

1.a – Company Identification

Producer and Distributor for Italy:



New Scientific Company S.r.l.  
 Via Torino, 12 – 22070 Fenegrò (CO)  
 Phone: + 39 031 938 132 – Fax: +39 031 3520 409  
 Internet: www.newscientific.com - E-mail: nscit@newscientific.com

Emergency Phone Nos:

- Producer/Distributor: +39 031 938 132
- Official Advisory Bodies: General and/or specific Nos. of the territory Health Authorities

1.b – Product and Component Identification

The sheet applies to the group of products known as “*ImmunoNephelometry Various Protein Kit and Reagents*” as identified in these charts:

Kit

Product Code	Component Code	Physical State
K.APS.RBP-S	R.APS.RBP	liquid
	W.SPC.RBP	liquid
	Y.SPR.RBP.MV	liquid
	Y.SPR.RBP.LV	liquid
KR.APS.RBP-S	R.APS.RBP	liquid

Product Code	Component Code	Physical State
K.APS.RBP-U	R.APS.RBP	liquid
	W.SPC.RBP	liquid
	Y.UPR.RBP.MV	liquid
	Y.UPR.RBP.LV	liquid
KR.APS.RBP-U	R.APS.RBP	liquid

Product Code	Component Code	Physical State
K.APS.CEI	R.APS.CEI	liquid
	W.SPC.CS1	liquid
	W.SPR.CS1.MV	liquid
	W.SPR.CS1.LV	liquid
KR.APS.CEI	R.APS.CEI	liquid

Product Code	Component Code	Physical State
K.APS.C1Q	R.APS.C1Q	liquid
	W.SPC.CS1	liquid
	Y.SPR.CS1.MV	liquid
	Y.SPR.CS1.LV	liquid
KR.APS.C1Q	R.APS.C1Q	liquid

Product Code	Component Code	Physical State
K.IMG.RBP-S	R.IMG.RBP.S	liquid
	R.IMG.RBP.B	liquid
	W.SPC.RBP	liquid
	Y.SPR.RBP.MV	liquid
	Y.SPR.RBP.LV	liquid
KR.IMG.RBP-S	R.IMG.RBP.S	liquid
	R.IMG.RBP.B	liquid

Product Code	Component Code	Physical State
K.IMG.RBP-U	R.IMG.RBP.U	liquid
	R.IMG.RBP.B	liquid
	W.SPC.RBP	liquid
	Y.UPR.RBP.MV	liquid
	Y.UPR.RBP.LV	liquid
KR.IMG.RBP-U	R.IMG.RBP.U	liquid
	R.IMG.RBP.B	liquid

Product Code	Component Code	Physical State
K.IMG.CEI	R.IMG.CEI	liquid
	W.SPC.CS1	liquid
	Y.SPR.CS1.MV	liquid
	Y.SPR.CS1.LV	liquid
KR.IMG.CEI	R.IMG.CEI	liquid

Product Code	Component Code	Physical State
K.IMG.C1Q	R.IMG.C1Q	liquid
	W.SPC.CS1	liquid
	Y.SPR.CS1.MV	liquid
	Y.SPR.CS1.LV	liquid
KR.IMG.C1Q	R.IMG.C1Q	liquid

Product Code	Component Code	Physical State
K.IMG.IGD	R.IMG.IGD	liquid
	W.SPC.PS1	liquid
	Y.SPR.PS1.MV	liquid
	Y.SPR.PS1.LV	liquid
KR.IMG.IGD	R.IMG.IGD	liquid

Product Code	Component Code	Physical State
K.IMG.FIN	R.IMG.FIN	liquid
	W.SPC.PS1	liquid
	Y.SPR.PS1.MV	liquid
	Y.SPR.PS1.LV	liquid
KR.IMG.FIN	R.IMG.FIN	liquid

Product Code	Component Code	Physical State
K.BNA.GBG	R.BNA.GBG	liquid
	W.SPC.CS1	liquid
	Y.SPR.CS1.MV	liquid
	Y.SPR.CS1.LV	liquid
KR.BNA.GBG	R.BNA.GBG	liquid

Product Code	Component Code	Physical State
K.BNA.C1Q	R.BNA.C1Q	liquid
	W.SPC.CS1	liquid
	Y.SPR.CS1.MV	liquid
	Y.SPR.CS1.LV	liquid
KR.BNA.C1Q	R.BNA.C1Q	liquid

Calibrators and Controls

Product Code	Physical State
W.SPC.RBP	liquid
W.SPC.CS1	liquid
W.SPC.PS1	liquid

Product Code	Physical State
W.SET.SPC.RBP	liquid
W.SET.SPC.CS1	liquid
W.SET.SPC.PS1	liquid

Product Code	Physical State
Y.SPR.RBP.MV	liquid
Y.SPR.RBP.LV	liquid
Y.UPR.RBP.MV	liquid
Y.UPR.RBP.LV	liquid
Y.SPR.CS1.MV	liquid
Y.SPR.CS1.LV	liquid
Y.SPR.PS1.MV	liquid
Y.SPR.PS1.LV	liquid

## 2.0 – Information on the Hazardous Substances of the Product

This information relates to all the components as identified in Paragraph 1.b.

### Hazardous Substances of Product

Chemical Name	Cas Number	Concentration (p/p%)	EEC Classification of the Pure Compound	Product Hazardness
Sodium azide (NA(N3))	26628-22-8	< 0.1	T+	<b>Non-hazardous</b>
R-phrases and S-phrases applicable to the compound in its pure state				
R28	Highly toxic on contact with the skin			
R32	Releases highly toxic gas upon contact with acids			
S28	In case of contact with the skin, wash immediately and thoroughly with water			

### Safety Precautions

As shown in the chart, the Products and Components are classified “Non-Hazardous” according to listed regulations.

However, as for all chemical and biological substances, safe laboratory practice and good personal hygiene are essential, in particular:

#### Handling

For all the components, adopt the precautions necessary to avoid accidental ingestion.

#### Disposal

Sodium azide can react with lead and copper forming an explosive compound.

For drain disposal, dilute with plenty of running water.

## 3.0 – Calibrators and Controls – Serum and Plasma of Human Origin

This information relates solely to the products shown under “Calibrators and Controls” in Paragraph 1.b.

### Declaration of the Producer of the Calibrators and Controls

The serum and/or plasma of human origin have been tested by a method approved by the “FDA – USA” and have been found negative for the presence of Hepatitis B surface antigen (HBsAg), anti-HCV antibodies and anti-HIV 1, 2, antibodies.

#### Handling and Disposal

Since no method of testing can for certain exclude the presence of pathogen agents, the materials of human origin must be considered as potentially infected and must be treated with the relative precautions, complying with the biological risk safety precautions.

## Reference Documents

This document has been prepared with specific reference to the following:

- European Economic Community – Council Directive of 7 June 1988 – 88/379/EEC
- European Economic Community – Commission Directive of 5 March 1991 – 91/155/EEC
- Italian Republic – Ministerial Decree of 28 January 1992 published in the Official Gazette of 28 February 1992, No. 50, S.O.

Reference should also be made to all other national and/or local regulations applicable.

### Document and Revision Identification

Code	Revision	Date	No. of Pages	Prepared by	Verified by
D.:SS_ImNef_Vari	05-IN	12.03.08	2	L. Massaro (D.G.)	R. Scaringi (R.Q.)
					