Contents Ref. 160001:

Summary

The Apacor Transportation Vial with Apafix™ offers standardised protocol for the handling of microbiological materials. Its ease of use allows for the correct procedures to be maintained for the routine collection, transportation, preservation, and the examination of stool samples for the identification of intestinal parasites.

Description

In the laboratory intestinal parasites are confirmed by the identification of cysts, protozoan trophozoites, larvae and helminth eggs.

The priorities of these clinical laboratories do not always permit the immediate examination of a fresh sample.

The prompt collection and transportation of these samples cannot always be guaranteed.

Furthermore, freezing, refrigeration and / or incubation of samples cannot ensure the full recovery of parasites at all stages of identification.

The Apacor Transportation Vial with Apafix™ will preserve the intestinal parasites in the faecal material until such time it can be examined by a qualified parasitologist.

Principles of Use

We provide a fixative for cysts, protozoan trophozoites, larvae and helminth eggs in a stabilised solution.

This method of transportation is commonly used for concentrating and temporary staining, such as Lugol's Iodine.

Composition

Each kit consists of 40 x 30ml transportation vials containing 15ml Apafix™ and instructions for use.

Sample Collection

Testing should be conducted by trained staff recognised by local regulatory requirements.

1. The patient should be warned before the collection of the sample against the use of substances such as oily laxatives, bismuth, antacids, anti-diarrheal medication and barium.

2. For optimum results, 3 samples should be collected from the patient over the course of 3 days. This will guarantee finding all stages of the parasite life cycle. Variable quantities of parasites can pass through a patient; therefore collecting samples over 3 days will guarantee a higher yield. Samples should be collected over a designated length of time to avoid prolonged hospital visits.

3. A clean container should be used to collect the sample. Place something in the toilet to catch the stool, such as a potty or an empty plastic food container, or spread clean newspaper or plastic wrap over the rim of the toilet. Please note: Urine must not contaminate the sample.

4. Each vial should have enough sample to bring the Apafix™ up to the 15 ml line. This is approximately an extra 5 ml of sample. This should be completed by using the collection spoon attached to the vial cap and selecting the appropriate slimy, bloody, watery areas of a sample. When sampling a formed stool, material can be taken from anywhere on the sample.

5. Shake the vial firmly until it has emulsified with the Apafix™. Please ensure that the cap has been closed tightly and that the sample has been agitated with the spoon.

6. Label the vial with the date, your name, and date of birth and return the vial(s) in a sealed bag.

APACOR

Transportation Vial with Apafix™

APACOR
UNIT 5, SAPPHIRE CENTRE
FISHPONDS ROAD, WOKINGHAM
BERKSHIRE, RG41 2QL, UNITED KINGDOM
TEL: +44 (0)118 979 5566
FAX: +44 (0)118 979 5186

EC REP
MDSS GmbH
Schiffaraben 41
30175 Hanover
Germany

IVD

CE

APA744 V1.2 01/2021

APAFIX™ SAFETY DATA SHEET

This Safety Datasheet complies with the requirements of Regulation (EC) No 1907/2006

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/ MIXTURE AND THE COMPANY/UNDERTAKING

1.1 Product Identifier: Apafix™

108801, 108887 145002, 145003, 145005 146003, 146004, 146005, 149901, 160001, 902500, 907500

1.2 Relevant identified uses of the substance or mixture and uses advised against: laboratory chemical (in vitro diagnostic)

1.3 Details of the supplier of the Safety Data Sheet:

Apacor Limited, Unit 5 Sapphire Centre, Fishponds Road, Wokingham, Berkshire, RG41 2QL, United Kingdom
+44 (0) 118 979 5566
technical@apacor.com

1.4 Emergency telephone number:

+44 (0)118 979 5566
(Monday-Friday 0900-1700 excluding UK Public Holidays)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]:
The mixture does not present a physical or chemical hazard.
See Section 16 for the full text of H-Statements mentioned in this section.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard statement(s)

NC Not Classified

Precautionary statements:

P261 – Avoid breathing vapour/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Contains Acetic Acid

2.3 Other hazards

No data available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component: **Acetic Acid**
CAS No: 64-19-7
EC No: 200-580-7
Index No: 607-002-00-6
Registration No: -
Classification: Skin Corr. 1A (H314), Flam. Liq. 3 (H226), Eye Dam. 1 (H318)
Concentration: < 10%

Component: **Menthol**
CAS No: 89-78-1
EC No: 201-939-0
Index No: 603-001-00-x
Registration No: 01-2119433307-44-xxxx
Classification: Flam. Liq. 2 (H225), Acute Tox 3 (H301 + H311 + H331), STOT SE 1 (H370)
Concentration: < 1%

Component: **Thymol**
CAS No: 89-83-8
EC No: 201-944-8
Index No: 604-032-00-1
Registration No: -
Classification: Acute Tox. 4 (H302), Skin Corr. 1B (H314), Aquatic Chronic 2 (H411)
Concentration: < 1%

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Consult a physician. Show this safety data sheet to the doctor in attendance.

