liquids. They shall be free from lumps and foreign matter and be non-staining and water washable.</p> <p>Silicone lubricants shall be clear, translucent or white gels or viscous liquids free from lumps and foreign matter and be non-staining.</p> <p>Ingredients</p> <p>Lubricants shall contain only ingredients that are safe for human use in contact with vaginal mucosa and skin during sexual intercourse. The ingredients shall be non-irritant and non-toxic and shall not liberate any toxic or harmful substance during storage and use.</p> <p>Lubricants shall be free from added fragrance, colour, spermicides, herbal ingredients and special ingredients that claim specific pleasure-enhancing properties.</p> <p>Silicone lubricants shall contain a minimum of 30% polydimethylsiloxane (dimethicone), with a viscosity of 5 cps (centipoise) and above (mixtures of polydimethylsiloxanes with different viscosities are permitted).</p> <p>Compatibility with condoms</p> <p>Lubricants shall be compatible with male and female condoms (any exceptions shall be noted in the labelling). Testing shall be conducted according to ASTM D7661 (5) and ISO 19671:2018 (6). When testing silicone lubricants containing volatile cyclomethicone, the conditioning of the condoms in the presence of the lubricants should be done under occlusive conditions, to prevent evaporative loss of the cyclomethicone.</p> <p>Preservatives</p> <p>Water-based lubricants shall be preserved against microbial contamination and shall contain suitable preservatives. The lubricant shall be manufactured under suitable conditions, to maintain control of bioburden.</p> <p>Sterility</p> <p>Lubricants may be supplied sterile in unit-dose containers.</p>

Table A11.1 *continued*

Requirements	Description
	<p>Manufacturer Lubricant shall be manufactured in accordance with certified quality management systems (QMS) and in compliance with national and regional regulatory requirements. The QMS shall comply with ISO 13485 (7). Lubricant shall have regulatory approval such as a CE Mark or United States Food and Drug Administration (US FDA) 510(k) clearance (8).</p> <p>Lubricity There are currently no specification requirements for lubricity, nor are there any recommended methods for measuring lubricity. Manufacturers who specify lubricity requirements should submit details of the specification and test method to UNFPA. Similarly, manufacturers who test for the retention of lubricity over the time of use should submit details of the test method and requirement.</p>
Composition	<p>The manufacturer shall submit to procurement agencies full composition details of the lubricant, with the quantities and specifications of individual ingredients used. Wherever available, the ingredients shall comply with corresponding pharmacopoeia specifications. When specific proprietary ingredients are used, their material safety information shall be submitted.</p> <p>Water-based lubricants shall be formulated to comply with the requirements listed next.</p> <ul style="list-style-type: none"> • Osmolality shall be less than 1200 mOsm/kg.¹ This osmolality limit can be achieved by keeping the total glycol content below about 8.3 mass fraction (%w/w).² • pH shall be in the range 5.0 to 7.0.³ • Viscosity shall be within the tolerance of $\pm 10\%$ of the value specified by the manufacturer. The manufacturer shall submit the method of determination of viscosity, giving details of equipment, temperature conditions, spindle speed, spindle number and shear rate. <p>Silicon-based lubricants shall be formulated to comply with the requirements listed next.</p>

¹ This requirement is under review and might be revised at a future date.

² This limit may be varied depending on the specific glycols used.

³ *Note:* Lubricants with a low buffering capacity that do not disturb the pH of the vagina or rectum are preferred.

Table A11.1 *continued*

Requirements	Description
	<ul style="list-style-type: none"> • Viscosity shall be within a tolerance of $\pm 10\%$ of the value specified by the manufacturer. The manufacturer shall submit the method of determination of viscosity, giving details of equipment, temperature conditions, spindle speed, spindle number and shear rate.
Biocompatibility	<p>Lubricants shall comply with the requirements of biocompatibility assessments conducted in accordance with ISO 10993-1 (9), for specific parameters of cytotoxicity (ISO 10993-5) (10) and skin irritation and sensitization (ISO 10993-10) (11).⁴ The toxicity study reports shall be reviewed and interpreted by a qualified toxicologist or other suitably qualified expert. Full reports of biocompatibility assessments shall be submitted as part of the product dossier.</p>
Bioburden levels	<p>Lubricants need not be sterile. However, they shall be subjected to control of microbial contamination by appropriate measures taken in formulation, manufacturing and packing operations. In the finished product, bioburden levels shall be maintained below 100 cfu (colony-forming units) per gram (USP 1111) (12). There shall be an absence of <i>Pseudomonas aeruginosa</i>, <i>Staphylococcus aureus</i>, <i>Candida albicans</i> and <i>Escherichia coli</i>. These requirements apply to both water-based and silicone-based lubricants.</p> <p>Bioburden levels shall be maintained at the above levels during storage and repeated opening of a container during multiple use.</p> <p>Lubricants shall comply with the evaluation of preservative efficacy, performed as per the requirements of a relevant pharmacopoeia.</p> <p>If the lubricant is supplied sterile in unit-dose containers, the sterility assurance level shall be 10^{-6}.</p>

⁴ Note: Some regulatory authorities require acute systemic toxicity to be assessed. For example, USFDA requires acute toxicity testing by intraperitoneal administration.

