

ROUSSELOT® X-PURE®

# LOW-ENDOTOXIN GELATINS FOR HEMOSTATICS



## HIGHLY PURIFIED AND SAFE GELATINS FOR IN-BODY HEMOSTATIC DEVICES

A new and powerful answer is available for controlling bleeding during surgery: Rousselot's X-Pure. Offering the world's lowest endotoxin levels acid porcine skin gelatin, the X-Pure range provides exceptionally safe gelatin solutions for in-body hemostatic use.

Reaching Further Together

 **Rousselot**

 **DARLING**  
INGREDIENTS

"EFFECTIVE HEMOSTATICS SAVE LIVES EVERY DAY.  
X-PURE'S LOW ENDOTOXIN LEVELS ENABLE YOU TO  
MANUFACTURE SAFE HEMOSTATIC PRODUCTS FOR  
IN-BODY APPLICATIONS."

## X-PURE: A NEW STANDARD IN HEMOSTATIC APPLICATIONS

Gelatin is widely employed in hemostats manufacturing, mainly in the form of sponges, strips, powder or (nano) fibers. In 95 % of these products, acid porcine skin gelatins are used, because of their greater stability and better foaming properties. For some purposes, lime bovine bone gelatins can also be preferred. With the X-Pure range, Rousselot offers the hemostatics market an acid porcine skin gelatin with an additional key benefit: the lowest endotoxin levels in the world.

## BLEEDING ACCOUNTS FOR 80% OF DEATHS IN SURGERY

Major trauma due to wounds leads to as many as five million deaths each year. Most of these deaths are the result of hemorrhaging during surgery. In fact, severe bleeding accounts for about 80% of deaths in the operating theatre<sup>1</sup>. This means stopping blood flow and promoting clotting are vital during surgery.

## AVOIDING EXPOSURE TO ENDOTOXINS

One of the challenges in applying hemostatic solutions is to avoid exposing the patient's body to harmful endotoxins, as these bacterial toxins can lead to immune response. This means low-endotoxin gelatins offer far greater safety in in-body applications like hemostatics.

## X-PURE, A HIGHLY PURIFIED AND EXCEPTIONALLY SAFE SOLUTION

X-Pure gelatins for hemostatics are highly purified gelling<sup>2</sup> gelatins, offering endotoxin levels that are unrivalled in the market. Check the table for details on the properties of our X-Pure range.

### References

<sup>1</sup>Gaunt T, Wolley C. Continuing Education in Anaesthesia Critical Care & Pain, Volume 14, Issue 6, 1 December 2014, Pages 251–255, doi.org/10.1093/bjaceaccp/mkt065

<sup>2</sup>Gelling gelatins according to EP/USP

<sup>3</sup>These levels are determined by means of the Charles River LAL (Limulus Amebocyte Lysate) assay, an FDA compliant method



## KEY BENEFITS OF ROUSSELOT® X-PURE® :

X-Pure offers numerous benefits over alternative hemostatic agents.

- Endotoxin levels<sup>3</sup> below 20 Endotoxin Units per gram (EU/g) or even below LAL analysis detection limits if required
- The world's lowest levels for acid porcine skin gelatin, along with the outstanding foaming properties you can expect from this specific gelatin
- Excellent absorption capacity: gelatin absorbs at least 40 times its own weight of blood and can expand by 200%
- Biocompatible and biodegradable
- Gelatin-based products are fast acting, and non-antigenic
- Easily grindable for syringe application, for instance, if you want to combine gelatin with thrombin
- Suitable for both human and veterinary hemostatic applications
- Gelatin is Generally Recognized As Safe (GRAS) by the USA's Food and Drug Administration (FDA) and compliant with the US, European and Japanese pharmacopeia.

Type	Endotoxin level (EU/g)	Targeted gel strength* (g)
X-Pure® 20 P	≤20	300 - 400
X-Pure® 10 P	≤10	300 - 400
X-Pure® 20 B	≤20	240 - 360
X-Pure® 10 B	≤10	240 - 360

\*Measured at 6.67%, 10°C.

For more information and/or an experimental sample of X-Pure®, please contact us at:

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