In case of eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

In case of skin contact: Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Consult a physician if discomfort continues.

If swallowed: Clean mouth with water and drink afterwards plenty of water. Consult a physician.

If inhaled: Move to fresh air. Consult a physician if discomfort continues.

4.2 Most important symptoms and effects, both acute and delayed

The most important symptoms and effects are described in the labelling Section 2.2 and/or Section 11.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician: Treat symptomatically. Have facilities in place to wash skin and eyes in case of exposure. Severe cases of exposure should receive prompt medical attention.

Eye contact – May cause eye irritation. May cause redness.

Skin Contact – May irritate the skin.

Ingestion – May irritate the mouth and throat. Small amounts will leave taste in mouth, larger amounts may cause nausea and vomiting.

Inhalation – Acute: May irritate the respiratory system and cause coughing. Delayed: Prolonged exposure to vapours or mists can cause damage to the mucous membranes of the respiratory system.

SECTION 5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

This product is non-combustible. Water spray, dry powder, carbon dioxide or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

In case of fire, toxic or irritating fumes or vapours may be formed. Contact with metals may form hydrogen gas which is flammable and can result in explosion.

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment, gloves and protective eye glasses. Ensure adequate ventilation, especially in confined areas.

6.2 Environmental precautions

Should not be released into the environment. Prevent product from entering drains. Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

Absorb spill with inert material (e.g. dry sand or earth), then place in a chemical waste container. After cleaning, flush away traces with water.

6.4 Reference to other sections

For disposal, see Section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Do not breathe vapours or spray mist. Ensure that ventilation is adequate before using this product. Avoid contact with skin and eyes. Take necessary personal protective precautions before using this product. Keep away from heat and flame.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool place. Keep container tightly closed in a dry well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

7.3 Specific end use(s)

The identified uses for this product are detailed in Section 1.2.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

	Acetic Acid 64-19-7
Austria	STEL: 20ppm STEL: 50mg/m^3 TWA: 10ppm TWA: 25 mg/m^3
Belgium	STEL: 15ppm STEL: 38 mg/m^3 TWA: 10ppm TWA: 25mg/m^3
Denmark	STEL: 20ppm STEL: 50 mg/m^3 TWA: 10ppm TWA: 25 mg/m^3
France	STEL: 10ppm STEL: 25 mg/m^3
Germany	STEL: 20ppm STEL: 50 mg/m^3 TWA: 10ppm TWA: 25 mg/m^3
Ireland	STEL: 15ppm STEL: 37 mg/m^3 TWA: 10ppm TWA: 25 mg/m^3
Italy	TWA: 10ppm TWA: 25 mg/m^3
Poland	STEL: 30 mg/m^3 TWA: 15 mg/m^3
Portugal	STEL: 10ppm TWA: 10ppm TWA: 25 mg/m^3
Spain	STEL: 15ppm STEL: 37 mg/m^3 TWA: 10ppm TWA: 25 mg/m^3
Sweden	STEL: 10ppm STEL: 25 mg/m^3 TWA: 5ppm TWA: 13 mg/m^3

8.2 Exposure controls

8.2.1 Appropriate Engineering Controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the workday. Ensure adequate ventilation, especially in confined areas.

8.2.2 Personal protective equipment

(a) Eye/face protection: Tightly fitting safety goggles. Face shield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

(b) Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves should satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

(c) Body Protection: Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

(d) Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the

respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

8.2.3 Environmental exposure controls

See section 6.2

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance: Form: liquid
Colour: Clear

b) Odour: pungent/acetic acid + distinct thyme smell

c) Odour threshold: no data available

d) pH: ≤1

e) Melting point / freezing point: no data available

f) Initial boiling point / boiling range: no data available

g) Flash point: Not applicable. The mixture is non-flammable.

h) Evaporation rate: no data available

i) Flammability (solid, gas): no data available

j) Upper/lower flammability or explosive limits: Not applicable. The mixture is non-flammable.

k) Vapour pressure: no data available

l) Vapour density: no data available

m) Relative density: no data available

n) Solubility (ies): soluble in water

o) Partition coefficient: n-octanol/water: no data available

p) Auto-ignition temperature: no data available

q) Decomposition temperature: no data available

r) Viscosity: no data available

s) Explosive properties: no data available

t) Oxidising properties: no data available

9.2 Other information

No data available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Reactions characteristic of weak acids.

10.2 Chemical stability

Stable under recommended handling and storage conditions under Section 7.

10.3 Possibility of hazardous reactions

May react vigorously or exothermically. Pressure may build up if reaction occurs in a sealed container. Will not polymerise.

10.4 Conditions to avoid

Avoid heat, direct sunlight and moisture. Avoid storage in freezing conditions. Avoid storage with incompatible materials. Avoid storage in an unstable manner or in a situation that would result in exposure to the product. It is advisable to store the product within some form of containment to prevent spillages reaching drainage systems.

10.5 Incompatible materials

Alkalis. Oxidising agents. Metals.

