

Safety Assessment

according to Regulation (EC) No. 1907/2006 (REACH)

for the products listed in the product list (page 2)

General Intended Use

Test sera for the detection of blood group antigens using the techniques described in the package insert. For IN-VITRO DIAGNOSTIC use only by qualified and trained personnel.

Exception:

Product name	Ref.	Justification
Control solution for monoclonal reagents	05.147-10	see intended purpose in the package insert

Technical Information Contact

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Classification of the mixtures

The products have been evaluated in accordance with Regulation (EC) No. 1272/2008 and classified as non-hazardous. Please observe the warnings and precautions in the instructions for use.

Preparation of a Safety Data Sheet in accordance with Article 31 of Regulation (EC) No. 1907/2006 (REACH)

A safety data sheet is not required for these products, as they are neither classified as hazardous nor contain hazardous components or substances with Community (EC) occupational exposure limits or substances of very high concern (SVHC) above their respective legal thresholds.

Consequently, in accordance with Regulation (EC) No. 1907/2006 (REACH), a safety data sheet is not necessary and is not available in this case.



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product list

Product name	Ref.	Size
Control solution for monoclonal reagents	05.147-10	10ml
Anti-H monoclonal, mouse clone: 10934C11	690091A	5ml
Anti-D (RH1), monoclonal IgM (human)	690121A	10ml
Anti-CDE (RH2,1,3) monoclonal IgM + IgG (human) OrthoClone	690141A	10ml
Anti-C (RH2), monoclonal IgM (human) OrthoClone	690211A	5ml
Anti-Cw monoclonal, human IgM clone: MS-110	690221A	3ml
Anti-c (RH4), monoclonal IgM (human) OrthoClone	690281A	5ml
Anti-E (RH3), monoclonal IgM (human)	690291A	5ml
Anti-E (RH3), monoclonal IgM (human) OrthoClone	690321A	5ml
Anti-e (RH5), monoclonal IgM (human) OrthoClone	690361A	5ml
Anti-N monoclonal, mouse clones: 20H12, MN879	690401A	5ml
Anti-K (KEL1) monoclonal, human IgM clone: AEK-4	690461A	10ml
Anti-Kell (KEL1), coombsreactive, polyclonal (human)	690482A	5ml
Anti-Xga Coombs-reactive, polyclonal, human	690632A	3ml
Anti-Kpa Coombs-reactive, polyclonal, human	690652A	3ml
Anti-P1 monoclonal, mouse clone: 650	691181A	5ml
Anti-S monoclonal, human IgM clone: MS-94	691241A	5ml



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