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APPLICATION NOTE

UNDERSTANDING AND CONTROLLING WATER ACTIVITY IN TOPICAL CREAMS, OINTMENTS



Topical products represent a large sub-industry of both the pharmaceutical and cosmetic industries. They include a variety of functions and form factors. Creams are described as semi-solid emulsion of oil and water that is thicker than lotions and are typically used to deliver a functional ingredient. Lotions are also emulsions but are usually thinner and more spreadable and are used for skin maintenance. Ointments are thicker and more solid in appearance and are used for the treatment of skin issues are to deliver antiseptics. Gels, such as toothpaste or hair gel, are defined as semi-solids that contain a gelling agent such as cellulose that helps trap water and gives a translucent appearance and smooth texture.

When we talk about the importance of water activity in products, we tend to focus on products that are taken internally and not on topical applications. However, it is just as important to consider the water activity of products that are typically applied on the outside of the body such as therapeutic creams, lotions, and other personal care products. Water activity impacts the texture of these products and contributes to the ease of application but also determines if the formulation will support the growth of microorganisms. Just as with oral products, applying topical products containing pathogenic organisms can be dangerous and lead to serious infections. In addition, water activity affects the rate of degradative chemical reactions that can reduce efficacy and produce off odors, ending the shelf life of the product.

WATER ACTIVITY BASICS

Water activity is defined as the energy status of water in a system and is rooted in the fundamental laws of thermodynamics through Gibb's free energy equation. It represents the relative chemical potential energy of water as dictated by the surface, colligative, and capillary interactions in a matrix. As water interacts with other molecules through various interactions, a portion of the energy held in the bonds of the water molecule is transferred to the interaction, thereby lowering the energy of the water molecule itself. The more interactions provided to water by the product ingredients, the lower the energy of water will become. This lowering of the energy of water also reduces its capability to escape into the vapor phase causing a reduction in vapor pressure. A water activity of 0.50 indicates that the water in the product has 50% of the energy that pure water would have in the same situation. The lower the water activity, the less the water in the system behaves like pure water. Notice that the definition provided here never mentions the term 'free water' as this term is often mistakenly used to define water activity but has no scientific meaning.

WATER ACTIVITY MEASUREMENT

To test topical products, water activity is measured by equilibrating the liquid phase water in the sample with the vapor phase water in the headspace of a closed chamber and measuring the Equilibrium Relative Humidity (ERH) in the headspace using a sensor. The relative humidity can be determined using a resistive electrolytic sensor, a chilled mirror sensor, a tunable diode laser (TDL), or a capacitive hygroscopic polymer sensor. Instruments from Novasina, like the Labmaster NEO, utilize a resistive electrolytic sensor (RES) to determine the ERH. Changes in ERH are tracked by changes in the electrical resistance of the electrolyte sensor. The challenge in testing the water activity of topical products can be volatile materials sometimes present in these formulations. If volatiles are present, only the RES and TDL sensors can be used to measure water activity. The RES sensor will need to be used with a redox filter, but with the filter in place, the RES sensor can be used to read any of the common topical products at a lower cost than the TDL sensor. Table 1 shows a survey of the water activity of common topical products as read when using the redox filter with the RES sensor.

Table 1. Water activity of common topical products as determined using a RES sensor and a redox filter.

Product	Water Activity
Hair Conditioner	0.977
Body Milk Lotion	0.971
Aloe Vera Gel	0.944
Anti-itch Cream	0.940
Colgate Sensitive Toothpaste	0.837
Antiseptic Ointment	0.533
Allergy Ointment	0.338

WATER ACTIVITY AND MICROBIAL GROWTH

For all topical products, of greatest concern is the microbial safety of these products. They must be processed correctly to reduce the microbial load and prevent the subsequent proliferation of any microorganisms. Water activity controls microbial growth because it impacts their ability to reproduce and grow. When a microorganism encounters an environment where the water activity is lower than their internal water activity, they experience osmotic stress and begin to lose water to the environment as it moves to lower energy (1). This loss of water reduces turgor pressure and retards normal metabolic activity. To continue reproducing, the organism must lower its internal water activity below that of the environment so water will move back into the cell. It tries to achieve this by concentrating solutes internally. The ability to reduce its internal water activity using these strategies is unique to each organism. Consequently, each microorganism has a unique limiting water activity below which they cannot grow (1,2). A list of the water activity lower limits for growth for common spoilage organisms can be found in Table 2.

Table 2. Water activity lower limits for growth for common spoilage organisms.

