

WP 4, deliverable 4.1 | Release 00.1, 13/04/2026

Deliverable 4.1

Updated Substances of Human Origin (SoHO) list of existing Preparation Processes (PPs)

Date of submission	13/04/2026
Work Package	4
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Dissemination level	Sensitive



**Co-funded by
the European Union**

GAPP-PRO, Piloting GAPP model approach for assessing and authorizing novel substances of human origin preparation PROCess, is a Joint Action co-funded by the Health Programme of the European Union. Grant Agreement 101128035 – EU4H-2022-JA-07, February 2024 – June 2027. Funded by the European Union.

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Introduction

The present report elucidates the list of Substances of Human Origin (SoHO) preparations.

The findings are based on the data analysis of the survey responses from Competent Authorities across different countries to questionnaires prepared within the framework of Work Package (WP4) and extracted from the survey report Deliverable 4.3.

Table 1 lists the abbreviations, and Table 2 and 3 present the lists of SoHO preparations, divided per authorised and ongoing.

Table 1. List of abbreviations used in Table 2 and Table 3

Abbreviations Used	
Acellular dermal matrix	ADM
anterior lamellar keratoplasty {donor tissue for anterior lamellar keratoplasty	ALK/DALK
Bowman Layer	BL
Chimeric Antigen Receptor T-cell	CART
Cluster of Differentiation marker	CD
Corneal Allogeneic Intrastromal Ring Segments	CAIRS
Descemet membrane endothelial keratoplasty	DMEK
Descemet stripping automated endothelial keratoplasty	DSAEK
penetrating keratoplasty	PK
Hematopoietic Progenitor Cell	HPC
Mononuclear Cell	MNC
T-cell Receptor T-cell	TCRT-T

List of Substances of Human Origin (SoHO)

The following charts provide 2 lists of SoHO preparation processes (PPs). Table 2 lists the already authorised PPs, whereas table 3 is related to the ongoing PPs. The SoHO preparations marked with an asterisk (*) are those not included in the EDQM Guidelines for Blood, Tissues and Cells. On the other hand, some SoHO, although there is no monograph, are included in the EDQM Guidelines: testicular tissue, lymphocyte.

Table 2. List of Authorised Preparation Processes per Substances of Human Origin (SoHO)

Blood and blood-derived cells		
Whole blood	Whole blood	
	Whole blood, leucocyte-depleted	
	Other:	Whole Blood, Leucocyte-Depleted for Exchange Transfusion Whole Blood, Leucocyte-Depleted, Plasma-Reduced for Exchange Transfusion
Red cells	Red cells	
	Red cells, buffy coat removed	
	Red cells, in an additive solution	
	Red cells, buffy coat removed, in an additive solution	
	Red cells, irradiated	
	Red cells, leucocyte-depleted	
	Red cells, leucocyte-depleted, in additive solution	
	Red cells, apheresis	
	Red cells, washed	
	Red cells, cryopreserved	

	Red cells, other	Red cells, apheresis, irradiated
		Red cells, washed, irradiated
		Red cells, cryopreserved, irradiated
		Red cells, leucocyte depleted, in additive solution, cryopreserved
		red cells, biotinylated
		Red cells, leucocyte depleted, in additive solution, washed,
		Red cells, apheresis, leucocyte depleted, in additive solution,
		Red cells, leucocyte-depleted, in additive solution, irradiated
		Red Cells, Leucocyte-Depleted, Suspended in Fresh Frozen Plasma for Exchange Transfusion
Platelets	Platelets, recovered, single unit	
	Platelets, recovered, single unit, leucocyte-depleted	
	Platelets, recovered, pooled	
	Platelets, recovered, pooled, leucocyte-depleted	
	Platelets, recovered, pooled, in additive solution	
	Platelets, recovered, pooled, leucocyte-depleted, in additive solution	
	Platelets, pooled, pathogen-reduced	
	Platelets, apheresis	
	Platelets, apheresis, leucocyte-depleted	
	Platelets, apheresis, leucocyte-depleted, in additive solution	
	Platelets, pathogen-reduced	
	Platelets, cryopreserved	
	Platelets, apheresis, in additive solution	

