

## **Safety Data Sheets for Immunohematology 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. These SDSs can be found at [orthoclinical.com](http://orthoclinical.com). Select Instructions for Use Library on the top right, then Safety Data Sheets. Follow the prompts on the screen to obtain the documents needed.

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.

This list of Ortho products or products distributed by Ortho indicates the products that are exempt and do not have a SDS. Print this exemption letter and file as proof that a 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 products.

## Immunochemistry – Safety Data Sheet (SDS) Information

**Not all products and systems are available in all regions.**

### Revision History

Date	Description of Change
2021-08-11	Updated letter and removed all references to non-exempt SDSs.
2020-02-21	Changed Blood Bank to Immunochemistry, updated instructions on how to find SDSs, changed 707119 from “No” to “Yes” as an SDS is available
2019-04-02	Added Catalog Numbers 6986735 and 6986736
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

# Immunohematology – SDS Information

## ABO Blood Grouping Reagents

ABO Blood Grouping Reagents		
SDS?	Catalog Number	Description
No	711220	Anti-A (Anti-ABO1) (Murine Monoclonal Blend) BioClone®
No	6901934	Anti-A (Anti-ABO1) (Murine Monoclonal Blend) BioClone®
No	7112276	Anti-A (Anti-ABO1) (Murine Monoclonal Blend) BioClone®
No	711320	Anti-B (Anti-ABO2) (Murine Monoclonal Blend) BioClone®
No	6901935	Anti-B (Anti-ABO2) (Murine Monoclonal Blend) BioClone®
No	7113276	Anti-B (Anti-ABO2) (Murine Monoclonal Blend) BioClone®
No	711520	Anti-A,B ((Anti-ABO3) Murine Monoclonal Blend) BioClone®
No	7115171	Anti-A,B (Anti-ABO3) (Murine Monoclonal Blend) BioClone®
No	711830	ORTHO® Anti-A <sub>1</sub> Lectin (Dolichos biflorus)
No	715120	ORTHO® Anti-A <sub>1</sub> Lectin (Dolichos biflorus)

## Anti-D Sera and Rh-hr Typing Reagents

Anti-D Sera and Rh-hr Typing Reagents		
SDS?	Catalog Number	Description
No	712105	Anti-D (RH1) for Slide and Modified Tube Tests
No	712380	Anti-D (Anti-Rh <sub>o</sub> ) for Slide and Modified Tube Tests
No	7172676	Anti-D (Anti-Rh <sub>o</sub> ) for Slide and Modified Tube Tests
No	7173676	Anti-D (RH1) (Human Monoclonal-Polyclonal Blend) BioClone®
No	717380	Anti-D (Anti-Rh <sub>o</sub> ) (Human Monoclonal-Polyclonal Blend) BioClone®
No	6901939	Anti-D (Anti-Rh <sub>o</sub> ) (Human Monoclonal-Polyclonal Blend) BioClone®
No	713080	Anti-C (Anti-RH2) (Monoclonal) BioClone®
No	713119	Anti-E (Anti-RH3) (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)

# Immunohematology – SDS Information

## Anti-Human Globulin Reagents

Anti-Human Globulin Reagents		
SDS?	Catalog Number	Description
No	716121	Anti-IgG,-C3d; polyspecific BioClone® (Clear)
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	7160676	Anti-Human Globulin (Rabbit and Murine Monoclonal) BioClone® (Clear) Anti-IgG, -C3d; polyspecific
No	7162376	Anti-Human Globulin (Rabbit and Murine Monoclonal) BioClone® (Clear) Anti-IgG, -C3d; polyspecific
No	716122	Anti-IgG,-C3d; polyspecific BioClone® (Green)
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	7169676	Anti-Human Globulin (Rabbit and Murine Monoclonal) BioClone® (Green) Anti-IgG, -C3d; polyspecific
No	716123	Anti-IgG (Clear)
No	716300	Anti-IgG (Rabbit) (Clear)
No	716360	Anti-IgG (Rabbit) (Clear)
No	716700	Anti-IgG (Rabbit) (Green)
No	716760	Anti-IgG (Rabbit) (Green)
No	716114	Anti-C3d BioClone®
No	716530	Anti-C3d BioClone®
No	716540	Anti-C3b,-C3d (Murine Monoclonal) BioClone®
No	716115	Anti-C3b,-C3d BioClone®

