ISE out			Rheumatoid Factor-Reagent R2	SDS	(6	-90-
	Z		R3330000053			- 00
CUSTOMISED SOLUTIONS	ш	REF	A-R1100004101		IVD	A.Y
FOR YOUR LABORATORY						Re 22

Safety Data Sheet (According to 1272/2008/EC)

Trade name: Rheumatoid Factor

Article number: R3330000053, A-R1100004101

Product Description: Rheumatoid Factor - Reagent R2 (RF Reagent 3rd Generation)

Identification of the substance / preparation and the company

1.1 Product identifiers

Product REF: Refer to the Header Product Description: Refer to the Header

1.2 Relevant identified uses of the substance or mixture and uses advices against

In vitro diagnostics.

1.3 Details of the supplier of the safety data sheet

Identification company: I.S.E. S.r.l.

Via delle Driadi, 45 00133 Roma - Italia

Tel. +39 0774+ 579365; FAX +39 0774 579305

E-mail: info@logotech-ise.com www.logotech-ise.com

Additional information from: I.S.E. S.r.I. - Regulatory Affairs E-mail: info@logotech-ise.com

1.4 Emergency telephone number

Emergency information: As above or call

Policlinico A. Gemelli - Largo Agostino Gemelli, 8 - Roma - Italy - Tel. + 39 063054343

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008

Void

For the full text of the H-Statements mentioned in the Section, see Section 16

Hazard designation: Void

2.2 Label elements

Labelling according to EC regulation 1272/2008

Label: Void
Signal word: Void
Hazard statements: Void
Precautionary statements: Void
Information pertaining to Void

particular dangers for man and

environment:



ISF Srl				Rheumatoid Factor-Reagent R2	SDS	(-90-
		Z		R3330000053			- 00
	CUSTOMISED SOLUTIONS	Е	REF	A-R1100004101		IVD	Y.A
	FOR YOUR LABORATORY						Re 22

2.3 Other hazards

Hazardous properties cannot be excluded.

Composition / information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

Chemical characterization: Mixture

Description: Void

Hazardous components: Void

Additional information: Void

4 First aid measures

4.1 Description of first aid measures

General information: Remove contaminated clothing

After inhalation: Supply fresh air, consult doctor in case breathing problems develop. Unconscious:

maintain adequate airway and respiration.

After skin contact: Wash with soap and water. If symptoms persists, consult doctor.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persists,

consult doctor. Do not apply neutralizing agents.

After swallowing: Rinse out mouth and then drink plenty of water. In case of persistent symptoms,

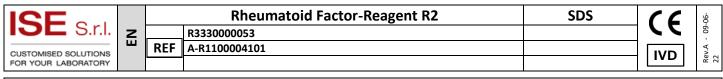
consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

After eye contact: May cause irritations.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.



5 Fire fighting measures

5.1 Extinguishing media

Suitable extinguishing agents: Carbon dioxide (CO2), extinguishing powder or water spray/fog. Fight larger fires with

water spray/fog or alcohol-resistant foam.

For safety reasons unsuitable

extinguishing agents:

None.

5.2 Special hazards arising from the substance or mixture

Special hazard caused by the material, its products of

combustion or flue gases:

No hazardous combustion products known.

5.3 Advice for firefighters

Protective equipment: Put on breathing apparatus. Gas-tight suit.

Additional information: Collect contaminated firefighting water separately. It must not enter drains.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Person-related safety Wear protective clothing. Do not breathe vapors. Avoid skin and eye contact. See

precautions: Section 8.

6.2 Environmental precautions

Measures for environmental Do not allow to enter drainage system, surface or ground water. Discharge according

protection: local regulations.

6.3 Methods and material for containment and cleaning up

Measures for Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders,

cleaning/collecting: sawdust).

Dispose of contaminated material as waste according to item 13.

Clean contaminated surfaces with an excess of water.

Wash clothing and equipment after handling.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

LS.F.S.r.L.



EN		Rheumatoid Factor-Reagent R2	SDS
		R3330000053	
	REF	A-R1100004101	

7 Handling and storage

7.1 Precautions for safe handling

Information for safe handling: Observe normal to strict hygiene standards.

Handle and open the container with care.

Ensure good ventilation / exhaustion at the workplace.

Do not inhale aerosols.

Avoid prolonged or repeated skin contact.

Avoid contact with eyes.

Make sure that all applicable workplace limits are observed.

Information about protection

against explosions and fires:

No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and containers:

Observe all local and national regulations for storage of water polluting products.

Information about storage in one common storage facility:

Not required

Further information about

Keep container tightly sealed.

storage conditions:

Protect from heat and direct sunlight.

Store in a cool place.

Recommend storage temperature: 2 - 8 °C.

7.3 Specific end use(s)

Void.

8 Exposure controls / personal protection

8.1 Control parameters

Additional information about design of technical systems:

No further data; see item 7.

Components with critical values Void

that require monitoring at the

workplace:

Additional information: The list that were valid during the compilation were used as basis.

8.2 Exposure controls

LS.F.S.r.L.

