World Health Organization

DRAFT WORKING DOCUMENT FOR COMMENTS:

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

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Comments should be submitted through the online platform by **08 July 2025**. Please note that only comments received by this deadline will be considered for the preparation of this document.
Our working documents are sent out electronically and uploaded into PleaseReview™. The working documents are also placed on the WHO Medicines website (https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/pharmaceuticals/working-documents-public-consultation) under the "Working documents in public consultation". If you wish to receive all our draft guidelines, please send your full name, organization / affiliation, and email address to nsp@who.int and your name will be added to our electronic mailing list and review platform.

SCHEDULE FOR DRAFT WORKING DOCUMENT QAS/25.977:

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

Description of activity	Date
Preparation of first draft working document.	Aug – Sept 2024
Mailing of the working document to the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations (EAP) inviting comments and posting of the working document on the WHO website for public consultation.	May – Jul 2025
Consolidation of comments received and review of feedback. Preparation of working document for discussion.	Aug – Sept 2025
Preparation of a working document for discussion and possible adoption by the Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP).	Sept 2025
Presentation to the fifty-ninth meeting of the ECSPP.	20 – 24 Oct 2025
Any other follow-up action as required.	TBC

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

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Background

The *World Health Organization (WHO)/United Nations Population Fund (UNFPA) specifications for plain lubricants* were recommended for adoption at the fifty-fourth meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations held in 2019 and published as Annex 11 in the WHO Technical Report Series, No 1025, 2020 (*1*).

This specification is for procurement of additional lubricants to be used with male and female condoms in reproductive health programmes.

These specifications were developed following a detailed technical review conducted at the 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), 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 *(2)*, 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 oly quaternary compounds should be avoided was found to be no longer supportable and has not been included in this specification.

To ensure the specifications remain relevant and current, UNFPA, in consultation with stakeholders, propose the revision of Annex 11 (WHO Technical Report Series No, 1025, 2020).

1. Introduction

The *WHO/UNFPA specifications for plain lubricants* provides the specifications for quality assurance and regulatory compliance of additional lubricants to be used with male and female condoms in reproductive health programmes.

These specifications are designed to ensure that lubricants meet stringent safety, efficacy, and quality standards, thereby safeguarding users from potential adverse effects. The document outlines the requirements for water-based and silicone-based lubricants, focusing on their physical properties, ingredient safety, compatibility with condoms, microbiological standards, biocompatibility requirements , shelf-life studies, packaging, labeling, and lot-by-lot testing. The document does not cover lubricants with added fragrances, colors, spermicides, herbal ingredients, or special ingredients claiming specific pleasure-enhancing properties. It also excludes lubricants intended for uses other than with male and female condoms in reproductive health programs.

Key updates in this specifications are as follows:

- The water-based lubricant viscosity specifications in this document are based on data submitted by manufacturers to UNFPA.
- The Specification for pH revised.
- Environmental control requirements for manufacturing lubricants included.
- Manufacturers shall confirm that the preservative system remains effective throughout the shelf-life of the product by testing.
- Validated microbiological test methods shall be used for testing to confirm they are effective in the presence of the preservatives used in the formulation.
- Manufacturers should also ensure the absence of the pathogen Burkholderia cepacia complex.
- Osmolality calculation method added.
- Purified water used in the manufacture of water-based lubricants shall be of pharmacopeia grade.

The primary target users of this document are manufacturers of lubricants, procurement agencies, regulatory authorities, and quality assurance personnel involved in the production, procurement, and distribution of lubricants for reproductive health programs. The guidelines are also relevant for

international organizations, non-governmental organizations (NGOs), and other stakeholders involved in reproductive health and family planning initiatives.

2. Requirements

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

Table 1: Generic requirements

Requirements	Description
Definition and general properties	**Description** 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. Silicone lubricants shall be clear, translucent or white gels or viscous liquids free from lumps and foreign matter and be non-staining.

