Octapharma Customer Letter_ Octaplasma® Guidance on Product Handling

Date of Issue: April 30, 2025

Subject: Guidance on Thawing and Handling of Octaplasma® (Solvent/Detergent-Treated Plasma) – Study Findings and Practice Recommendations

Dear Health Care Professional,

Octapharma Canada is committed to continuous quality improvement and advancing evidence-based best practices for the safe and effective use of our plasma-derived products. In response to valuable feedback from several hospital transfusion services, we initiated a study to address key operational questions regarding **Octaplasma®**, our solvent/detergent (S/D) treated, pathogen-inactivated plasma.

Why This Study Was Conducted

Octaplasma® is typically thawed at 37°C for up to 30 minutes and, if unused, can be refrigerated for up to five days per the Product Monograph. However, some hospital partners reported two practical challenges:

1. **Desire to reduce thawing time** to match the more rapid thaw of frozen plasma, particularly in trauma and emergency situations.
2. **Appearance of particulate matter** in refrigerated plasma bags starting from day two post-thaw, raising concerns about product quality and usability.

To explore these concerns, we launched a targeted investigation to optimize product handling, reduce unnecessary waste, and support institutions in maintaining high transfusion standards without compromising safety.

Summary of Key Findings

Thawing Time

Octaplasma® was observed to **fully thaw in 20–26 minutes** using either a standard water bath or dry tempering system. Water baths provided faster and more consistent thawing times compared to dry systems, bringing S/D plasma thaw performance closer to that of frozen plasma.

Post-Thaw Storage and Particulate Formation

Particulate matter was detected in a subset of bags stored under refrigeration after 48 hours. Gel electrophoresis confirmed that the **precipitate was proteinaceous in nature** and appeared due to cold-induced precipitation. Importantly, the **particulate matter was found to be re-solubilized** with re-warming to 37°C, as recommended in the Product Monograph.

Re-warming and Coagulation Integrity

Octaplasma® bags exhibiting particulates were re-warmed and **subjected to a full coagulation panel testing** including PT, INR, aPTT, Fibrinogen, FVIII, vWF:Ag and vWF:Ac, and Protein S (free

antigen). All results demonstrated normal hemostatic profiles, **confirming the clinical integrity of re-warmed** product.

Practical Implications for Clinical Use

- **Faster thawing** can be achieved with current methods while remaining within approved guidelines.
- **Precipitates are reversible** with re-warming and do not impair product safety or function.
- **Visual inspection should occur after re-warming to 37°C** to ensure precipitates are re-solubilized before infusion.
- **Product wastage can be reduced**, especially in emergency preparedness scenarios that require pre-thawed plasma.

Although the results are not yet sufficient to warrant changes to the product monograph, they offer **strong practical guidance** for institutions that pre-thaw plasma or require rapid product turnaround.

Supporting Tools for Laboratory Practice

To further assist transfusion service teams in applying these findings, Octapharma Canada has developed a **Discard Decision Tree**, included with this communication. This job aid is designed as a **practical tool** to guide blood bank technologists and laboratory staff through standardized decision-making when assessing thawed Octaplasma® prior to use. *See Appendix 1*.

The tool visually summarizes:

- Appropriate steps for **visual inspection** of refrigerated, thawed Octaplasma®
- **Rewarming procedures** before any discard decisions are made
- Conditions under which **precipitate-containing units** may still be safely reconstituted and used

By incorporating this guidance into standard operating procedures (SOPs), hospital teams can enhance consistency, **reduce unnecessary discards**, and **improve response readiness**, particularly during trauma or emergency transfusions. *See Appendix 2*.

We encourage your teams to post the Discard Decision Tree in relevant lab areas and include it in **staff training and orientation materials** related to plasma handling.

Octapharma remains committed to supporting your practice change initiatives and can provide additional printed copies, orientation slide decks, or Q&A sessions with Medical Affairs upon request.

Reaffirming the Clinical Value of Octaplasma®

We would also like to take this opportunity to reaffirm the **clinical advantages of Octaplasma®**, beyond its convenience of use:

- **Pathogen Inactivation**: Offers enhanced viral safety through solvent/detergent treatment.

- **Reduced TRALI Risk**: Prepared exclusively from male donors and pooled to ensure uniformity, Octaplasma® significantly lowers the risk of **transfusion-related acute lung injury (TRALI)**.
- **Lower TACO Incidence**: Its standardized volume and composition support a **lower incidence of transfusion-associated circulatory overload (TACO)** compared to variable-volume frozen plasma.

These safety enhancements contribute to improved patient outcomes and represent significant progress in modern transfusion medicine.

Next Steps

We encourage hospitals to **incorporate these findings** into their local transfusion protocols, especially for emergency departments, trauma teams, and massive transfusion pathways. Octapharma Canada is available to support you with:

- Staff training sessions
- Protocol updates and SOP revisions
- Practical guides for handling thawed Octaplasma®

If you have any questions or require implementation support, please contact our Medical Information team at **medinfo.canada@octapharma.com**

We thank you for your ongoing collaboration and shared commitment to delivering the highest standard of care to Canadian patients.

Sincerely,

Dimpy Modi
Medical Affairs Associate
On behalf of Octapharma Canada Inc.

Appendix 1: Standard Operating Procedure for Transfusion Teams

Octaplasma® Discard Decision Tree (PDF Attached, this will be available to customers in the form of a hyperlink).

Appendix 1:

Standard Operating Procedure for Transfusion Teams *Handling Octaplasma®*

Title: Visual Inspection and Handling of Thawed and Refrigerated Octaplasma®
Applicable To: Transfusion Services / Blood Bank Technologists
Effective Date: May 2025
Version: 1.0

Purpose

To provide standardized procedures for the visual inspection, handling, and discard decisions related to **thawed** and **refrigerated** Octaplasma® (S/D plasma) units, based on recent clinical guidance and product stability data.

Scope

This procedure applies to all staff involved in the thawing, storage, and preparation of Octaplasma® for patient use in transfusion services.

Background

Octaplasma® is a pathogen-inactivated, solvent/detergent-treated plasma product with improved viral safety and reduced risks of **TRALI** and **TACO**. Recent post-thaw handling studies indicate that particulate matter may form in refrigerated plasma, which is resolubilized upon rewarming. This SOP ensures correct interpretation and decision-making regarding visual inspection and discard criteria.

Procedure

For Frozen Octaplasma®

1. Thaw Octaplasma® using a validated method for 20-26 minutes (or until complete thaw is achieved).
2. Conduct visual inspection of the Octaplasma®.
3. If the unit fails to reach clarity, shows signs of contamination or denatured proteins, discard per institutional biohazard policy.

For Refrigerated Octaplasma® (2–8°C, up to 5 days post-thaw):

1. Conduct visual inspection:
    - Slight reversible protein precipitation may be present, this can be resolubilized by rewarming the bag **to 37°C** for up to 10 minutes.
    - If particulate matter dissolves after warming, the product is acceptable for use
    - If insoluble matter persists, the product should be **discarded.**

2. Record disposition in the blood product management log.

Decision Tools

Refer to:

- **Frozen Octaplasma® Discard Decision Tree**
- **Refrigerated Octaplasma® Discard Decision Tree**

Post these aids in the blood bank and include in staff onboarding and training.

Documentation

- Record all visual inspections and outcomes in transfusion tracking system
- Log all discards with reason and time

Training

All staff must review this SOP and receive hands-on training with the updated decision tools. Octapharma Medical Affairs can assist with customized sessions and materials.