	Platelets, other	Platelets, recovered, pooled, leucocyte-depleted, in additive solution, pathogen reduced, washed
		Platelets, apheresis, leucocyte-depleted, in additive solution, pathogen reduced, washed
		Platelets, recovered, pooled, leucocyte-depleted, in additive solution, washed
		Platelets, apheresis, leucocyte-depleted, in additive solution, washed
		Platelets, recovered, pooled, leucocyte-depleted, in additive solution, irradiated
		Platelets, apheresis, leucocyte-depleted, in additive solution, irradiated
		Platelets, irradiated
Plasma and Cryoprecipitate	Plasma, fresh frozen	
	Plasma, fresh frozen, pathogen reduced	
	Cryoprecipitate	
	Cryoprecipitate, pathogen reduced	
	Plasma, fresh frozen, cryoprecipitate-depleted	
	Dried plasma	
	Other	Plasma, fresh, non-frozen
Granulocytes	Granulocytes, apheresis	
	Granulocytes, pooled	
Haematopoietic progenitor cells	Bone marrow stem cells Autologous	Volume reduction for products with a large amount of volume
		Cryopreservation of the above-mentioned processed products (for further processing for ATMP)
	Bone marrow stem cells Allogeneic	Plasma reduction for minor blood incompatibility
		Volume reduction for products with a large amount of volume
		CD3/ CD19-depletion for stem cell transplantation

		Cryopreservation of the above-mentioned processed products (for further processing for ATMP)
		Density gradient when major or bidirectional blood group incompatibility
		Cryopreservation as a starting product for further processing for MSC cultivation
		Cryopreservation of the above-mentioned processed products
	Peripheral blood stem cells Autologous	Volume reduction for products with a large amount of volume
		CD34 selection when autologous autoimmune indications
		Cryopreservation of the above-mentioned processed products (for further processing for ATMP)
	Peripheral blood stem cells Allogeneic	Volume reduction for products with a large amount of volume
		CD34 selection when graft failure in an Allogeneic recipient
		A(beta) TCR/CD19-depletion for stem cell transplantation
		CD3/ CD19-depletion for stem cell transplantation
		Cryopreservation of the above-mentioned processed products (for further processing for ATMP)
	Allogeneic HPC products (cord blood)	Density gradient when major or bidirectional blood group incompatibility
		Cryopreservation as a starting product for further processing for MSC cultivation
		Cryopreservation of the above-mentioned processed products
	Allogeneic MNC/HPC products for DLI	Plasma reduction for minor blood incompatibility
		Volume reduction for products with a large amount of volume
		Cryopreservation of the above-mentioned processed products
	Allogeneic and autologous MNC products	CD3 or CD4/8 selection for CAR-T of TCR-T products for ATMP, followed by cryopreservation for further processing
	Autologous cartilage	Processing up to cell suspension (and merged with MSC in tissue glue) for defects of cartilage in the knee

Umbilical cord blood progenitors	Haematopoietic progenitor cells		
Tissue/cell components			
Adipose	Adipose tissue		
Cardiovascular	Cardiovascular, valve. Cryopreserved aortic/pulmonary heart valve allograft		
	Cardiovascular, valve. Decellularized aortic/pulmonary heart valve allograft		
	Cardiovascular, valve. Cryopreserved pericardium		
	Vascular tissue. Cryopreserved artery/vein		
	Vascular tissue. Decellularized pulmonary artery/vein		
Amniotic membrane	Amniotic membrane sheet		
	Derivatives of the amniotic membrane		
Musculoskeletal	Musculoskeletal, bone. Frozen bone		
	Musculoskeletal, bone. Dehydrated/Freeze-dried bone		
	Musculoskeletal, bone. Demineralized bone		
	Musculoskeletal, cartilage. Frozen meniscus		
	Musculoskeletal, cartilage. Osteochondral allograft		
	Musculoskeletal, tendon. Tendons with bone		
	Musculoskeletal, tendon. Tendons without bone		
	Other	Cranial flap of human origin for autologous use	
		Tympano-ossicular tissues and bone flaps	
		cryopreserved meniscus	
		frozen cartilage	
		Autologous bone (skull bone flap)	
		DBM (demineralized bone matrix)	

