GUIDELINES FOR THE USE OF SOLVENT DETERGENT TREATED PLASMA
1.0 Policy Statement

1.1 Each facility shall develop and maintain written policies and standard operating procedures to ensure that blood products are transfused for the clinically appropriate conditions and are used according to manufacturer’s instructions.

   1.1.1 Each facility shall have policies and procedures for:
   - The transfusion and administration of blood products and the generation and maintenance of transfusion records.
   - The operation of infusion devices and associated equipment.

1.2 An informed consent policy shall be established to ensure recipients are properly informed before receiving blood components and blood products. The recipient shall receive information that includes a description of blood components or blood products, the associated risks and benefits as well as alternatives to transfusion if appropriate. The policy shall identify the process of obtaining recipient informed consent including the opportunity to ask questions and obtain satisfactory answers. All recipients shall be notified in writing that they have received blood components and blood products.

2.0 Definitions

2.1 Solvent Detergent Treated Plasma (S/D Plasma): available in Canada as OCTAPLASMA™, is a human derived plasma product which is treated by virus inactivated solvent detergent.

2.2 Frozen plasma (FP): interpreted as any plasma product, e.g.: Apheresis Fresh Frozen Plasma (FFPA), Frozen Plasma (FP), Cryosupernatant Plasma, and Cryoprecipitate.

2.3 National Advisory Committee (NAC): is an interprovincial medical and technical advisory body to the provincial and territorial health ministries and the blood supplier Canadian Blood Services (CBS). Its mandate is to provide professional leadership in assisting in identifying, designing and implementing cost-effective blood utilization management initiatives for the optimization of patient care throughout Canada. The NAC has developed a framework for the appropriate use and distribution of solvent detergent treated plasma in Canada based on the recommendations of the Canadian Agency for Drugs and Technologies in Health (CADTH) Report.
2.4 **Blood Product**: therapeutic product derived from human plasma and produced by a manufacturing process.

2.5 **Transfusion Medicine Laboratory**: Hospital Blood Bank

### 3.0 General Information

#### 3.1 Background:

3.1.1 S/D Plasma is restricted to the treatment of specific patients who require a high volume of transfusions annually because they have congenital or acquired thrombotic thrombocytopenic purpura (TTP) or, hemolytic uremic syndrome (HUS) with associated factor H deficiency or, clotting factor deficiencies for which specific licensed concentrates may not be readily available and who have experienced an allergic reaction to frozen plasma or have a pre-existing lung disorder or need frozen plasma but a blood group compatible product is not available in a timely manner.

3.1.2 Each 200 ml of OCTAPLASMA™ contains human plasma proteins (9.0-14.0 g), Sodium Citrate Dehydrate (0.88-1.48 g), Sodium Dihydrogenphosphate Dehydrate (0.06-0.24 g), Glycine (0.80-1.20 g), TNBP (< 2.0 mcg/ml), Octoxynol (< 5.0 mcg/ml).

3.1.3 When stored at ≤ -18°C the shelf life of OCTAPLASMA™ is 48 months.

3.1.4 Solvent detergent treatment inactivates enveloped viruses such as HIV, HBV and HCV but is not effective against non-enveloped viruses.

#### 3.2 The National Advisory Committee on Blood and Blood Products released a framework for appropriate use and distribution of solvent detergent treated plasma (S/D Plasma) in May 2012 [www.nacblood.ca](http://www.nacblood.ca). The recommendations within this framework should be followed as indicated.

#### 3.3 Distribution of Solvent Detergent Treated Plasma:

3.3.1 Canadian Blood Services (CBS) is the distributor of the S/D Plasma and will maintain a small inventory at the CBS site in St. John’s, NL. Hospitals may obtain S/D Plasma from CBS by completing the CBS
Guidelines for the Use of Solvent Detergent Treated Plasma

Solvent Detergent Plasma Request Form (SDPRF) F800052 (the form is available at [www.blood.ca](http://www.blood.ca)) or by communicating the request verbally to the CBS Medical Director (contact numbers are available at [www.blood.ca](http://www.blood.ca)).

3.3.2 Physician requests for S/D Plasma are made through the Transfusion Medicine Laboratory.

3.3.3 CBS issues S/D Plasma to requesting Transfusion Medicine Laboratories provided the product request is in accordance with provincial recommendations for use and approved by the Canadian Blood Services Medical Director.

3.3.4 Blood products must be transported in accordance with the environmental and handling conditions specified in the manufacturer’s instructions.

3.3.5 Collaboration between facilities must occur prior to transferring blood products. Notification must be given to the receiving facility that inventory will be transferred.

3.3.6 Hospitals are required to document and report the final disposition of all S/D Plasma units to Canadian Blood Services. Hospital Solvent Detergent Plasma Disposition Report forms are to be completed monthly and emailed to sdplasmadisposition@blood.ca.

3.3.7 S/D Plasma resource information can be obtained from the Provincial Blood Coordinating Program website for education for physicians, nurses and laboratory personnel. [http://www.health.gov.nl.ca/health/bloodservices/index.html](http://www.health.gov.nl.ca/health/bloodservices/index.html)

3.3.8 The full product monograph for OCTAPLASMA™ can be found at [www.octapharma.com](http://www.octapharma.com) or can be obtained by contacting Octapharma Canada Inc. at 1-888-438-0488.

