

2 February 2017

Dear Health Care Professional,

RE: Octaplasma® thawing instructions and information

This advisory letter is being provided by Octapharma to improve the thawing experience of Octaplasma® (Solvent Detergent (S/D) Treated Human Plasma).

This is in response to recent reports regarding visible fibrin threads and clumping observed in the Octaplasma® bag during thawing. These fibrin threads may be visible as the bag thaws, especially while it still contains an “ice block” of frozen plasma. These flakes should disappear as the plasma warms. We recognize that thawing procedures may vary from site to site and it is recommended to ensure the bag is fully thawed and no visible threads should be present prior to infusion.

A recent publication (Heger et al.) investigated and validated the thawing process for Octaplasma® (also referred to as Octaplas® and OctaplasLG globally) using different devices available on the market.^{1,2}

Table 1: Thawing recommendations for Octaplasma® using different thawing devices ^{1,2}

Thawing device	Maximal thawing capacity	Recommended thawing conditions for Octaplasma®*
“classical” water bath (MB-13A, Julabo)	n.s.	30 min at 37 °C (for 1-4 bags) or up to 60 min (for >4 bags)
Water bath systems (DH4 QuickThaw®)	4 bags	25 min at 37 °C
Dry tempering systems (Plasmatherm)	4 bags	30 min at 37 °C (for single bags) or 45 min at 37 °C for up to 4 bags Recommendation: 1 to max. 2 Octaplasma® bags
Dry tempering systems (SAHARA-III)	3 bags	40 min (fast tempering program)
Microwave oven (transfusio-therm® 2000)	3 bags	5-10 min (set temperature of 30 °C)

*All Octaplasma® bags should be thawed in the delivered secondary outer wrapper; n.s., not specified

The study concludes that Octaplasma® can be thawed using all tested devices without any negative influence on the plasma quality, presupposed that optimized settings defined for this plasma product are used.

All Octaplasma® bags thawed by different devices and optimized thawing conditions (acc. to Table 1) were clear and free of solid and gelatinous particles, indicating no protein denaturation or overheating. Thawing up to 60 min at +37 °C had no impact on the plasma quality. There were no significant differences observed

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in global coagulation parameters, coagulation factors, protease inhibitors and markers of activated coagulation. All parameters remained within both normal plasma range and product specifications.^{1,2}

Based on the results from Heger et al., updates have been made to the Canadian product monograph:³

- 1) Octaplasma® thawing can be done in the outer wrapper for **not less than 30 minutes** in a circulating water bath at +30°C to +37°C. The minimum thawing time is 30 minutes at 37°C. The thawing time depends on the number of bags in the water bath. If more plasma bags are thawed in parallel, the thawing time can be prolonged, but **should not be longer than 60 minutes**.³
- 2) Using a dry tempering system such as the SAHARA-III, place the Octaplasma® bags on the agitation plate according to the manufacturer instructions and thaw plasma using the fast tempering function. When a +37°C blood component temperature is indicated on the temperature display, terminate the tempering process and remove the bags.³

Octapharma does not recommend the use of its products in any manner other than those described in each product's complete prescribing information. Please refer to the Octaplasma® Package Insert for approved indications and uses, as well as pertinent prescribing information. Should you have any questions regarding this information, or any other questions relating to Octaplasma®, please do not hesitate to contact us via email: medinfo@octapharma.ca or by calling us at 1-888-438-0488.

Kind regards,



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References:

1. A. Heger et al. Poster Presentation. ECTH Congress, Hague Netherlands. 28 – 30 September 2016
2. A. Heger et al. Poster presentation ISBT Congress, Dubai, United Arab Emirates. September 3 - 8, 2016
3. OCTAPLASMA® Canadian product Monograph, Date of Approval: January 16, 2017