Table A11.1 *continued*

Requirements	Description
Shelf-life and stability	<p>Lubricants shall have a minimum shelf-life of 3 years from the date of manufacture.</p> <p>To ensure compatibility with condom-storage recommendations and shelf-life estimates, real-time studies shall be conducted within the temperature range of 28 °C to 35 °C. The humidity shall be maintained at (75 ± 5%) relative humidity (RH), to ensure conformity with Zone IVb (hot, higher humidity) requirements.</p> <p>In line with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guideline Q1A(R2) (13), accelerated studies shall be conducted at 40 ± 2 °C and 75 ± 5% RH. Manufacturers may elect to use higher temperatures such as 50 °C and 60 °C, providing the results can be correlated with real-time shelf-life estimates at 28 °C to 35 °C.</p> <p>For water-based lubricants, manufacturers should include freeze/thaw cycling in their stability studies, to confirm that the lubricants can tolerate freezing. Manufacturers should also confirm that osmolality remains within specifications at the end of the stability study and undertake intermediate osmolality measurement if any significant changes occur to the water content and/or viscosity of the lubricant, and, in the case of lubricants packed in sachets, the weight of the sachets during the course of the study.</p> <p>Critical parameters, including pH, bioburden, viscosity, odour, physical condition, etc., shall be monitored during stability studies. For water-based lubricants, preservative assays and microbiological challenge tests shall be conducted during stability studies. Silicone lubricants containing cyclomethicone should be monitored for weight loss due to any loss of volatile material through the packaging.</p> <p>Lubricants shall remain within the manufacturer's specification for the duration of the shelf-life period.</p> <p>The data and report on accelerated stability studies and ongoing real-time studies shall be submitted as part of the product dossier.</p>

Table A11.1 *continued*

Requirements	Description
Compatibility with condoms	<p>The manufacturer should submit reports of compatibility studies conducted on the use of lubricant with male and female condoms made from natural rubber latex and synthetic materials. The toxicity study reports shall be reviewed and interpreted by an appropriately qualified person to assess toxicology reports, e.g. a pharmacologist, pharmacist, microbiologist or a laboratory medicine specialist.</p> <p>If any biocompatibility or toxicity risks are identified, a risk/benefit analysis shall be included in the report. Full reports of biocompatibility assessments shall be submitted as part of the product dossier</p> <p>Any exceptions from testing or incompatibilities shall be noted.</p>
Packaging	<p>Individual containers</p> <p>Lubricants shall be packed in tamper-evident containers that facilitate multiple delivery of lubricant. Examples are collapsible/squeeze tubes and containers with a suitable delivery system for application of lubricant.</p> <p>It is recommended that containers should be made of recyclable materials that are compatible with the lubricant, as substantiated by stability studies and shelf-life claims. The containers shall not have sharp edges. They shall not liberate any toxic or harmful substance during storage and use of the product. The individual containers shall be free from leakage of lubricant.</p> <p>The recommended nominal contents for multi-dose containers are 35 g, 50 g and 82 g. Other sizes may be considered, depending upon programme requirements. The recommended nominal contents for a single-dose sachet is 3 g for silicone lubricants and 4–5 g for water-based lubricants.</p> <p>Pack contents are based on the amount of lubricant that can be expressed from the pack under normal use. This will be evaluated by weighing 20 full primary containers individually and weighing them again after squeezing out their contents. Alternatively, the weight of lubricant expressed may be determined directly by collecting it in a tared container or dish.</p>

