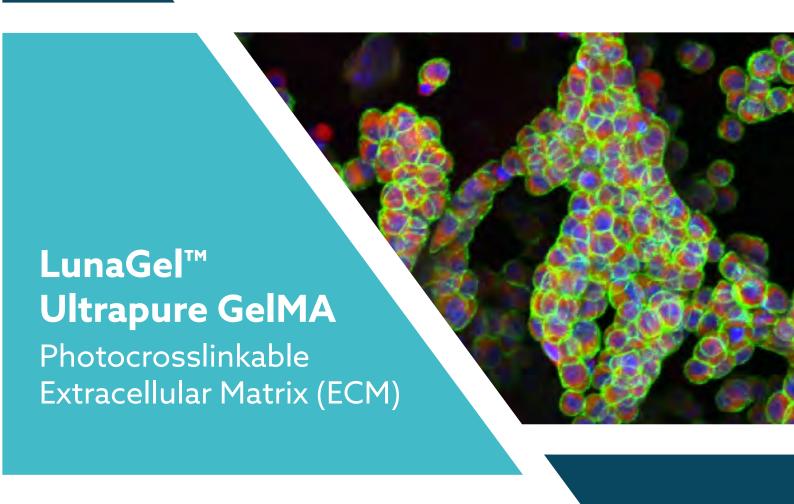


LunaGel™ Ultrapure GelMA Photocrosslinkable Extracellular Matrix (ECM)

LunaGel™ Ultrapure GelMA (gelatin methacryloyl) is a highly purified photocrosslinkable extracellular matrix (ECM) based on Rousselot X-Pure® GelMA that allows unprecedented control over matrix porosity and stiffness in 3D cell culture applications.







BACKGROUND

Gelatin methacryloyl (GelMA) has become a widely adopted biomaterial for a range of biomedical applications, including 3D cell culture, bioprinting, tissue engineering, and regenerative medicine, due to its versatility biocompatibility. However, conventional GelMA contains high levels of endotoxin and significant batch-to-batch variability, which can adversely affect cell viability, function, differentiation, and overall experimental reproducibility. LunaGel™ Ultrapure GelMA, powered by Rousselot's X-Pure® GelMA, addresses these critical issues head-on, marking a significant advancement as the world's first ready-to-use, contamination-free, visible light crosslinking-compatible GelMA innovation offers researchers an unparalleled level of consistency, purity, and ease of use, setting a new standard for precision and reliability in the field.

IMPURITIES IN CONVENTIONAL GELMA IMPACT CELL FUNCTION

GelMA is a bioink and hydrogel derived from the natural biomolecule gelatin, modified with methacryloyl groups to introduce photocrosslinkable properties. It is widely used in tissue engineering, 3D bioprinting, and regenerative medicine for creating cell-supportive matrices that mimic the extracellular matrix (ECM), promoting cell adhesion, proliferation, and differentiation. GelMA's tuneable mechanical and biochemical properties allow for the development of customized scaffolds tailored to specific tissue types and research applications, closely mimicking the physicochemical properties of natural tissues.

Despite its widespread adoption, GelMA's application and clinical translation has been hindered by challenges related to its purity and consistency. The presence of high levels of impurities (Figure 1),

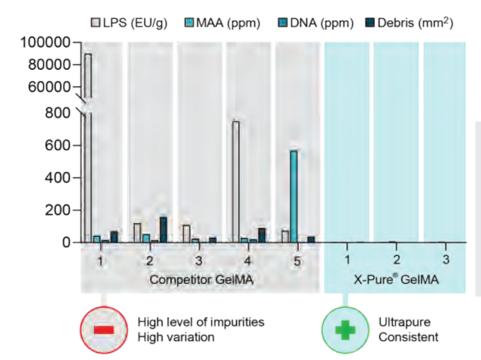


Figure 1. Rousselot's X-Pure® GelMA demonstrates consistently low levels of impurities, a quality maintained across various batches. In contrast, analysis of commercially available GelMA products reveals high and variable levels of soluble impurities such as lipopolysaccharides (LPS), methacrylic acid (MAA), and DNA, as well as insoluble debris present in all products.

including endotoxins (lipopolysaccharides), particles, nucleic acids, and cytotoxic reactants such as methacrylic acid (MAA), can significantly impact cellular behaviour, affecting viability, differentiation, and the overall integrity of the engineered tissues. Indeed, recent studies demonstrate a significant impact of endotoxin contamination on cell behaviours and drug responses in preclinical models, suggesting that such contaminants may lead to misinterpretation of both compound potency and safety¹.

