SAFETY DATA SHEET

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING	
1.1 Product Identifiers	
Product Name	NEFA
Cat. No.	FA115
1.2 Relevant identified uses of the substance or mixture and uses advised against.	For *in vitro* diagnostic use. Do not pipette by mouth. Handle laboratory reagents in accordance with Good Laboratory Practice.
1.3 Details of the supplier of the safety data sheet	
Company	Randox Laboratories Ltd., 55 Diamond Road, Crumlin, Co. Antrim, United Kingdom, BT29 4QY
Telephone	+44 (0) 28 9442 2413
Fax	+44 (0) 28 9445 2912
E-mail Address	**sds@randox.com**
Website	www.randox.com
1.4 Emergency Telephone Number	
Emergency Phone No.	+44 (0) 28 9442 2413 (GMT, English spoken, Mon - Fri. 08.40-17.20)

SECTION 2. HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
2.1.1 Regulation (EC) No. 1272/2008 (CLP)	**R1a. Buffer, R1b. Enzyme/Coenzyme, R2a. Enzyme Diluent, R2c. Enzyme Reagent** Not hazardous mixtures according to Regulation (EC) No. 1272/2008 (CLP). **CAL. Standard** Flam. Liq. 3: H226; Acute Tox. 2: H300; Eye Dam. 1: H318; Aquatic Chronic 3: H412; **R2b. Maleimide** Acute Tox. 3: H301; Skin Corr. 1B: H314; Skin Sens. 1: H317
2.1.2 Additional Information	
2.2 Label Elements	
Labelling according to Regulation (EC) No. 1272/2008 [CLP]	
Product Name	NEFA
Hazard Pictogram (s)	**CAL Standard**  **R2b. Maleimide**  **R1a. Buffer, R1b. Enzyme/Coenzyme, R2a. Enzyme Diluent, R2c. Enzyme Reagent**

	None assigned
Signal Word (s)	**CAL. Standard**: Danger **R2b. Maleimide**: Danger **R1a. Buffer, R1b. Enzyme/Coenzyme, R2a. Enzyme Diluent, R2c. Enzyme Reagent:** None assigned
Hazard Statement (s)	**CAL Standard** Flam. Liq. 3: H226 - Flammable liquid and vapour. Acute Tox. 2: H300 - Fatal if swallowed. Eye Dam. 1: H318 - Causes serious eye damage. Aquatic Chronic 3: H412 - Harmful to aquatic life with long lasting effects. **R1b Maleimide** Acute Tox. 3: H301 - Toxic if swallowed Skin Corr. 1B: H314 - Causes severe skin burns and eye damage Skin Sens. 1: H317 - May cause an allergic skin reaction **R1a. Buffer, R1b. Enzyme/Coenzyme, R2a. Enzyme Diluent, R2c. Enzyme Reagent** None assigned
Precautionary Statement (s)	**CAL Standard** P210 – Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 – Keep container tightly closed P240 – Ground/bond container and receiving equipment P241 – Use explosion-proof electrical/ventilating/lighting/equipment P242 – Use only non-sparking tools P243 – Take precautionary measures against static discharge P264 – Wash thoroughly after handling P270 – Do not eat, drink or smoke when using this product P273 - Avoid release to the environment. P280 – Wear protective gloves/protective clothing/eye protection/face protection P301 + P312 – If swallowed call a doctor P303 + P361 + P353 – If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower P305 + P351 + P338 – If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P370 + P378 – In case of fire, use extinguisher P403 + P235 – Store in a well ventilated place. Keep cool. P405 – Store locked up. **R1b Maleimide** P273 - Avoid release to the environment. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER/doctor. P391 - Collect spillage. **R1a. Buffer, R1b. Enzyme/Coenzyme, R2a. Enzyme Diluent, R2c. Enzyme Reagent** Not applicable
Supplemental Hazard information (EU)	None
2.3 Other Hazards	Components R1b & R2c. contain Sodium Azide (<0.1%w/v). Avoid ingestion or contact with skin or mucous membranes. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such

	reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances – Not applicable

3.2 Mixtures

EC Classification No. 1272/2008

Component Name	Hazardous Chemical	Concentration (% w/v)	CAS No.	REACH Reg. No.	Hazard Statement(s)
R1a. Buffer	Methanol	0 – 0.5%	67-56-1	Not applicable	Flam. Liq. 2: H225; Acute Tox. 3: H331; Acute Tox. 3: H311; Acute Tox.3: H301; STOT SE 1: H370
	Triton X100	0 – 0.5%	9002-93-1	Not applicable	Acute Tox. 4: H302; Eye Dam. 1: H318; Aquatic Chronic 2: H411;
R1b. Enzyme/Coenzymes & R2c. Enzyme Reagent	Sodium azide (Sodium azide (as NaN_3))	0 – 0.1%	26628-22-8	Not applicable	Acute Tox. 2: H300; Aquatic Acute 1: H400; Aquatic Chronic 1: H410
R2a. Enzyme Diluent	Triton X100	0 – 0.5%	9002-93-1	Not applicable	Acute Tox. 4: H302; Eye Dam. 1: H318; Aquatic Chronic 2: H411;
R2b. Maleimide	Maleimide	90-100%	541-59-3	Not applicable	Acute Tox. 3: H301; Skin Corr. 1B: H314; Skin Sens. 1: H317
CAL. Standard	Isopropanol (Propan-2-ol)	1-10%	67-63-0	Not applicable	Flam. Liq. 2: H225; Eye Irrit. 2: H319; STOT SE 3: H336
	Triton X-100	1-10%	9002-93-1	Not applicable	Acute Tox. 4: H302; Eye Dam. 1: H318; Aquatic Chronic 2: H411;

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures	
Inhalation	If inhaled, move victim to fresh air, rest and maintain a half-upright position. Use artificial respiration if necessary. Immediately seek medical attention.
Skin Contact	If skin contact occurs, remove contaminated clothes, rinse skin with plenty of cold water or shower. Seek medical attention.
Eye Contact	If eye contact occurs, first rinse with plenty of cold water for several minutes, then immediately seek medical attention.
Ingestion	If ingested, rinse mouth. Do not induce vomiting. Give plenty of water to drink. Immediately seek medical attention.
Self-protection of the first aider	Wear appropriate personal protective equipment (see section 8.2.2)
4.2 Most important symptoms and effects, both acute and delayed	Toxic if swallowed Causes severe skin burns and eye damage
4.3 Indication of any immediate medical attention and special treatment needed	Call an internal person trained in First Aid if available, or contact a physician.

SECTION 5. FIREFIGHTING MEASURES	
5.1 Extinguishing media	As appropriate for surrounding fire
5.2 Special hazards arising from the substance or mixture	May emit toxic fumes under fire conditions.
5.3 Advice for firefighters	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6. ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	Ensure adequate ventilation. Wear appropriate Personal Protective Equipment *e.g.* laboratory coat, gloves, safety glasses and mask.
6.2 Environmental Precautions	Not determined
6.3 Methods and materials for containment and cleaning up	Use appropriate spill absorbent kit as instructed by the manufacturer. Alternatively mop up with an absorbent material and hold for waste disposal.
6.4 Reference to other sections	Refer to Section 8 & 13

SECTION 7. HANDLING AND STORAGE	
7.1 Precautions for safe handling	Wear personal protective equipment (see section 8.2.2). Wash thoroughly after handling. Do not use if skin is cut or scratched. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke when using this product.
7.2 Conditions for safe storage, including any incompatibilities	Store at temperatures and conditions as indicated on the product label.
7.3 Specific end use (s)	For *in vitro* diagnostic use.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION	
8.1 Control Parameters	Not determined
8.2 Exposure Controls	
8.2.1 Appropriate engineering controls	Ensure adequate ventilation.
8.2.2 Personal protective equipment	
Eye/Face Protection	Approved safety glasses
Hand Protection	Standard laboratory rubber or latex gloves
Skin Protection	A laboratory coat is recommended
Respiratory Protection	Appropriate respiratory protection
8.2.3 Environmental Exposure Controls	Not determined

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES	
9.1 Information on basic physical and chemical properties	
Appearance	R1a, R2a, CAL - Liquid

	R1b, R2b, R2c - Solid
Colour	R1a, R2a, CAL - Colourless R2c - Pale yellow R1b - Off white
Odour	Not determined
Odour threshold (ppm)	Not determined
pH	R1a, R1b – pH 6.9 R2a – pH 7 R2b, R2c, CAL - Not determined
Melting point / Freezing point	R2b – 91 to 93ºC
Initial boiling point and boiling range	Not determined
Flash point (ºC)	CAL - 50
Evaporation rate	Not determined
Flammability (solid, gas)	Not determined
Upper/lower flammability or explosive limits	Not determined
Vapour pressure	Not determined
Vapour Density	Not determined
Relative Density	Not determined
Solubility(ies)	R1b, R2b, R2c – water soluble
Partition coefficient: (n-octanol/water)	Not determined
Auto ignition temperature (°C)	Not determined
Decomposition temperature (ºC)	Not determined
Viscosity (mPa.s)	Not determined
Explosive properties	Not determined
Oxidising properties	Not determined
9.2 Other information	Not determined

