

Personal Lubricants & Osmolality

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Osmolality

What is it?

Why is it important?

How is it measured?

What is Osmolality?

- Osmolality is the concentration of a solution expressed as Osmoles of solute per Kg of solvent
- Osmolality takes into account how many “particles” are formed when a solute dissolves in a solvent
- $\text{Osmoles} = \text{moles} \times i$ where i is the van't Hoff factor
- Osmolality determines the “colligative” properties of solutions:
 - Osmotic pressure
 - Vapour pressure/boiling point of the solution
 - Freezing point of the solution

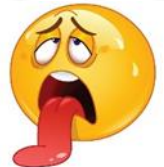
Why Is Osmolality Important?

- All our cells are contained within a semipermeable cell membrane
- Osmolality determines if water will flow into or out of cells

Low osmolality → osmotic pressure pumps water into cells



High osmolality → osmotic pressure sucks water out of cells



Iso-osmolality → happy cells



Safety of Lubricants and Osmolality

- Paper published in 2011: “Identification of Personal Lubricants that can Cause Rectal Epithelial Cell Damage and Enhance HIV Type 1 Replication in Vitro”, Othell Begay et al *
- Most commercial lubricants have high osmolality (2,000–6,000 mOsm/kg water)
 - Vaginal secretions 260–370 mOsm/kg water
 - Semen 250–380 mOsm/kg water

Raised safety issues about personal lubricants associated with high osmolality

* AIDS RESEARCH AND HUMAN RETROVIRUSES Volume 27, Number 00, 2011
Mary Ann Liebert, Inc.
DOI: 10.1089/aid.2010.0252

WHO Advisory Note Published in 2011

- Limit osmolality to less than 1,200 mOsm/kg
 - Keep glycol content below ca 8.3% mass fraction (w/w)
- Avoid lubricant formulations containing polyquaternium 15 specifically, and perhaps polyquaternary compounds in general
 - pH 4.5 is preferable for vaginal lubricants
 - pH 5.5 – 7 appropriate for anal and general use

Global Consultation on Personal Lubricant 2016

- UNFPA, WHO, USAID and IPPF hosted a Meeting in Bangkok 8–10 November 2016, Thailand, to review the safety of personal lubricants
- Attended by experts in sexual and reproductive health, lubricant manufactures and many other organisations
- Reviewed latest available evidence on the safety, efficacy, and acceptability of personal lubricants
- Endorsed the Advisory Note recommendations for osmolality and pH
- Established the requirements specified in the WHO/UNFPA Specification for Additional Lubricants

Measurement of Osmolality

- Most commercial osmometers measure freezing point depression or vapour pressure depression
 - Normal working range up to 2,000 mOsmol/Kg water
 - Viscosity of personal lubricants limits this range
- Most personal lubricants have to be diluted before measurement
 - Osmolality often reported for the diluted lubricant
 - Calculation required to estimate osmolality of the undiluted lubricant

How to Back Calculate Undiluted Osmolality

- Definition of Osmolality: concentration of a solution in terms of osmoles of solute per Kg of water (solvent)
- 100 g of undiluted gel contains W_u g of water where W_u is the percentage water in the undiluted gel (w/w)
- $\text{Osmolality} = \text{Osmoles Solute} \times 1,000/W_u$
- Added water = $100 \times n$ g where n is dilution ratio (1:n)
- $\text{Diluted Osmolality} = \text{Osmoles Solute} \times 1,000/(W_u + 100n)$
- $\text{Multiplication Factor} = (W_u + 100n)/W_u$

Questions?

Thank you for your attention