Requirements	Description
	Ingredients 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. Lubricants shall be free from added fragrance, colour, spermicides, herbal ingredients and special ingredients that claim specific pleasure enhancing properties. Purified water used in the manufacture of water-based lubricants shall of pharmacopeia grade, for example meeting the requirements of the United States Pharmacopeia (USP), the European Pharmacopoeia (Ph.Eur) or the International Pharmacopoeia (Ph.Int). 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). **Compatibility with condoms** 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 (3) and ISO 19671:2018 (4). 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. **Preservatives** Water-based lubricants shall contain suitable preservatives to protect against microbial contamination. The lubricant shall be manufactured under conditions to maintain control of bioburden. The effectiveness of the preservative system shall be confirmed by testing, for example, using USP <51>. Manufacturers shall confirm that the preservative system remains effective throughout the shelf-life of the product. **Sterility** Lubricants may be supplied sterile in unit dose containers.

Requirements	Description
	Manufacture 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 (*5*). Lubricant shall have regulatory approval such as a CE Mark or United States Food and Drug Administration (US FDA) 510(k) clearance (*6*). Manufacturers are advised to follow the guidance given in WHO Technical Report Series, No. 1010, 2018, Annex 8, Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (7). The HVAC system and classification of clean rooms in production areas should be appropriately designed and operated based on the assessment of the risk of potential contamination of the product. It is strongly recommended that positive air pressures are maintained in the chemical handling, mixing and primary packaging areas to prevent ingress of any contamination. The appropriate cleaning and sanitisation procedures shall be used for all equipment, manufacturing areas and primary packaging materials to prevent contamination. **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. **Viscosity** There are inadequate published data to determine the optimum viscosity for water-based lubricants. The viscosity specifications in this specification are based on data submitted by manufacturers to UNFPA. Water-based lubricants usually exhibit shear thinning viscosity behaviour, the measured viscosity being highly dependent on the conditions used to make the measurement. For this reason, viscosities specified in this specification for water-based lubricants are

Requirements	Description
	based on measurements made at (25 ± 2) °C using a Brookfield or equivalent rotational viscometer with spindle number LV-4 at a rotation speed of 60 rpm.
Composition	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. Water-based lubricants shall be formulated to comply with the requirements listed below: • Osmolality shall be less than 1200 mOsm/kg water. This osmolality limit can be achieved by keeping the total glycol content below about 8.3 mass fraction (%w/w).[Note 1] • If it is necessary to dilute the lubricant to measure the osmolality, the measured value shall be multiplied by a dilution factor based on the water content of the lubricant before and after dilution and not on the ratio of lubricant volumes before and after dilution. • The pH shall be in the range 4.0 to 7.0 with a tolerance of ± 1.0 [Note 2]. The initial viscosity of water-based lubricants shall be specified by the manufacturer in the range 5,000 to 20,000 cPs. A tolerance of ± 15% shall be applied to the specified value. The viscosity shall be measured using a Brookfield or equivalent rotational viscometer at (25 ± 2) °C fitted with spindle number LV-4 at a rotation speed of 60 rpm. The initial viscosity of silicone lubricants shall be specified by the manufacturer along with the method and conditions of measurement. A tolerance of ± 15% shall be applied to the specified value. The viscosity of silicone and water-based lubricants shall not fall by more than 30% from the initial value over the shelf-life period of the product. Accelerated stability studies may be used to confirm this.
Biocompatibility	Lubricants shall comply with the requirements of biocompatibility assessments conducted in accordance with ISO 10993-1 (*8*), for specific parameters of cytotoxicity (ISO 10993-5) (*9*), skin sensitization (ISO 10993-10) (*10*) and ISO 10993-23 (11). [Note 3] The toxicity study reports shall be reviewed and interpreted

Requirements	Description
	by a qualified toxicologist or other suitably qualified expert. Full reports of biocompatibility assessments shall be submitted as part of the product dossier.

Note 1: This limit may be varied depending on the specific glycols used.

Note2 : Lubricants with a low buffering capacity that do not disturb the pH of the vagina or rectum are preferred.