Personal protective equipment



LIV		Rheumatoid Factor-Reagent R2	SDS
		R3330000053	
	REF	A-R1100004101	

General protective and hygienic Keep away from foodstuffs, beverages and food.

measures: Do not inhale gases / fumes / aerosols.

Avoid close or long term contact with the skin.

Avoid contact with the eyes.

Wash hands during breaks and at the end of the work.

Breathing equipment: If all workplace limits are observed and good ventilation is ensured, no special

precautions necessary.

Protection of hands: Protective gloves. The glove material has to be impermeable and resistant to the

product / the substance / the preparation.

Selection of the glove material on consideration of the penetration times, rates of

diffusion and the degradation.

Check the permeability prior to each new use of the glove.

To avoid skin problems reduce the wearing of gloves to the required minimum. Due to missing tests no recommendation to the glove material can be given for the product /

the preparation / the chemical mixture.

Material of gloves: The selection of the suitable gloves does not only depend on the material but also on

further marks of quality varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of the glove: The exact breakthrough time has to be found out by the manufacturer of the

protective gloves and has to be observed.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General infomation

Appearance: Liquid

Colour: Clear

Odour: Odourless

Odour threshold: No data available

pH value: No data available

Change in condition:

Melting point / Melting range: No data available

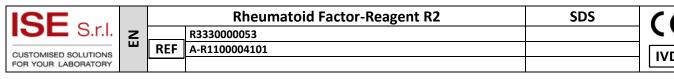
Boiling point / Boiling range: No data available

Evaporation rate: No data available

Flash point / Flash point range: Not applicable



5/9



Self-inflammability: Product is not self-igniting.

Danger of explosion: Product is not explosive.

Density: No data available

Solubility in / Miscibility with

water:

Soluble

9.2 Other information

No data available

10 Stability and reactivity

10.1 Reactivity

Stable reactivity until expiry date if stored in recommended conditions.

10.2 Chemical stability

Stable until expiry date under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Thermal decomposition / Sunlight conditions to be avoided: Heat

10.5 Incompatible products

Materials to be avoided: Void

10.6 Hazardous decomposition products

Void

11 Toxicological information

11.1 Information on toxicological effects

No information available

12 Ecological information

12.1 Toxicity

No information available



ISF or			Rheumatoid Factor-Reagent R2	SDS	(6	-90-
	Z		R3330000053			- 09
CUSTOMISED SOLUTIONS	Е	REF	A-R1100004101		IVD	A
FOR YOUR LABORATORY						Re 22

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

No data available.

12.6 Other adverse effects

Water hazard class 1 (self-assessment):

Slightly hazardous for water.

13 Disposal considerations

13.1 Waste treatment methods

Product

Recommendation: Disposal must be made according to official regulations.

European waste catalogue: Waste disposal key numbers from EWC have to be assigned depending on origin and

processing.

Contaminated packaging

Recommendation: Disposal must be made according to official regulations.

Recommended cleaning agent: Water, if necessary with cleaning agent.

14 Transport information

14.1 UN number

ADR/RID, IMDG, IATA: Not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA: Not restricted

14.3 Transport hazard class(es)

LS.F.S.r.L.

ADR/RID, IMDG, IATA: Not applicable



ICE		Rheumatoid Factor-Reagent R2	SDS	(-06-
S.r.I. Z		R3330000053			- 09
CUSTOMISED SOLUTIONS	REF	A-R1100004101		IVD	v.A
FOR YOUR LABORATORY				שעו	Re 22

14.4 Packaging group

ADR/RID, IMDG, IATA: Not applicable

14.5 Environmental hazards

Marine pollutant: No

14.6 Special precautions for user

No dangerous goods in sense of these transport regulations.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

No data available.

15 Regulatory information

15.1 Safety, health and evironmental regulations/legislation specific for the substance or mixture

Designation according to EC

guidelines:

The product needs to be classified and labelled in accordance with EC Directives /

relevant national laws.

National regulations

Degree to be applied in case of -

technical fault:

Water hazard class

Water hazard class 1 (self-assessment):

Slightly hazardous for water

15.2 Chemical Safety Assessment

Void

16 Other information

In vitro diagnostics use only.

Each human donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

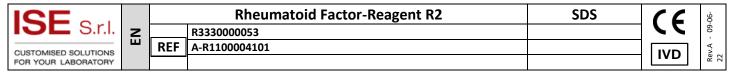
Department issuing SDS: I.S.E. S.r.l., Regulatory Affair Office

The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification.

The information and recommendations contained herein are based upon information or tests believed to be reliable. I.S.E. does not guarantee the accuracy or completeness of this information or recommendations contained herein, NOR SHALL



8/9



ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

This information is not a substitute for the advice of a health care professional, nor is it a recommendation for any particular course of treatment. It is not intended to supplement, modify or supersede any information provided with respect to the medical use of the product. I.S.E. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

It remains the user's own responsibility to make sure that the information is appropriate and complete for his specific use of this product.

The user is also responsible for observing any laws and applicable guidelines.

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1B: Skin corrosion/irritation - Category 1B

Eye Dam. 1: Serious eye damage/eye irritation - Category 1

STOT SE 3: Specific target organ toxicity (single exposure) - Category 3

LS.F.S.r.l.