1. Product and Company Information

Product code + name: 830A, RA Latex Kit

Product description: A serologic kit for the detection of RA (rheumatoid factor) Antibodies.

Latex particles in the reagent will agglutinate (clump) in the presence of

rheumatoid factor antibodies

Supplier/Manufacturer: Lorne Laboratories Ltd

Address: Unit 1 Cutbush Park Industrial Estate

Danehill Lower Earley Berkshire RG6 4UT United Kingdom

 Phone number:
 +44(0) 0118 921 2264

 Fax number:
 +44(0) 0118 986 4518

 e-mail address:
 info@lornelabs.com

 Web-site address:
 www.lornelabs.com

2. Composition/Information on the components

Contains no hazardous substances in reportable quantities

Component nameConcentrationR phrasesClassificationSodium azide<0.1%</td>R28, R32, R50/53PoisonousN-N-Dimethylformamide<0.5%</td>R61, R20/21, R36Toxic

3. Hazard Identification

Classification of the substance or mixture (67/548/CEE or 1999/45/CE):

Kit,R

T, Toxic

R61 May cause harm to the unborn child

For Positive Control: Components from human origin have been tested and found negative for the presence of HbSAg, HCV and antibody to HIV (1/2). However handle cautiously as potentially infectious

CAS	CHEMICAL NAME	%	EC NUMBER EINECS / ELINCS	EC INDEX NUMBER	CLASSIFICATION ACCORDING TO CLP REGULATION		SYM.	R PHRASE
R 68-12-2	N-N-Dimethylformamide	C>0.5	200-679-5	616-001-00-X	Repr.1B Acute Tox.4* Eye Irrit.2	H360D*** H332/H312 H319	T+	R61 R20/21 R36

4. First Aid measures

Eye Contact: Immediately flush eyes with plenty of water for at least 15 minutes,

lifting the upper and lower eyelids. Seek immediate medical advice

Skin Contact: Wash the contacted area with soap and water. Remove contaminated

clothing and shoes. Get medical aid if irritation develops or persists

Ingestion: If victim is conscious and alert, wash out mouth with water. Get medical

aid. Drink large amounts of water

Inhalation: Remove from exposure and move to fresh air immediately. If breathing

is difficult, get medical aid

4.2 Most important symptoms and effects, both acute and delayed

May cause harm to the unborn child.

4.3 Indication of any immediate medical attention and special treatment needed

Eyes: In the event of irritation, seek medical assistance. **Skin:** Get medical aid if irritation develops or persists.

Ingestion: Seek medical assistance.

Notes to Physician: Treat symptomatically and supportively.

5. Fire Fighting measures

Extinguishing Media: Not flammable. Use media to suit the surroundings

Unsuitable Extinguishing Media:

Special hazards of product:

In the event of fire, NOx fumes may form Precipitate fumes formed with water

Protective fire fighting equipment: Suitable clothing and footwear

6. Accidental release measures

Personal Precautions Spillage: Wear rubber gloves and protective clothing

Spillages: Do not inhale the fumes. Avoid contact with the skin, eyes and

clothing. Use proper personal protective equipment as indicated

in Section 8

Environmental precautions: Do not allow it to enter the drainage system. Avoid pollution of

the soil, water supplies and drains

Methods and material for containment and cleaning up:

Sweep up material with absorbent substances and place into a

suitable disposal container. Clean well with water

7. Handling and Storage

Handling: Wear rubber gloves and protective clothing

Storage: Storage temperature should be controlled to between 2 and 8°C. Store in the original

container securely closed. Keep away from foodstuffs

8. Exposure Controls / Personal Protection

VLA-ED: 10 ppm - 30 mg/m3 dermal resorption (N-N-Dimethylformamide)

Respiratory Protection: In the event of fumes forming/aerosols, use suitable respiratory

protection

Hand Protection: Wear suitable gloves, e.g. latex or plastic gloves

Eye Protection: Wear appropriate protective eyeglasses or chemical safety goggles as

described by European Standard EN166

Hygiene measures: Wash hands before breaks and after work. Do not eat, drink or smoke

in the workplace.