Note 3: Some regulatory authorities require acute systemic toxicity to be assessed. For example, USFDA requires acute toxicity testing by intraperitoneal administration

Bioburden levels	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 *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Candida albicans*, *Escherichia coli* and *Burkholderia cepacia* complex. These requirements apply to both water-based and silicone-based lubricants. Bioburden levels shall be maintained at the above levels during storage and repeated opening of a container during multiple use. Lubricants shall comply with the evaluation of preservative efficacy, performed as per the requirements of a relevant pharmacopoeia. All microbiological test methods shall be validated to confirm they are effective in the presence of the preservatives used in the formulation. If the lubricant is supplied sterile in unit-dose containers, the sterility assurance level shall be 10^{-6}.
Shelf-life and stability	Lubricants shall have a minimum shelf-life of 3 years from the date of manufacture. 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. 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

Requirements	Description
	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. 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 i-n sachets, the weight of the sachets during the course of the study. 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. Lubricants shall remain within the manufacturer's specification for the duration of the shelf-life period. The data and report on accelerated stability studies and ongoing real-time studies shall be submitted as part of the product dossier.
Compatibility with condoms	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, for example, a pharmacologist, pharmacist, microbiologist or a laboratory medicine specialist. 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 Any exceptions from testing or incompatibilities shall be noted.
Packaging	**Individual containers** Lubricants shall be packed in hermetically sealed 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.

Requirements	Description
	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. 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. 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. **Secondary packing** The individual containers shall be packed in secondary distribution packages of an appropriate size as per programme requirements (for example, 25 units per secondary pack). Cardboard boxes shall be Forest Stewardship Council (FSC; or equivalent) marked/certified. They shall only contain paper/ cardboard. Plastic coating shall not be used. **Shipper cartons** Shipper cartons shall be FSC (or equivalent) marked/ certified. They shall be made of a minimum of 40% recycled/ post-consumer material. The shipper carton should only contain paper/cardboard. Plastic coating shall not be used. By 2020, the plastic carton liner shall be made from recycled material/plastic and biodegradable plastic. 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.
Labelling	**Individual containers**

Requirements	Description
	Labelling requirements may be subject to local regulatory requirements. Subject to any local requirements, the individual containers shall be marked with the details listed below. • 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 • 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.** **Secondary packaging** • 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

Requirements	Description
	Shipper cartons (or as per UNFPA shipping instructions to be provided by the buyer) • 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.

Table 2: Lot-by-lot testing Requirements

Parameter	Requirements	Verification
Description	Water-based lubricant shall be clear, translucent or white gel or viscous liquid, free from lumps and foreign matter, and water washable. Silicone lubricants shall be clear, translucent or white gels or viscous liquids free from lumps and foreign matter and be non-staining.	Visual inspection on samples weighing about 5 g, drawn from five individual containers from each lot
pH	Shall be in the range 4.0 to 7.0 with a tolerance of ± 1.0	Inspection of a composite sample weighing about 10 g, drawn from five individual containers
Initial Viscosity water-based lubricants	Shall be within tolerance of ±15 % of the specified viscosity value	Viscosity shall be measured at (25 ± 2) °C using a Brookfield or equivalent rotational viscometer with spindle number LV-4 at a rotation speed of 60 rpm.
Initial viscosity silicone lubricants	Shall be within tolerance of ±15 % of the specified viscosity value	Viscosity shall be measured as specified by the manufacturer
Bioburden	Bioburden levels shall be maintained below 100 cfu per gram. There shall be an absence of *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Candida albicans, Escherichia coli* and *Burkholderia cepacia* complex. Sterility (if claimed) shall be to the sterility assurance level of 10–6.	Testing as: per The International Pharmacopoeia (*14*), United States Pharmacopeia *(USP) (15) or* European Pharmacopoeia (*16*). Recommended testing frequency: • 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

Parameter	Requirements	Verification
		lots. If a lot fails, then full testing shall be reinstated until 10 consecutive lots have passed.
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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