Safety Data Sheets for Blood Bank Products

Dear Valued Customer:

Ortho Clinical Diagnostics (Ortho) provides Safety Data Sheets (SDS) for any Ortho products that contain hazardous materials at or above regulated thresholds.

Under normal conditions of use, the products that contain hazardous substances would not expose the user to a chemical hazard. However, since some products may contain biological materials, standard precautions should be used when handling all products.

The list of Ortho Clinical Diagnostics' products or products distributed by Ortho indicates the products that have an SDS and the products that are exempt and do not have an SDS.

- Those products with Yes in the first column of the list have an SDS. The SDS can be found at www.orthoclinical.com or on the listed manufacturer's website. Select your country on the bottom right, then Resources, Technical Documents, Material Safety Data Sheets. Follow the prompts on the screen to obtain the documents that you need. Print the SDS for your records.
- Those products with No in the first column of the list do not require an SDS. Print this exemption letter and file it to prove that an SDS is not required.

For more information on these products, please refer to the package insert or instructions for use (IFU). We recommend that you file this letter and the list of products with your SDS records for documentation purposes.

Thank you for your continued support of Ortho Clinical Diagnostics products.

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Blood Bank Products – Safety Data Sheets (SDS) Information

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Revision History

Date	Description of Change
2021-05-24	Changed ID-MTS™ GEL CARDS to “Yes” SDS. Updated directions to locate SDSs.
2019-04-04	Changed AlbaQ-Chek® Simulated Whole Blood Controls from “Yes” to “No”. Per Alba, SDS not required under Regulation EC No 1272/2008 (CLP) and EC No 1907/2006.
2018-01-25	Added ORTHO™ Sera Products
2016-03-22	Added Catalog Number 6986722 ORTHO™ 7% BSA - SDS not required but one is provided
2014-08-25	Multiple changes throughout document
2013-05-15	Initial release of document

ABO Blood Grouping Reagents

ABO Blood Grouping Reagents		
SDS?	**Catalog Number**	**Description**
No	711220	Anti-A (Murine Monoclonal Blend) BioClone®

No	6901934	Anti-A (Murine Monoclonal Blend) BioClone®
No	711320	Anti-B (Murine Monoclonal Blend) BioClone®
No	6901935	Anti-B (Murine Monoclonal Blend) BioClone®
No	711520	Anti-A,B (Murine Monoclonal Blend) BioClone®
No	711830	ORTHO® Anti-A_1 Lectin (Dolichos biflorus)

Anti-D Sera and Rh-hr Typing Reagents

Anti-D Sera and Rh-hr Typing Reagents		
SDS?	**Catalog Number**	**Description**
No	712380	Anti-D (Anti-Rh_o) for Slide and Modified Tube Tests
No	717380	Anti-D (Anti-Rh_o) (Human Monoclonal-Polyclonal Blend) BioClone®
No	6901939	Anti-D (Anti-Rh_o) (Human Monoclonal-Polyclonal Blend) BioClone®
No	713080	Anti-C (Anti-RH2) (Monoclonal) BioClone®
No	713180	Anti-E (Anti-RH3) (Monoclonal) BioClone®
No	714080	Anti-c (Anti-RH4) (Monoclonal) BioClone®
No	714180	Anti-e (Anti-RH5) (Monoclonal) BioClone®
No	715480	ORTHO® Rh-hr Control (Human and Bovine)

Anti-Human Globulin Reagents

Anti-Human Globulin Reagents		
SDS?	**Catalog Number**	**Description**
No	716080	Anti-Human Globulin (Rabbit and Murine Monoclonal) BioClone® (Clear) Anti-IgG,-C3d; polyspecific
No	716000	Anti-Human Globulin BioClone® (Rabbit and Murine Monoclonal) (Clear) Anti-IgG,-C3d; polyspecific
No	716910	Anti-Human Globulin BioClone® (Rabbit and Murine Monoclonal) (Green) Anti-IgG,-C3d; polyspecific
No	716980	Anti-Human Globulin BioClone® (Rabbit and Murine Monoclonal) (Green) Anti-IgG,-C3d; polyspecific
No	716300	ORTHO® Anti-IgG (Clear)
No	716360	ORTHO® Anti-IgG (Clear)

No	716700	ORTHO® Anti-IgG (Green)
No	716760	ORTHO® Anti-IgG (Green)
No	716530	Anti-C3d BioClone®
No	716540	Anti-C3b,-C3d BioClone®

Antibody Enhancement Media

Antibody Enhancement Media		
SDS?	**Catalog Number**	**Description**
No	718100	ORTHO® Bovine Albumin Solution 22% concentration, pH 7.2
No	718280	ORTHO® Bovine Albumin Solution 22% concentration, pH 7.2
No	718300	ORTHO® Polymerized Bovine Albumin, pH 7.2
No	718380	ORTHO® Polymerized Bovine Albumin, pH 7.2
Yes	6902525	ORTHO® Antibody Enhancement Solution
Yes	6902526	ORTHO® Antibody Enhancement Solution

Rare Antisera

Rare Antisera		
SDS?	**Catalog Number**	**Description**
No	715130	Anti-Fy^a
No	725230	Anti-Fy^b
No	715150	Anti-K (Anti-Kell)
No	721030	Anti-k (Anti-Cellano)
No	715280	Anti-Le^a (LE1) (Murine Monoclonal) BioClone® 2.0
No	715380	Anti-Le^b (LE2) (Murine Monoclonal) BioClone® 2.0
No	715530	Anti-P1 (Goat)
No	715850	Anti-M (Rabbit)
No	715950	Anti-N (Rabbit)
No	723030	Anti-S
No	721830	ORTHO® Anti-s
No	721130	Anti-C^w (Anti-rh^{w1})