Microorganism	aw limit	Microorganism	aw limit
<i>Clostridium botulinum</i> E	0.97	<i>Penicillium expansum</i>	0.83
<i>Pseudomonas fluorescens</i>	0.97	<i>Penicillium islandicum</i>	0.83
<i>Escherichia coli</i>	0.95	<i>Fusarium verticillioides</i>	0.83
<i>Clostridium perfringens</i>	0.95	<i>Aspergillus fumigatus</i>	0.82
<i>Salmonella</i> spp.	0.95	<i>Penicillium cyclopium</i>	0.81
<i>Clostridium botulinum</i> A B	0.94	<i>Saccharomyces baillii</i>	0.8
<i>Vibrio parahaemolyticus</i>	0.94	<i>Penicillium martensii</i>	0.79
<i>Bacillus cereus</i>	0.93	<i>Aspergillus niger</i>	0.77
<i>Rhizopus nigricans</i>	0.93	<i>Aspergillus ochraceus</i>	0.77
<i>Listeria monocytogenes</i>	0.92	<i>Aspergillus restrictus</i>	0.75
<i>Bacillus subtilis</i>	0.91	<i>Aspergillus candidus</i>	0.75
<i>Staphylococcus aureus</i> (anaerobic)	0.9	<i>Eurotium chevalieri</i>	0.71
<i>Saccharomyces cerevisiae</i>	0.9	<i>Eurotium amstelodami</i>	0.7
<i>Candida</i>	0.88	<i>Zygosaccharomyces rouxii</i>	0.62
<i>Staphylococcus aureus</i> (aerobic)	0.86	<i>Monascus bisporus</i>	0.61

MICROBIAL CONCERNS FOR TOPICALS

The water activity levels of topical products vary depending on the type, as shown in Table 1, but in general, lotions and creams tend to have water activity levels higher than the 0.85 aw cutoff for pathogenic organisms. For these products, microbial safety is provided by aseptic handling and packaging where the package protects the product until it is used. In addition, many of these lotions have a lower pH, as low as 4.7, which works in combination with aw to provide protection against microbial growth (3). If the pH and water activity levels are not sufficiently low enough to stop microbial growth, preservatives such as phenoxyethanol or salicylic acid would then need to be implemented. For ointments and gels whose water activity is less than 0.85 aw, but higher than 0.70 aw, the main microbial concern would be mold growth. To prevent mold growth in these systems, preservatives against mold such as sodium benzoate are included in the formulation. For ointments whose water activity is less than 0.70 aw, microbial growth is not a concern, and the product is shelf stable.

FORMULATION STRATEGIES TO CONTROL WATER ACTIVITY

In a marketplace where the demand for natural and preservative-free choices continue to increase in demand, controlling the water activity to lower values through formulation adjustments is a way to avoid the use of chemical preservatives in topicals while still providing protection against microbial growth. The most common method for lowering water activity is through the removal of water by drying. However, the challenge presented by this option is to maintain the desirable viscosity characteristics provided by moisture that aid in the application of the topicals. Consequently, the most desirable method for lowering water activity would be through the addition of ingredients that lower the energy of water by providing water binding sites. The advantage of this reformulation approach is that it lowers the energy of water to prevent microbial growth while maintaining moisture levels to preserve product texture. Some options for lowering water through formulation include the addition of:

- Humectants (e.g., glycerin, propylene glycol): polar compounds that provide water-binding sites
- Polyols and sugars: Reduce water availability through hydrogen bonding with water
- Water-in-oil emulsions: Naturally lower aw due to limited water exposure

ROLE OF PACKAGING

Unexpected changes in the water activity of topical products during transport or storage can lead to undesirable alterations in texture and microbial stability. A decrease in water activity often results in texture changes, while an increase can compromise microbial safety. These shifts typically occur when the product is exposed to relative humidity levels that differ from its own water activity. Since most topical formulations have high water activity, they are more likely to encounter storage environments with lower humidity, leading to moisture loss. To mitigate this, packaging with effective moisture barrier properties is essential—though excessive packaging should be avoided to control costs. Modeling tools are available to help select optimal packaging materials that maintain water activity across varying storage conditions.

REGULATORY CONSIDERATION

Topical products must be manufactured under a safety program that identifies the most likely risks and outlines the critical control points that will be used to ensure safety. The guidelines for safety programs concerning personal care creams, lotions, and ointments will be found in the local Pharmacopeia. In terms of applying water activity as an effective control point in these products, the specific guidelines of importance would be USP <922> Water Activity and ISO 29621 for cosmetics.

CONCLUSION

Water activity is a powerful parameter for optimizing the safety, stability, and performance of creams and lotions. By understanding and controlling water activity, formulators can improve product quality, extend shelf life, and reduce dependence on preservatives through targeted reformulations. Particularly important is the synergistic relationship between water activity and pH, which together can enhance microbial protection—even in preservative-free formulations.

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References

1. Beuchat, L. 1983. Influence of water activity on growth, metabolic activities and survival of yeasts and molds. Journal of Food Protection 46(2):135-141.
2. Scott, W. 1957. Water relations of food spoilage microorganisms. Advances in Food Research 7:83-127.
3. Leistner, L. 1985. Hurdle technology applied to meat products of the shelf-stable product and intermediate- moisture food types. In Properties of Water in Foods pg. 309-329. Martinus Nijhoff Publishers, Boston, MA.

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