The findings highlight three main points:

Influence on Metabolic Activity:
Even small amounts of endotoxin significantly reduce the metabolic activity, proliferation, and gene expression of both immune (macrophages) and cancer cells, suggesting less than optimal growth conditions.

Inflammatory Reaction:
Endotoxin contamination triggers a potent inflammatory response in immune and other cells, disrupting intra- and intercellular communication and creating undesirable and unpredictable outcomes in cellular behaviour and interaction.

3 Immunotherapy Effectiveness:
Endotoxin contamination significantly undermines the effectiveness of macrophage-based immunotherapies, affecting their therapeutic potential.



LUNAGEL™ ULTRAPURE GELMA: THE BETTER ALTERNATIVE

LunaGel™ Ultrapure GelMA is powered by Rousselot's X-Pure® GelMA, the world's first GelMA produced under GMP-ready conditions, ensuring guaranteed ultra-low impurity levels, batch-to-batch consistency, and tuneable mechanical properties – perfect for the 3D culture of sensitive cell types, preclinical animal models, and similar. Compared to conventional "home-made" or competitor GelMA, X-Pure® formulations stand out by providing highly consistent properties from batch-to-batch (Figure 2), and improved cell responses.

The low endotoxin levels of LunaGel™ Ultrapure GelMA make it one of the most versatile hydrogels available for sensitive biomedical and pharmaceutical applications, including:

- 3D bioprinting
- Tissue engineering
- 3D cell culture
- Regenerative medicine (preclinical and clinical)
- Medical devices
- Advanced therapy medicinal products (ATMP)

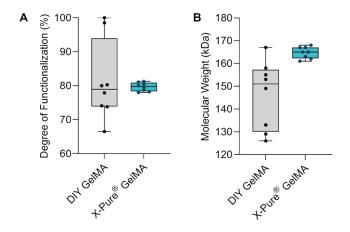


Figure 2. X-Pure® GelMA exhibits consistent degrees of functionalization from batch-to-batch and a narrow molecular weight distribution, allowing for unparalleled reproducibility and quality.

With the increasing use of 3D in vitro models for preclinical research and development, scientists must consider common contaminants found in natural biomaterials, as these can significantly impact cell behaviours and the predictive value of these cell-based models. LunaGel™ Ultrapure GelMA provides a contaminant-free, ready-to-use 3D cell culture substrate for even the most sensitive cell types and applications.

PRODUCT SPECIFICATIONS

Option	High stiffness (0 - 25 kPa), 7.5ml Low stiffness (0 - 6.5 kPa), 10 ml
Kit Contents	5 ml LunaGel™ Ultrapure GelMA ECM solution supplied as a sterile 1.5x (High stiffness) or 2x (Low stiffness) stock solution in PBS.
	5 vials of lyophilized photoinitiator, sterile.
Use	3D cell culture, organoids, immune cells, tissue engineering, bioprinting.
Formulation	Contains ECM proteins collagen type I, III, IV, and V, as well as connective tissue glycoproteins and proteoglycans. No active growth factors present.
Physical State	ECM supplied as solution
рН	6.5 - 7.5
Cell Recovery	Use LunaGel™ Cell Recovery Kit (SKU0015).
Storage	Stored at 4 - 8 °C, protected from light. Ships at ambient temperature.
Expiry	12 months from the manufacture date. Following reconstitution in buffer, store the photoinitiator solution at 4 – 8 °C protected from light, and use within 7 days.

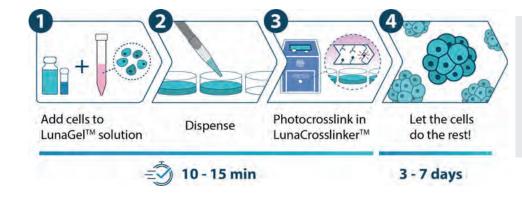


Figure 3. LunaGel™ UltraPure GelMA comes in a ready-to-use format including sterile LAP photoinitiator, enabling users to create 3D cell culture samples within just minutes.



¹ Heinrich MA, Heinrich L, Ankone MJK, Vergauwen B, Prakash J. Endotoxin contamination alters macrophage-cancer cell interaction and therapeutic efficacy in pre-clinical 3D in vitro models. Biomater Adv. 2023 Jan;144:213220. doi: 10.1016/j.bioadv.2022.213220. Epub 2022 Nov 26. PMID: 36476713.