3.3.9 Patient name, health care number, diagnosis of patient and requesting physician name and date must be provided to the Transfusion Medicine Laboratory for release of S/D Plasma. The lot number of the product must be recorded on the request form.
3.3.10 OCTAPLASMA™ is available in 200 ml bags. The total human plasma protein concentration is 45-70 mg/ml.

4.0 Indications, Dosing, Administration and Monitoring

4.1 Indications:
4.1.1 Recommended for:
4.1.1.1 Specific patients who require a high volume of transfusions annually because they have congenital or acquired thrombotic thrombocytopenic purpura (TTP) or, hemolytic uremic syndrome (HUS) with associated factor H deficiency or clotting factor deficiencies for which specific licensed concentrates may not be available and who have experienced an allergic reaction to frozen plasma or who have a pre-existing lung disorder or who need frozen plasma but a group compatible product is not available in a timely manner.

4.1.2 Contraindicated in patients with:
4.1.2.1 IgA deficiency with documented antibodies against IgA.
4.1.2.2 Severe deficiencies of protein S.
4.1.2.3 Relative contraindications in patients with plasma protein allergies, previous reaction to FFP or OCTAPLASMA™, pulmonary edema and/or manifest or latent cardiac decompensation.
4.1.2.4 Relative contraindications in patients who are hypersensitive to any of the ingredients in OCTAPLASMA™.

4.1.3 Not recommended for:
4.1.3.1 Patients with IgA deficiency.
4.1.3.2 Patients who have severe deficiencies of protein S
4.1.3.3 Patients who have had a previous reaction to OCTAPLASMA™ (It should be used cautiously in patients who have had a previous reaction to frozen plasma).
4.1.3.4 Patients who have fluid in the lungs or cardiac failure.

4.1.4 Special patient populations:
4.1.4.1 Pregnant and lactating women – the safety of OCTAPLASMA™ use in this patient population has not been
established. OCTAPLASMA™ should only be used during pregnancy and lactation if the benefit outweighs the potential risk.

4.1.4.2 **Pediatric patients** – there is insufficient evidence available to allow a recommendation for use of this product in this patient population. OCTAPLASMA™ should only be administered in pediatrics if the benefit outweighs the potential risk.

4.2 **Dosing in Adults:**

4.2.1 Dosing of S/D Plasma depends upon the individual patient’s clinical situation and underlying disorder and should be in adherence with existing facility transfusion policies.

4.2.2 The manufacturer recommends:
- 12-15 mls/kg body weight as a starting dose.
- 5-20 mls/kg body weight to achieve an adequate haemostatic effect in minor and moderate hemorrhages.
- Expert advice of a hematologist in the event of major hemorrhage or surgery.

4.3 **Administration:**

4.3.1 OCTAPLASMA™ must be administered intravenously via an infusion set with a filter.

4.3.2 The manufacturer recommends the infusion rate should not exceed 1 ml/kg body weight/min.

4.3.3 S/D Plasma must be ABO group compatible and administered intravenously with a filter infusion set.

4.3.4 OCTAPLASMA™ should be administered under the supervision of qualified health professionals experienced in the use of anticoagulation agents and the management of coagulation disorders.

4.4 **Monitoring:**

4.4.1 Hospitals will be required to **report the disposition of S/D Plasma to Canadian Blood services**. Monitoring of S/D Plasma is necessary to ensure appropriateness of use and mitigate potential escalating costs.
4.4.2 The patient’s coagulation factor levels should be monitored with the measurement of prothrombin time (PT), partial thromboplastin time (PTT) and/or specific coagulation factor assays.

4.4.3 All adverse transfusion events must be reported as per facility policy. 
4.4.3.1 Signs and symptoms of a transfusion reaction may include but are not limited to hypervolemia, pulmonary edema, cardiac failure, nausea and vomiting, fatigue, tremor, hypocalcemia, rash, pruritus, chills and hemolytic reactions.

5.0 Records Management

5.1 The recipient transfusion data file in the Transfusion Medicine laboratory shall be retained indefinitely.

5.2 All transfusion records in the recipient’s medical chart shall be retained in accordance with health care facility’s policy.

5.3 For each blood product issued, a record system shall be in place which documents:
    5.3.1 Recipient’s name and identification number
    5.3.2 Blood product name and manufacturer
    5.3.3 Lot number
    5.3.4 Volume and/or potency
    5.3.5 Dosage/vials issued
    5.3.6 Visual inspection
    5.3.7 Date and time of issue
    5.3.8 Identity of the person issuing the blood product
    5.3.9 Identity of the person transporting the blood product to the recipient’s location.

5.4 Records for all facilities shall ensure that it is possible for blood products to be traced from its source to final disposition (i.e. transfusion). The record system must provide a means to locate and access all records related to a given blood product. These records must be kept indefinitely. The Transfusion Medicine Laboratory shall develop and maintain records that demonstrate that the quality system is operating in an effective manner.
6.0 References

6.1 Canadian Agency for Drugs and Technologies in Health (CADTH). CADTH optimal use report; Optimal therapy recommendation for the use of solvent/detergent-treated human plasma. Canada: CADTH; May 2011.