# Immunohematology – SDS Information

## 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
No	7182671	ORTHO® Bovine Serum Albumin, 22% Protein Concentration, pH 7.2
No	7183376	ORTHO® Bovine Albumin Solution Polymerized Bovine Solution
No	7183671	ORTHO® Polymerized Bovine Solution, pH 7.2

## Rare Antisera

Rare Antisera		
SDS?	Catalog Number	Description
No	715130	Anti-Fy <sup>a</sup> (FY1)
No	715121	Anti-Fy <sup>a</sup> (FY1)
No	715122	Anti-Fy <sup>b</sup> (FY2)
No	725230	Anti-Fy <sup>b</sup> (FY2)
No	6901859	Anti-Le <sup>a</sup> (LE1) (Monoclonal) BioClone® 2.0
No	715280	Anti-Le <sup>a</sup> (LE1) (Murine Monoclonal) BioClone® 2.0
No	6901860	Anti-Le <sup>b</sup> (LE2) (Monoclonal) BioClone® 2.0
No	715380	Anti-Le <sup>b</sup> (LE2) (Murine Monoclonal) BioClone® 2.0
No	715125	Anti-P1 (Goat)
No	715530	Anti-P1 (Goat)
No	714103	Anti-S (MNS3)
No	723030	Anti-S (MNS3)
No	714104	Anti-s (MNS4)
No	721830	Anti-s (MNS4)
No	715150	Anti-K (Anti-Kell)
No	721107	Anti-Cellano (KEL2)

## Immunohematology – SDS Information

Rare Antisera		
SDS?	Catalog Number	Description
No	721030	Anti-k (Anti-Cellano) (KEL2)
No	713121	Anti-C <sup>w</sup> (RH8) Polyclonal IgM
No	721130	Anti-C <sup>w</sup> (Anti-rh <sup>w1</sup> )
No	721380	Anti-Jk <sup>a</sup> (JK1) (Monoclonal) BioClone®
No	721480	Anti-Jk <sup>b</sup> (JK2) (Monoclonal) BioClone®

### Reagent Red Blood Cells

Reagent Red Blood Cells		
SDS?	Catalog Number	Description
No	6901861	Affirmagen®
No	7192041	Affirmagen® (Pooled Cells)
No	7192042	Affirmagen® (Pooled Cells)
No	719220	Affirmagen® 4
No	7196041	Selectogen®
No	7191041	Surgiscreen®
No	7196771	Group O Di <sup>a</sup> Positive (3%) (Diego)

# Immunohematology – SDS Information

## BioVue® System

BioVue® System		
SDS?	Catalog Number	Description
No	707118	Anti-K (Anti-K1) (Monoclonal) Control Ortho BioVue® System (K/Control Cassette)
No	707136	Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Ortho BioVue® System (ABD Confirmation Cassette)
No	707401	Anti-Human Globulin Anti-IgG (Rabbit) (Green) Ortho BioVue® System (IgG Cassette)
No	707451	Anti-Human Globulin Anti-IgG (Rabbit) (Green) Ortho BioVue® System (IgG Cassette)
No	707156	Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Control Reverse Diluent Ortho BioVue® System (ABO-Rh/Reverse Grouping Cassette)
No	707101	Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Control Reverse Diluent Ortho BioVue® System (ABO-Rh/Reverse Grouping Cassette)
No	707351	Anti-IgG, -C3d; polyspecific (Rabbit and Murine Monoclonal) (Green) Ortho BioVue® System (Poly Cassette)
No	707301	Anti-IgG, -C3d; polyspecific (Rabbit and Murine Monoclonal) (Green) Ortho BioVue® System (Poly Cassette)

# Immunohematology – SDS Information

## Quality Control Kits

Quality Control Kits		
SDS?	Catalog Number	Description
No	6842785	ORTHO CONFIDENCE™ WB