SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	API 20E reagent kit (SDS Transport)
Registration number	-
Synonyms	None.
Product code	20120
Issue date	23-January-2020
Version number	01

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	In vitro diagnostic medical device
Uses advised against	None known.

1.3. Details of the supplier of the safety data sheet

Supplier

Company name	bioMerieux UK Limited
Address	Grafton Way, Basingstoke Hampshire RG22 6HY
Telephone	(44) 1256.461881
Fax	(44) 1256.816863
e-mail	uktechnical@biomerieux.com

Manufacturer

Company name	bioMérieux SA
Address	Chemin de l'Orme - 69280 Marcy-l'Etoile - France
Telephone	+33(0)478877656
Fax	+(1) 919 470 6819
e-mail	gcs_microbiology@biomerieux.com

1.4. Emergency telephone number	999 or Call a POISON CENTRE or doctor/physician

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended

Physical hazards		
Flammable liquids	Category 2	H225 - Highly flammable liquid and vapour.
Health hazards		
Acute toxicity, oral	Category 4	H302 - Harmful if swallowed.
Acute toxicity, dermal	Category 4	H312 - Harmful in contact with skin.
Skin corrosion/irritation	Category 1A	H314 - Causes severe skin burns and eye damage.
Serious eye damage/eye irritation	Category 1	H318 - Causes serious eye damage.
Specific target organ toxicity - single exposure	Category 3 respiratory tract irritation	H335 - May cause respiratory irritation.
Environmental hazards		
Hazardous to the aquatic environment, long-term aquatic hazard	Category 3	H412 - Harmful to aquatic life with long lasting effects.

Hazard summary Causes severe skin burns and eye damage. Harmful in contact with skin. Harmful if swallowed. Dangerous for the environment if discharged into watercourses.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains: 1-NAPHTHOL, ACETIC ACID, IRON (III) CHLORIDE, POTASSIUM HYDROXIDE

Hazard pictograms

Signal word Danger

Hazard statements

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements

Prevention

P260	Do not breathe mist/vapours.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Response

P301 + P312	IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313	If eye irritation persists: Get medical advice/attention.

Storage

P403	Store in a well-ventilated place.

Disposal Not available.

Supplemental label information None.

2.3. Other hazards This mixture does not meet vPvB / PBT criteria of Regulation (EC) No 1907/2006, Annex XIII.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	Index No.	Notes
ETHANOL	10 - < 20	64-17-5 200-578-6	01-2119457610-43-XXXX	603-002-00-5	
Classification:	Flam. Liq. 2;H225, Eye Irrit. 2;H319, Aquatic Chronic 2;H411				
ACETIC ACID	5 - < 10	64-19-7 200-580-7	01-2119475328-30-XXXX	607-002-00-6	#
Classification:	Flam. Liq. 3;H226, Acute Tox. 4;H312, Skin Corr. 1A;H314, Eye Dam. 1;H318, Acute Tox. 4;H332, Aquatic Chronic 3;H412				B
POTASSIUM HYDROXIDE	5 - < 10	1310-58-3 215-181-3	01-2119487136-33-XXXX	019-002-00-8	
Classification:	Acute Tox. 4;H302, Skin Corr. 1A;H314, Eye Dam. 1;H318, Aquatic Chronic 3;H412				
1-NAPHTHOL	1 - < 3	90-15-3 201-969-4	-	604-029-00-5	
Classification:	Acute Tox. 4;H302, Acute Tox. 4;H312, Skin Irrit. 2;H315, Eye Dam. 1;H318, Acute Tox. 2;H330, STOT SE 3;H335, Aquatic Chronic 2;H411				
IRON (III) CHLORIDE	1 - < 3	7705-08-0 231-729-4	-	-	
Classification:	Acute Tox. 2;H300, Skin Corr. 1C;H314, Eye Dam. 1;H318, Aquatic Chronic 2;H411				

List of abbreviations and symbols that may be used above

#: This substance has been assigned Union workplace exposure limit(s).
M: M-factor
PBT: persistent, bioaccumulative and toxic substance.
vPvB: very persistent and very bioaccumulative substance.
All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments The full text for all H-statements is displayed in section 16.

SECTION 4: First aid measures

General information Not available.

4.1. Description of first aid measures

Inhalation Not available.