SECTION 10. STABILITY AND REACTIVITY	
10.1 Reactivity	Not determined
10.2 Chemical Stability	Stable under recommended storage conditions
10.3 Possibility of hazardous reactions	Not determined
10.4 Conditions to avoid	Not determined
10.5 Incompatible materials	Not determined
10.6 Hazardous decomposition products	Not determined

SECTION 11. TOXICOLOGICAL INFORMATION
11.1 Information on toxicological effects

Acute toxicity Ingestion Inhalation Skin Contact Eye Contact	Not determined Not determined Not determined Not determined Not determined
Skin corrosion/irritation	Not determined
Serious eye damage/eye irritation	Not determined
Respiratory or skin sensitization	Not determined
Germ cell mutagenicity	Not determined
Carcinogenicity	Not determined
Reproductive toxicity	Not determined
Summary of evaluation of the CMR properties	Not determined
STOT – Single exposure	Not determined
STOT- Repeated exposure	Not determined
Aspiration hazard	Not determined
11.2 Other information	Not determined

SECTION 12. ECOLOGICAL INFORMATION	
12.1 Toxicity	Not determined
12.2 Persistence and degradability	Not determined
12.3 Bioaccumulative potential	Not determined
12.4 Mobility in soil	Not determined
12.5 Results of PBT and vPvB assessment	Not determined
12.6 Other adverse effects	Not determined
12.7 Additional information	Not determined

SECTION 13. DISPOSAL CONSIDERATIONS	
13.1 Waste Treatment Methods	Each disposal facility must determine proper disposal methods of the substance or mixture and any contaminated packaging to comply with Local and National Environment Regulations. Refer to section 6.
13.2 Additional Information	Not determined

SECTION 14. TRANSPORT INFORMATION	
14.1 UN Number	Not classified as hazardous for transport
14.2 UN Proper Shipping Name	Not determined
14.3 Transport hazard class (es)	Not applicable
14.4 Packing Group	Not applicable
14.5 Environmental Hazards	Not determined

14.6 Special Precautions for User	Refer to section 7
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

SECTION 15. REGULATORY INFORMATION

This safety data sheet complies with the requirements of Regulation (EU) 2015/830

15.1 Safety, health and environmental Regulations/legislation specific for the substance or mixture	Not determined
15.2 Chemical Safety Assessments	A CSA has not been carried out

SECTION 16. OTHER INFORMATION

Text of Hazard Statements in Section 3

Skin Irrit. 2: H315 - Causes skin irritation.
Skin Corr. 1B: H314 - Causes severe burns and eye damage
Skin Sens. 1: H317 - May cause an allergic skin reaction
Eye Irrit. 2: H319 - Causes serious eye irritation.
STOT SE 1: H370 - Causes damage to organs
STOT SE 2: H371 - May cause damage to organs .
STOT SE 3: H335 - May cause respiratory irritation.
STOT SE 3: H336 - May cause drowsiness or dizziness
Eye Dam. 1: H318 - Causes serious eye damage.
Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects.
EUH032 - Contact with acids liberates very toxic gas.
Acute Tox. 2: H300 - Fatal if swallowed.
Acute Tox. 3: H301 - Toxic if swallowed
Acute Tox. 3: H311 - Toxic in contact with skin
Acute Tox. 3: H331 - Toxic if inhaled
Acute Tox. 4: H302 - Harmful if swallowed.
Aquatic Acute 1: H400 - Very toxic to aquatic life.
Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects
Aquatic Chronic 2: H411 - Toxic to aquatic life with long lasting effects.
Aquatic Chronic 3: H412 - Harmful to aquatic life with long lasting effects.
Flam. Liq. 2: H225 - Highly Flammable liquid and vapour
Flam. Liq. 3: H226 - Flammable liquid and vapour

Revision

Supersedes Revision B: Changes in section 2 (classification) and section 3

The information provided herein is believed to be correct as of the date hereof but does not purport to be all-inclusive and shall be used only as a guide. The information present in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. The recipient of our products is responsible for observing any National Laws and guidelines applicable.