HYDRA CHRONIC
Berlin

Barrier Integrity Framework

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INTRODUCTION

Most formulations developed for compromised skin barriers are not assessed against the physiological conditions they are intended to address. They are evaluated for safety and stability as required by regulation, but not for physiological coherence: whether their component logic holds under the specific conditions of barrier-impaired skin.

This gap is not a regulatory failure. It is a structural absence. No systematic framework exists for evaluating whether a formulation is coherent for compromised barriers specifically, as distinct from being safe, stable, or effective in general.

The Barrier Integrity Framework was developed to provide that assessment.

THE ASSESSMENT PRINCIPLE

Physiological coherence, as defined by this Framework, is not a claim about efficacy. It is a structural judgment: whether the component logic of a formulation is internally consistent and compatible with the physiological conditions of compromised skin barriers.

A formulation is assessed against defined criteria derived from peer-reviewed dermatological and pharmaceutical literature across four dimensions. Each dimension is evaluated independently. Qualification for public recognition under this Framework requires fulfillment of all four dimensions. What does not meet this threshold receives no public recognition.

THE FOUR DIMENSIONS

Dimension 1: Barrier Architecture

Whether the formulation establishes a physiologically coherent barrier architecture. This includes the presence of structurally relevant lipids compatible with lamellar organization of the stratum corneum, a coherent strategy for transepidermal water loss control, and the absence of internal structural contradictions.

Dimension 2: pH Coherence
Whether the formulation operates within the functional pH corridor for compromised skin barriers (pH 4.5-5.0) and maintains this pH under conditions of use. pH directly regulates serine protease activity in the stratum corneum. A formulation outside this corridor actively destabilizes compromised barriers. Non-fulfillment of Dimension 2 is classified as safety-relevant, independent of all other dimensions.

Dimension 3: Membrane Compatibility
Whether the formulation is free of components that disrupt the lipid membrane structure of the stratum corneum, and whether the formulation is internally coherent at the system level. Membrane compatibility is evaluated for the formulation as a whole, not ingredient by ingredient. Non-fulfillment of Dimension 3 is classified as safety-relevant, independent of all other dimensions.

Dimension 4: Delivery Logic
Whether active components are positioned to reach their intended site of action under compromised barrier conditions, and whether the vehicle system supports rather than counteracts this positioning. Non-fulfillment of Dimension 4 indicates functional incoherence, not safety risk.

THE SIGNET SYSTEM

Formulations that meet the qualification threshold across all four dimensions are eligible for recognition under the Hydra Chronic Signet system.

The Hydra Chronic Signet is awarded to formulations that satisfy all four dimensions.

The Signet Distinction is awarded to formulations that satisfy all four dimensions and demonstrate exceptional coherence, where the component architecture reflects active barrier support rather than passive compatibility with barrier-impaired skin.

What does not meet the qualification threshold receives no public recognition.

METHODOLOGICAL LIMITS

The Framework evaluates physiological coherence from formulation composition and peer-reviewed literature. It does not conduct laboratory testing, clinical trials, or in vitro permeation studies. Assessments are based on mechanistic inference from published evidence, applied consistently across all audited formulations.

The Framework does not constitute a safety assessment, a regulatory filing, or a medical claim. It does not evaluate general cosmetic efficacy, regulatory compliance, or product safety in the sense defined by applicable cosmetic regulation. These remain the responsibility of the manufacturer. The Framework addresses a defined and bounded question: whether a formulation is physiologically coherent for compromised skin barriers.

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PRIMARY LITERATURE

The following sources constitute the core evidence base underlying the present Framework criteria. Full methodological documentation for each dimension is maintained in the internal Barrier Integrity Index methodology series.

Bouwstra, J.A. et al. (2003). Structure of the skin barrier. Advanced Drug Delivery Reviews. 55(9), 789-793.

Effendy, I. & Maibach, H.I. (1995). Surfactants and experimental irritant contact dermatitis. Contact Dermatitis. 33(4), 217-225.

Elias, P.E. & Feingold, K.R. (2001). Skin as an organ of protection. Journal of Investigative Dermatology. 116(2), 168-169.

Fluhr, J.W. & Darlenski, R. (2012). Skin surface pH: mechanism, measurement, significance. In: Textbook of Aging Skin. Springer, Berlin.

Hachem, J.P. et al. (2003). pH directly regulates epidermal permeability barrier homeostasis, and stratum corneum integrity/cohesion. Journal of Investigative Dermatology. 121(2), 345-353.

Hachem, J.P. et al. (2005). Sustained serine proteases activity by prolonged increase in pH leads to degradation of lipid processing enzymes and profound alterations of barrier function and stratum corneum integrity. Journal of Investigative Dermatology. 125(3), 510-520.

Hadgraft, J. & Lane, M.E. (2005). Skin permeation: the years of enlightenment. International Journal of Pharmaceutics. 305(1-2), 2-12.

Holleran, W.M. et al. (2006). Sphingolipids are required for mammalian epidermal barrier function. Journal of Lipid Research. 47(9), 2103-2111.

Man, M.Q. et al. (2009). Optimization of physiological lipid mixtures for barrier repair. Journal of Investigative Dermatology. 129(9), 2333-2340.

Noh, S. et al. (2015). Skin pH is the master switch of kallikrein 5-mediated skin barrier destruction in a murine atopic dermatitis model. Journal of Investigative Dermatology. 135(2), 414-422.

Rawlings, A.V. & Matts, P.J. (2005). Stratum corneum moisturization at the molecular level. Journal of Investigative Dermatology. 124(6), 1099-1110.

Schmid-Wendtner, M.H. & Korting, H.C. (2006). The pH of the skin surface and its impact on the barrier function. Skin Pharmacology and Physiology. 19(6), 296-302.

Voegeli, R. et al. (2009). Increased stratum corneum serine protease activity in acute eczematous atopic skin. British Journal of Dermatology. 161(1), 70-77.

Williams, A.C. & Barry, B.W. (2004). Penetration enhancers. Advanced Drug Delivery Reviews. 56(5), 603-618.