Skin contact Take off immediately all contaminated clothing. Immediately flush skin with plenty of water. Get medical attention if irritation develops and persists.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth thoroughly. If swallowed: immediately call a poison centre or doctor/physician.

4.2. Most important symptoms and effects, both acute and delayed Burning pain and severe corrosive skin damage. Causes serious eye damage. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. May cause respiratory irritation.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

SECTION 5: Firefighting measures

General fire hazards Highly flammable liquid and vapour.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture Vapours may form explosive mixtures with air. Vapours may travel considerable distance to a source of ignition and flash back. During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist/vapours. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

For emergency responders Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Keep combustibles (wood, paper, oil etc) away from spilled material. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water.

Small Spills: Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

6.4. Reference to other sections For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not get in eyes, on skin, or on clothing. Do not taste or swallow. Avoid prolonged exposure. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight. Store in tightly closed container. Store in a well-ventilated place. Keep in an area equipped with sprinklers. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s) Not available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
ACETIC ACID (CAS 64-19-7)	STEL	50 mg/m3
		20 ppm
	TWA	25 mg/m3
		10 ppm
ETHANOL (CAS 64-17-5)	TWA	1920 mg/m3
		1000 ppm
IRON (III) CHLORIDE (CAS 7705-08-0)	STEL	2 mg/m3
	TWA	1 mg/m3
POTASSIUM HYDROXIDE (CAS 1310-58-3)	STEL	2 mg/m3

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU, 2017/164/EU

Components	Type	Value
ACETIC ACID (CAS 64-19-7)	STEL	50 mg/m3
		20 ppm
	TWA	25 mg/m3
		10 ppm

Biological limit values No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no effect levels (DNELs) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

Appropriate engineering controls Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Eye wash facilities and emergency shower must be available when handling this product.

Individual protection measures, such as personal protective equipment

General information Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection Wear safety glasses with side shields.

Skin protection

- Hand protection Wear protective gloves. Use protective gloves made of: Nitrile.

- Other Wear appropriate chemical resistant clothing.

Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal hazards	Not available.
Hygiene measures	When using do not smoke. Keep away from food and drink. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.
Environmental exposure controls	Inform appropriate managerial or supervisory personnel of all environmental releases. Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. Fume scrubbers, filters or engineering modifications to the process equipment may be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Liquid.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	78.5 °C (173.3 °F) estimated
Flash point	12.8 °C (55.0 °F) estimated
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	56.26 hPa estimated
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

9.2. Other information

Density	1.02 g/cm3 estimated
Percent volatile	21.86 % estimated
Specific gravity	1.02 estimated
VOC	22.39 % estimated

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
10.5. Incompatible materials	Acids. Strong oxidising agents. Maleic anhydride.

10.6. Hazardous decomposition products No hazardous decomposition products are known.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation May cause irritation to the respiratory system. Prolonged inhalation may be harmful.

Skin contact Causes severe skin burns. Harmful in contact with skin.

Eye contact Causes serious eye damage.

Ingestion Causes digestive tract burns. Harmful if swallowed.

Symptoms Burning pain and severe corrosive skin damage. Causes serious eye damage. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. May cause respiratory irritation.

11.1. Information on toxicological effects

Acute toxicity In high concentrations, vapours are anaesthetic and may cause headache, fatigue, dizziness and central nervous system effects. Harmful in contact with skin. Harmful if swallowed.

Components	Species	Test Results
1-NAPHTHOL (CAS 90-15-3)		
Acute		
Inhalation		
LC50	Rat	> 0.097 mg/l, 4 Hours
ACETIC ACID (CAS 64-19-7)		
Acute		
Dermal		
LD50	Rabbit	1060 mg/kg
Inhalation		
LC50	Rat	11.4 mg/l, 4 Hours
Oral		
LD50	Rat	3.31 g/kg
ETHANOL (CAS 64-17-5)		
Acute		
Inhalation		
LC50	Mouse	39 mg/l, 4 Hours
Oral		
LD50	Rat	6.2 g/kg
IRON (III) CHLORIDE (CAS 7705-08-0)		
Acute		
Oral		
LD50	Rat	28 mg/kg

Skin corrosion/irritation Causes severe skin burns and eye damage.

Serious eye damage/eye irritation Causes serious eye damage.