		Osteochondral autograft
Neuronal	Other	Peripheral nerve regeneration guides from the umbilical cord vessels
Ocular	Ocular, corneal. Organ-cultured corneal donor tissue for anterior lamellar keratoplasty (ALK/DALK)	
	Ocular, corneal. Cold-stored corneal tissue for anterior lamellar keratoplasty (ALK/DALK)	
	Ocular, corneal. Organ-cultured corneal tissue for Descemet membrane endothelial keratoplasty (DMEK)	
	Ocular, corneal. Cold-stored corneal tissue for Descemet membrane endothelial keratoplasty (DMEK)	
	Ocular, corneal. Organ-cultured corneal tissue for Descemet stripping automated endothelial keratoplasty (DSAEK)	
	Ocular, corneal. Cold-stored corneal tissue for Descemet stripping automated endothelial keratoplasty (DSAEK)	
	Ocular, corneal Organ-cultured corneal tissue for penetrating keratoplasty (PK)	
	Ocular, corneal. Cold-stored corneal tissue for penetrating keratoplasty (PK)	
	Ocular, corneal. Organ-cultured corneal tissue for tectonic purposes	
	Ocular, corneal. Cold-stored corneal tissue for tectonic purposes	
	Ocular, corneal. Cryopreserved cornea for tectonic purposes	
	Ocular, sclera	
Other Mature cells	Other	Limbal stem cells
Pancreatic islets	Pancreatic islets	
Reproductive	Ovarian tissues	
	Reproductive cells and embryos. Sperm	
	Reproductive cells and embryos. Oocytes	
	Reproductive cells and embryos. Embryos	
Skin	Acellular dermal matrix (ADM)	

	Skin. Deep-frozen skin allograft	
	Skin Glycerol-preserved skin allograft	
	Skin. Cryopreserved skin allograft	
	Other	Acellular dermis graft packaged in pouches and in sterile water (ready to use)
		Cold-stored skin (2-8°C)
		Autologous fibroblasts and chondrocytes
Other, Not covered above		
Donor Human Milk		
Intestinal microbiota or faecal microbiota		
Testicular stem cells		

Table 3. List of Ongoing Preparation Processes per Substances of Human Origin (SoHO)

Blood and blood- derived cells		
Red cells	other	Red cells, leucocyte-depleted, irradiated (only for particular indications)
		Red cells, plasma diluted
		Red cells, washed, leucocyte-depleted, irradiated
		Red cells, frozen-thawed-washed, leucocyte-depleted, irradiated
		Red cells, frozen-thawed-washed, plasma diluted, leucocyte-reduced for exchange transfusion
		Red cells, leucocyte-depleted from whole blood
		Red cells, leucocyte-depleted for intrauterine transfusion
		Red cells for neonatal and infant small-volume transfusion
Platelets	Other	Platelets, apheresis, leucocyte-depleted, path-reduced
		platelets, recovered, pooled, leucocyte-depleted, path-reduced
		Platelet, apheresis, leucocyte-depleted, irradiated, Irradiated 1.3. product
		Platelets, washed
		Platelets, pooled, irradiated
		Platelets, leucocyte-reduced, irradiated
		Platelets, apheresis, irradiated
		Platelets, reduced volume for neonatal and infant small-volume transfusion
Plasma and Cryoprecipitate	Other	Plasma, fresh frozen, irradiated
		Plasma, fresh frozen, pathogen reduced, Irradiated