Blood Bank Products – SDS Information

Rare Antisera		
SDS?	**Catalog Number**	**Description**
No	721380	Anti-Jk[a] (Monoclonal) BioClone®
No	721480	Anti-Jk[b] (Monoclonal) BioClone®

Reagent Red Blood Cells

Reagent Red Blood Cells		
SDS?	**Catalog Number**	**Description**
No	719210	Affirmagen® (Pooled Cells)
No	719310	ORTHO® A_2 Cells (Pooled Cells)
No	719000	ORTHO® Pooled Screening Cells
No	719610	Selectogen®
No	719100	Surgiscreen®
No	719510	Resolve® Panel A
No	719520	Resolve® Panel B
Yes	719410	ORTHO Ficin Panel System Resolve® Panel C Untreated and Treated
No	719810	ORTHO® Coombs Control (Pooled Cells)
No	719201	0.8% Affirmagen®
No	719211	0.8% Affirmagen® 3
No	6902314	ORTHO® 0.8% Pooled Screening Cells
No	6902315	0.8% Selectogen®
No	6902316	0.8% Surgiscreen®
No	6902317	0.8% Resolve® Panel A
No	6902318	0.8% Resolve® Panel B
No	6902319	0.8% Resolve® Panel C
Yes	Z488	FETALSCREEN™ II

Blood Bank Products – SDS Information

ID-MTS™ Gel Cards

ID-MTS™ GEL CARDS		
SDS?	**Catalog Number**	**Description**
Yes – not required but one is provided	MTS084014	Anti-Human Globulin Anti-IgG, -C3d Polyspecific (Rabbit), MTS™ Anti-IgG, -C3d Card
Yes – not required but one is provided	MTS084024	Anti-Human Globulin, Anti-IgG (Rabbit), MTS™ Anti-IgG Card
Yes	MTS085014	MTS™ Buffered Gel Card
Yes	MTS080014	MTS™ Anti-A (Murine Monoclonal) Card
Yes	MTS080015	MTS™ Anti-B (Murine Monoclonal) Card
Yes	MTS080016	MTS™ Anti-A,B (Murine Monoclonal Blend) Card
Yes	MTS080017	MTS™ A/B Monoclonal Grouping Card
Yes	MTS081221	MTS™ Anti-D (Monoclonal) (IgM) Card
Yes	MTS080515	MTS™ A/B/D Monoclonal and Reverse Grouping Card
Yes	MTS081115	MTS™ A/B/D Monoclonal Grouping Card
Yes	MTS081001	MTS™ Monoclonal Control Card
Yes	MTS080024	MTS™ Monoclonal Rh Phenotype Card
Yes	MTS080210	MTS™ Anti-C (Monoclonal) Card
Yes	MTS080212	MTS™ Anti-E (Monoclonal) Card
Yes	MTS080310	MTS™ Anti-c (Monoclonal) Card
Yes	MTS080312	MTS™ Anti-e (Monoclonal) Card

ID-MTS™ Products

ID-TMS™ Products		
SDS?	**Catalog Number**	**Description**
No	MTS9230	MTS™ Diluent 2
No	MTS9330	MTS™ Diluent 2 Plus

Blood Bank Products – SDS Information

Quality Control Kits

Quality Control Kits		
SDS?	**Catalog Number**	**Description**
No	6902096	ORTHO® Confidence System
No	Z498	AlbaQ-Chek® Simulated Whole Blood Controls

ORTHO™ Generic Reagents

ORTHO™ Generic Reagents		
SDS?	**Catalog Number**	**Description**
Yes	213680	ORTHO ProVue™ Solution A
Yes	213681	ORTHO ProVue™ Solution B
No	6844285	ORTHO™ 7% BSA (5 mL)
Yes	6986722	ORTHO™ 7% BSA (12 mL) SDS not required but one is provided

Hemo bioscience

Hemo bioscience		
SDS?	**Catalog Number**	**Description**
No http://www.hemobioscience.com/	H360	ELU*clear*
No http://www.hemobioscience.com/	H9000	C3 Control Cells

Blood Bank Products – SDS Information

ORTHO™ Sera Products

ORTHO™ Sera Products		
SDS?	**Catalog Number**	**Description**
Yes	6904546	ORTHO™ Sera Anti-Fy[a] SDS not required but one is provided
Yes	6904547	ORTHO™ Sera Anti-Fy[b] SDS not required but one is provided
Yes	6904548	ORTHO™ Sera Anti-Jk[a] SDS not required but one is provided
Yes	6904549	ORTHO™ Sera Anti-Jk[b] SDS not required but one is provided
Yes	6904550	ORTHO™ Sera Anti-S SDS not required but one is provided
Yes	6904551	ORTHO™ Sera Anti-s SDS not required but one is provided
Yes	6904552	ORTHO™ Sera Anti-K SDS not required but one is provided
Yes	6904553	ORTHO™ Sera Anti-D (IAT) SDS not required but one is provided
Yes	6904555	ORTHO™ Sera Anti-N SDS not required but one is provided
Yes	6904556	ORTHO™ Sera Anti-P1 SDS not required but one is provided
Yes	6904557	ORTHO™ Sera Anti-Le[a] SDS not required but one is provided
Yes	6904558	ORTHO™ Sera Anti-Le[b] SDS not required but one is provided
Yes	6904624	ORTHO™ Sera Anti-D (DVI) SDS not required but one is provided
Yes	6904840	ORTHO™ Sera Papain