9. Physical and Chemical properties

Physical State: Liquid
Colour: White
Odour: Odourless

pH: Approximately 8.0-8.4

Flash Point (°C):

Solubility in water (kg/m³):

Vapour Pressure (kPa):

Density (kg/m³):

Viscosity:

Not applicable

10. Stability and Reactivity

Reactivity: Not known

Chemical Stability: Stable under normal temperatures and pressures.

Possibility of hazardous reactions: Not known

Materials to avoid: High temperatures

Incompatible Materials: Strong oxidising agents. Halogens. Halogenated

hydrocarbons. Alkaline metals. Nitrates. Metal oxides. Non-metal oxides. Reducing agents. Aluminium tri-ethyl.

Hazardous decomposition products: In the event of fire: see section 5

Hygiene measures: Wash hands before breaks and after work. Do not eat,

drink or smoke in the workplace

11. Toxicological Information

Acute Toxicity: Under normal circumstances and use, these products are unlikely to be acutely

toxic

Skin sensitisation: Under normal circumstances and use, these products are unlikely to sensitise

skin

Quantitative data on the toxicity of this product are not available

THE FOLLOWING APPLIES TO NN- DIMETHYLFORMAMIDE (pure substance):

Acute toxicity

LD50 oral rat : > 5.85 mg/kg 4h LD50 skn rat: > 3.160 mg/kg LD50 inh rat: 3040 ppm

Information on toxicological effects:

Through contact with the eyes: Can cause irritations. Risk of cutaneous

absorption.

If swallowed: gastro-intestinal disorders vomiting. Causes headaches.

Teratogenic substance.

12. Ecological Information

Mobility: The product is freely miscible with water

Persistence/Degradability: Some of the ingredients are expected to be resistant to

biodegradation

Ecological data for this product is not available.

THE FOLLOWING APPLIES TO NN- DIMETHYLFORMAMIDE (pure substance): Toxicity: EC50 test (mg/l): Fish (L. Macrochirus) LC50 7100 mg/l (96h)

Crustaceans (Daphnia magna) EC50 > 100 mg/l (48h)

(P. Subcapitata) EC50 > 1000 mg/l (72h)

Receptor medium: Data not known

Observations: The toxicity is not very high

Persistence and degradability: Test: COD = DOC D 100% ThOD 21 d

Biotic degradation classification: Easily biodegradable product **Abiotic degradation depending on pH:** Data not available

Bioaccumulative potential:

Test:

Bioaccumulation:Risk 0.3-1.2 (56 d) (C. Carpio)Observations:Non-bioaccumulable product.Mobility in soil:Repartition: log P(oct)= -0.85Results of PBT and vPvB assessment:Data not available.

Other adverse effects: Highly purifiable. If suitable handling conditions are maintained.

no ecological problems are to be anticipated.

13. Disposal

Product Disposal: This material will be classified as 'biological waste' under the COPA (Special

Waste) Regulations 1980 and must be disposed of in accordance with those

regulations

Container Disposal: Empty containers may contain hazardous residues. Containers shall be

disposed of by incineration as soon as possible

14. Transport information

UN Number:
UN Proper Shipping Name:
Data not available

15. Labelling Information

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

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 and Regulation (EU) 453/2010.

Polish Act/ Regulations: Act of 25 February 2011 / Regulation of the Minister of Health of 28 May 2010.

Chemical safety assessment

No chemical safety assessment has been carried out.

16. Other Information

MSDS first issued: 01 July 2013 including 453/2010

MSDS data revised: Not applicable

Uses and restrictions: Customers are urged to ensure that the product is entirely suitable for

their own purpose. It is the customers' responsibility to ensure that a suitable and sufficient assessment of the risks created by the use of the product is undertaken. The use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagent is

in use

This product is intended for in vitro diagnostic use only

Not for use in humans

UK Legislation: Health and Safety at Work etc Act, 1974, and relevant Statutory

Provisions

SI 1993/1746: Chemicals (Hazard Information and Packaging)

Regulations, 1993

SI 1988/1657: The Control of Substances Hazardous to Health

Regulation

Hazard statements

H312: Harmful in contact with skin **H319:** Causes serious eye irritation

H332: Harmful if inhaled

H360D: May damage the unborn child