		Cryoprecipitate, irradiated	
		Cryoprecipitate, pathogen-reduced, irradiated	
		Plasma, fresh frozen, cryoprecipitate-depleted, Irradiated	
		Dried plasma, irradiated	
		Plasma, recovered, pooled, leucocyte-depleted, fresh frozen, secured by quarantine (1.4a),	
		Plasma, apheresis, leucocyte-depleted, fresh frozen, secured by quarantine (1.4a),	
		Plasma, recovered, pooled, leucocyte-depleted, fresh frozen, pathogen reduced (1.4b),	
		Plasma, apheresis, leucocyte-depleted, fresh frozen, pathogen reduced (1.4b)	
		Plasma, from donors lacking IgA to patients with an allergic reaction to IgA	
		Plasma reduced volume for neonatal and infant small volume transfusion	
Peripheral blood mononuclear cells	Donor lymphocyte infusion (DLI)*		
	Mononuclear cells*		
	Other	T cells	
		Peripheral blood mononuclear cells for cell therapy	
Tissue / cell components			
Adipose	Adipose cells (isolated from the adipose tissue)*		
	Other	Bone marrow mononuclear cells	
Cardiovascular	Vascular tissue. Fresh vessels		
	Cardiac muscle		
	Cardiac cells		
	Other	Cold-stored artery/vein allograft (2-8°C),	

		Dehydrated or freeze-dried umbilical vessels
		Decellularized pericardium
Other Membrane	Membrane, dura mater	
	Membrane, fascia lata*	
	Membrane, pericardium	
	Other	Eye drops obtained from the amniotic membrane
		Membrane, fascia rectus
Musculoskeletal	Musculoskeletal, cartilage. Fresh Cartilage*	
	Musculoskeletal, ligament	
Neuronal	Neuronal, nerve*	
Ocular	Ocular, conjunctival	
	Other	Organ-cultured corneal tissue for Hemi-DMEK, quarter DMEK, mini DMEK
		Cold-stored corneal tissue for Hemi-DMEK, quarter DMEK, mini DMEK
		Organ-cultured corneal tissue for Bowman Layer transplantation (BL)
		Cold-stored corneal tissue for Bowman Layer transplantation (BL)
		Organ-cultured corneal tissue for Corneal Allogeneic Intrastromal Ring Segments (CAIRS)
		Cold-stored corneal tissue for Corneal Allogeneic Intrastromal Ring Segments (CAIRS)
Other Mature cells	Mature cells, hepatocytes	
	Mature cells, keratinocytes	
	Other	Hepatic stem cells, hepatocytes, hepatocyte tissues
Pancreatic islets	Pancreatic islet cells	
Parathyroid	Parathyroid	
Reproductive	Testicular tissues*	

Skin	Skin. Fresh skin allograft	
	Skin. Lyophilized skin allograft	
	Other	Lyophilized skin allograft (dermal)
		Keratinocytes for ATMP
Umbilical cord	Umbilical cord tissue*	
Other, Not covered above		
The connective tissue of large nerves		
Vaginal microbiota (incl. bedside preparation)		
Microbial lysate obtained / derived from human microflora		
Hair transplants		
Autologous skin (bedside preparation)		
Adipose tissue for lipofilling (bedside preparation)		
Other		Extracellular matrix of adipose tissue
Blood components for topical use or injection, not covered above		
Platelet Rich Plasma EDQM Guide T&C, Chapter 33, page 399, 5 th edition		Autologous (bedside preparation)
		Allogeneic
Platelet Poor Plasma		Autologous (bedside preparation)
		Allogeneic
Platelet Concentrate		Autologous
		Allogeneic
Platelet Lysate		Autologous
		Allogeneic
Platelet Gel		
Other		
Epidural blood patch (EBP)		
Exosomes		