10.6 Hazardous decomposition products

Under normal use – none

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information of toxicological effects

Acute toxicity:

Product: The mixture has not been tested for toxicological properties. This information refers to acetic acid as a pure substance.

Inhalation: Industry – Dermal; Long term systemic effects 22mg/kg/day Haematological effects

Eye contact: no data available

Skin contact: no data available

Ingestion: Sodium salt of acetic acid, pH 6-7

Skin corrosion/irritation: Dose: 0.5ml, 4 hr, Rabbit Primary dermal irritation index: 1.1 OECD Guideline 404 10% solution. Slightly irritating.

Serious eye damage/eye irritation: OECD 405, rabbit, 10% solution, 4 hour, 0.1ml. Erythema = 2.67, corneal swelling = 87%.

Respiratory or skin sensitisation: no data available

Germ cell mutagenicity: no data available

Carcinogenicity: no data available

Reproductive toxicity: no data available

Specific target organ toxicity - single exposure: no data available

Specific target organ toxicity - repeated exposure: no data available

Aspiration hazard: no data available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

The mixture has not been tested for ecotoxicological properties.

The following information contained in section 12 refers to acetic acid as a pure substance.

Acute toxicity – fish: LC50, 96 hours: > 1000 mg/l, Onchorhynchus mykiss (Rainbow trout)
OECD 203 (Fish, Acute Toxicity Test)
Freshwater, semi-static.
Mortality

Acute toxicity – aquatic invertebrates: EC_{50}, 48 hours: > 300.82 mg/l, Daphnia magna
OECD Guideline 202.
Static, freshwater.
Mobility.
Test substance potassium acetate; result based on the acetate ion.

Acute toxicity – aquatic plants: EC_{50}, 72 hours: > 300.82 mg/l, Static, saltwater, Skeletonema costatum.
Test substance potassium acetate; result based on the acetate ion.

Acute toxicity – microorganisms: EC_{50}: 850 mg/l, Industry - Dermal; Long term systemic effects 22 mg/kg/day
Pseudomonas putida, static, freshwater, 16 hour

Acute toxicity – terrestrial: Not available.

Chronic toxicity – fish early life stage: Not available.

Short term toxicity – embryo and sac fry stages: Industry - Dermal; Long term systemic effects 22 mg/kg/day
No supplied or registered information.
Chronic toxicity – aquatic invertebrates: Not available.
Toxicity to soil: Not available.
Toxicity to terrestrial plants: Not available.
12.2 Persistence and degradability
Phototransformation: Water - DT_{50}: 26.7 days
Degradation by hydroxyl radicals.
Calculated value.
Stability (hydrolysis): Scientifically unjustified.
Biodegradation: Water – Degradation (%) 96%: 20 days
Readily biodegradable – Half life: 2 days
Biological oxygen demand: No information available.
Chemical oxygen demand: No information available.
12.3 Bioaccumulative potential
BCF: 3.16, QSAR calculation. Fish, freshwater. Not bioaccumulating.
12.4 Mobility in soil
No information available.
12.5 Results of PBT and vPvB assessment
PBT or vPvB not classified according to current EC criteria.
12.6 Other adverse effects
No information available.
12.7 Additional information
No information available.

SECTION 13: DISPOSAL CONSIDERATIONS
Proper waste management of the mixture and its container must be determined in accordance with directive 2008/98/EC.
13.1 Waste treatment methods
13.1.1 Product/packaging disposal
Do not pour into drains or waterways. Recycle of dispose of waste in compliance with current, local legislation, preferably via a certified waste company.

SECTION 14: TRANSPORT INFORMATION
IATA/DOT/IMDG/TDG - Not regulated
14.1 UN number: Not applicable
14.2 UN proper shipping name: Not applicable
14.3 Transport hazard class(es): Not applicable
14.4 Packing group: Not applicable
14.5 Environmental hazards: Not applicable
14.6 Special precautions for user: Not applicable

SECTION 15: REGULATORY INFORMATION
15.1 Safety, health and environmental regulations/ legislation specific for the substance or mixture
National regulations: Industry – Dermal; Long term systemic effects 22mg/kg/day
EU legislation: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended).
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended).
Regulation (EU) 453/2010.
15.2 Chemical Safety Assessment
A chemical safety assessment was not carried out for this mixture.

SECTION 16: OTHER INFORMATION
The information in this datasheet is based on our current level of knowledge and on national and international regulations. The mixture must not be used for other purposes than those specified in Section 1. It is at all times the responsibility of the use to take all necessary measures to comply with legal requirements and local regulations. The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Full text of H-Statements referred to under sections 2 and 3
H226 – Flammable liquid and vapour
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
P261 – Avoid breathing vapour/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
The above information is believed to be correct but does not purport to be all inclusive and shall be used as a guide. Apacor shall not be held liable for any damages resulting from handling or from contact with the above product, since the user's working conditions are not known by Apacor.

EC REP
MDSS GmbH
Schiffaraben 41
30175 Hanover
Germany