Table A11.1 *continued*

Requirements	Description
	<p>Secondary packing</p> <p>The individual containers shall be packed in secondary distribution packages of an appropriate size as per programme requirements (e.g. 25 units per secondary pack).</p> <p>Cardboard boxes shall be Forest Stewardship Council (FSC; or equivalent) marked/certified. They shall only contain paper/cardboard. Plastic coating shall not be used.</p> <p>Shipper cartons</p> <p>Shipper cartons shall be FSC (or equivalent) marked/certified. They shall be made of a minimum of 40% recycled/post-consumer material.</p> <p>The shipper carton should only contain paper/cardboard. Plastic coating shall not be used.</p> <p>By 2020, the plastic carton liner shall be made from recycled material/plastic and biodegradable plastic.</p> <p>The recommendations relating to packaging in this specification may be varied depending on the intended use of the lubricant. Full details of the required packaging should be agreed in advance and specified in purchase orders.</p>
<p>Labelling</p>	<p>Individual containers</p> <p>Labelling requirements may be subject to local regulatory requirements. Subject to any local requirements, the individual containers shall be marked with the details listed next.</p> <ul style="list-style-type: none"> • Contents (specify if it is water- or silicone-based lubricant) • The quantity of lubricant that can be expressed from the container in normal use • If in a multi-dose container, advice on the amount of lubricant to be used • Manufacturer's name and address • Batch/lot number • Expiry date (in YYYY-MM format) • Storage conditions – store at an average temperature below 30 °C and avoid exposure to direct sunlight • Warnings/special notes, if any • Maximum time period in which the contents can be used after the container was first opened • A list of any ingredients that may be an irritant or that could cause allergic reactions

Table A11.1 *continued*

Requirements	Description
	<ul style="list-style-type: none"> • A statement that the lubricant is compatible with male and female condoms (any exceptions, such as male polyurethane condoms, shall be stated on the package) • A statement that lubricant is not a contraceptive and does not protect against pregnancy, sexually transmitted infections and HIV. To protect against pregnancy and sexually transmitted infections, the lubricant must be used with a condom. <p>Secondary packaging</p> <ul style="list-style-type: none"> • Contents • Quantity • Manufacturer’s name and address • Batch/lot number • Date of manufacture and expiry date (in YYYY-MM format) • Storage conditions • Warnings/special notes, if any <p>Shipper cartons (or as per UNFPA shipping instructions to be provided by the buyer)</p> <ul style="list-style-type: none"> • UNFPA logo • UNFPA project number • UNFPA purchase order (PO) number • Country of destination • Contents as water-based lubricants • Quantity • Manufacturer’s name and address • Batch/lot number • Date of manufacture (in YYYY-MM format) • Expiry date (in YYYY-MM format) • Weight • Volume • Storage conditions text: “Store in well-ventilated, dry storage conditions with an average temperature of less than 30 °C away from direct sources of heat including sunlight” • Warnings/special notes, if any, to be defined by the manufacturer • Any special shipping instructions defined by the manufacturer

2.1 Lot-by-lot testing requirements

The manufacturer shall submit a certificate of analysis for each batch/lot of lubricant supplied, confirming conformance to the requirements specified in this section. This section may also be used by accredited/approved laboratories for the independent testing of lubricants.

Parameter	Requirements	Verification
Description	<p>Water-based lubricant shall be clear, translucent or white gel or viscous liquid, free from lumps and foreign matter, and water washable.</p> <p>Silicone lubricants shall be clear, translucent or white gels or viscous liquids free from lumps and foreign matter and be non-staining.</p>	Visual inspection on samples weighing about 5 g, drawn from five individual containers from each lot
pH	5.0 to 7.0	Inspection of a composite sample weighing about 10 g, drawn from five individual containers
Viscosity	Shall be within tolerance of $\pm 10\%$ of the specified viscosity value	<p>The manufacturer's method of giving equipment, temperature condition, spindle, speed, etc., shall be used. Testing is to be completed on a representative sample from each lot, either from the bulk immediately before packaging or from sufficient individual containers in order to provide an adequate sample size for the viscometer.</p>
Bioburden	<p>Bioburden levels shall be maintained below 100 cfu per gram. There shall be an absence of <i>Pseudomonas aeruginosa</i>, <i>Staphylococcus aureus</i>, <i>Candida albicans</i> and <i>Escherichia coli</i>.</p> <p>Sterility (if claimed) shall be to the sterility assurance level of 10⁻⁶.</p>	<p>Testing as: per <i>The International Pharmacopoeia (14)</i>, United States Pharmacopeia (<i>USP</i>) (<i>15</i>) or European Pharmacopoeia (<i>16</i>).</p> <p>Recommended testing frequency:</p> <ul style="list-style-type: none"> • for the first 10 production lots, every lot shall be tested; • subject to all 10 lots conforming to specification, the testing frequency may be reduced to one in every 10 lots. If a lot fails, then full testing shall be reinstated until 10 consecutive lots have passed.

Table continued

Parameter	Requirements	Verification
Packaging and labelling	Shall comply with requirements of packaging and labelling as given in Section 2, except for material of construction.	Visual observation on samples of 13 containers per lot/batch

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