Respiratory sensitisation Due to partial or complete lack of data the classification is not possible.

Skin sensitisation Due to partial or complete lack of data the classification is not possible.

Germ cell mutagenicity Due to partial or complete lack of data the classification is not possible.

Carcinogenicity Due to partial or complete lack of data the classification is not possible.

Reproductive toxicity Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - single exposure May cause respiratory irritation.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Due to partial or complete lack of data the classification is not possible.

Mixture versus substance information No information available.

Other information Not available.

SECTION 12: Ecological information

12.1. Toxicity Harmful to aquatic life with long lasting effects. Based on available data, the classification criteria are not met for hazardous to the aquatic environment, acute hazard.

Components		Species	Test Results
1-NAPHTHOL (CAS 90-15-3)			
Aquatic			
Fish	LC50	Carp, hawk fish (Cirrhinus mrigala)	1.3 - 1.6 mg/l, 96 hours
ACETIC ACID (CAS 64-19-7)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	65 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus)	75 mg/l, 96 hours
ETHANOL (CAS 64-17-5)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	7.7 - 11.2 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	> 100 mg/l, 96 hours
IRON (III) CHLORIDE (CAS 7705-08-0)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	9.6 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus)	20.26 mg/l, 96 hours
POTASSIUM HYDROXIDE (CAS 1310-58-3)			
Aquatic			
Fish	LC50	Western mosquitofish (Gambusia affinis)	80 mg/l, 96 hours

12.2. Persistence and degradability No data is available on the degradability of any ingredients in the mixture.

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

1-NAPHTHOL	2.85
ACETIC ACID	-0.17
ETHANOL	-0.31

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil No data available.

12.5. Results of PBT and vPvB assessment This mixture does not meet vPvB / PBT criteria of Regulation (EC) No 1907/2006, Annex XIII.

12.6. Other adverse effects The product contains volatile organic compounds which have a photochemical ozone creation potential.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

UN number UN3316

UN proper shipping name CHEMICAL KIT

Transport hazard class(es)

class 9

Subsidiary risk -

Packing group	II
Environmental hazards	No.
Transport hazard class(es)	
Tunnel restriction code	E
Label(s)	9
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Transport hazard class(es)	
Hazard No. (ADR)	Not available.

RID

14.1. UN number	UN3316
14.2. UN proper shipping name	CHEMICAL KIT
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
14.4. Packing group	II
14.5. Environmental hazards	No.
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

ADN

14.1. UN number	UN3316
14.2. UN proper shipping name	CHEMICAL KIT
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
14.4. Packing group	II
14.5. Environmental hazards	No.
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IATA

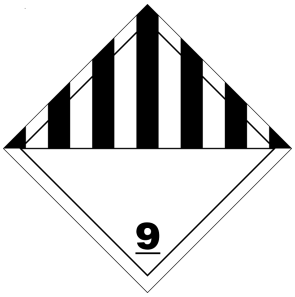
UN number	UN3316
UN proper shipping name	Chemical kit
Transport hazard class(es)	
class	9
Subsidiary risk	-
Packing group	II
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Environmental hazards	No.
ERG Code	9L

IMDG

UN number	UN3316
UN proper shipping name	CHEMICAL KIT
Transport hazard class(es)	
class	9
Subsidiary risk	-
Packing group	II
Environmental hazards	
Marine pollutant	No.
EmS	F-A, S-P
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

ADN; ADR; IATA; IMDG; RID



SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

IRON (III) CHLORIDE (CAS 7705-08-0)

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

ETHANOL (CAS 64-17-5)

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

ACETIC ACID (CAS 64-19-7)
ETHANOL (CAS 64-17-5)

Other regulations	The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.
National regulations	Young people under 18 years old are not allowed to work with this product according to EU Directive 94/33/EC on the protection of young people at work, as amended. Follow national regulation for work with chemical agents in accordance with Directive 98/24/EC, as amended.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	Not available.
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any H-statements not written out in full under Sections 2 to 15	H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.
H300 Fatal if swallowed.
H302 Harmful if swallowed.
H312 Harmful in contact with skin.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H330 Fatal if inhaled.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

Revision information Transport Information: Material Transportation Information

Training information Follow training instructions when handling this material.

Disclaimer bioMérieux SA cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.