H. Pylori Ag Rapydtest®

APACOR

H. pylori Ag Rapydtest®

BACTERIOLOGY

SINGLE USE IN VITRO DIAGNOSTIC DEVICE

H. pylori Ag Rapydtest®

Intended Use

The H. pylori Ag Rapydtest® is a lateral flow chromatographic immunoassay for the qualitative detection of H. pylori antigen in human faecal specimen. It is intended to be used by professionals as a screening test and provides a preliminary test result to aid in the diagnosis of infection with H. pylori.

Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

Summary and Explanation of the Test

Helicobacter pylori (H. pylori) a gram-negative, helical, rod-shaped bacterium, colonizes the gastric mucosa of approximately one-half of the world population[1]. H. pylori infection is a risk factor for a variety of gastrointestinal diseases including non-ulcer dyspepsia, duodenal and gastric ulcers and active, chronic gastritis[2-6]. Therefore elimination of H. pylori may be the most promising strategy to reduce the incidence of gastric cancer[7].

H. pylori can be transmitted through the ingestion of food or water that is tainted with faecal matter. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. pylori infection.

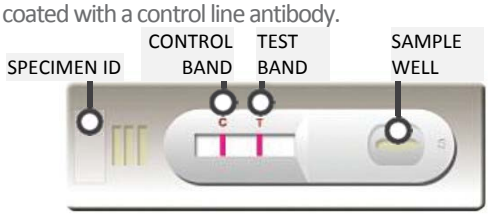
H. pylori infection is currently detected by invasive testing methods based on endoscopy and biopsy (i.e. histology, culture) or non-invasive testing methods such as Urea Breath Test (UBT), serologic antibody test and stool antigen test. UBT has a high accuracy but requires expensive lab equipment and use of a radioactive reagent[8]. Serologic antibody tests detect IgG specific to H. pylori, and cannot distinguish between current active infections and past infections. The stool antigen test detects antigen present in the faeces, which indicates an active H. pylori infection. It can also be used to monitor the effectiveness of treatment and the recurrence of an infection, and is not affected by the use of Proton Pump Inhibitors (PPI)[9].

The H. pylori Ag Rapydtest detects H. pylori antigen present in the faecal specimen by using specific antibodies. The test can be performed within 10 minutes by minimally skilled personnel without the use of laboratory equipment.

Test Principle

The H. pylori Ag Rapydtest® is a lateral flow chromatographic immunoassay. The test strip in the cassette device consists of:

1. a burgundy coloured conjugate pad containing anti-H. pylori specific antibody conjugated with colloidal gold (anti-H. pylori conjugate); and
2. a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with anti-H. pylori antibody, and the C band is pre-coated with a control line antibody.



When an adequate volume of extracted faecal specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The H. pylori antigen, if present in the specimen, will bind to the anti-H. pylori conjugate. The immunocomplex is then captured on the membrane by the pre-coated antibody, forming a burgundy coloured T band, indicating an H. pylori positive test result. Absence of the T band suggests an H. pylori negative test result.

The test contains an internal control (C band) which should exhibit a burgundy coloured band of the immunocomplex of the control antibodies regardless of the colour development on the T band. If no control (C band) develops, the test result is invalid and the specimen must be retested with another device.

Reagents and Materials Provided

1. Individually sealed foil pouches containing:
   a. One cassette test device.
   b. One desiccant.
2. Sample collection tubes, each containing 1ml of extraction buffer.
3. Plastic droppers for transferring watery stool.
4. Patient ID stickers.
5. One package insert (instruction for use).

Materials Required but not Provided

1. Clock or timer.
2. A container to hold faecal specimen.

Warnings and Precautions

For in Vitro Diagnostic use

1. This package insert must be read completely before performing the test. Failure to follow the insert can give inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use any kit components beyond their stated expiration date.
4. Do not use the components from any other type of test kit as a substitute for the components in this kit.
5. Bring all reagents to room temperature (15°C - 30°C) before use.
6. Do not scoop stool sample as this may lead to excess faecal specimen that tends to clog the sample pad and interfere with sample migration.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the universal precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Avoid extraction buffer contact with skin or eyes. Do not ingest.
11. Dispose of all specimens and materials used to perform the test as biohazardous waste.
12. The test results should be read 10-15 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside of the 10-15 minute window should be considered invalid and must be repeated.
13. Do not perform the test in a room with strong air flow, ie electric fan or strong air-conditioning.

Reagent Preparation and Storage Instructions

All reagents are ready to use as supplied. Store unopened test devices at 2°C - 30°C. If stored at 2°C - 8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures over 30°C.

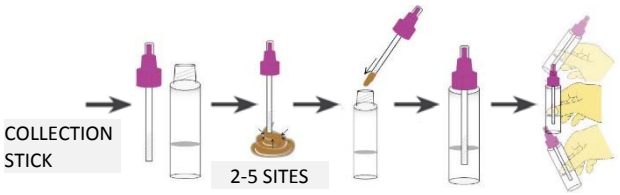
Specimen Collection and Handling

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

To prepare specimens using solid stool samples follow Procedure A below. To prepare specimens using watery stool samples follow Procedure B below.

Procedure A: Solid stool samples

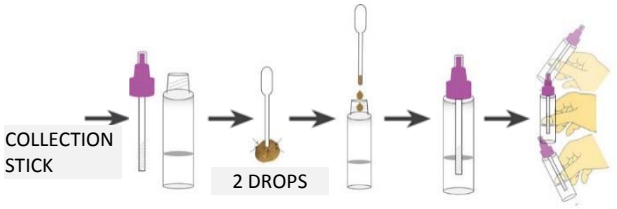
1. Collect a random stool sample in a clean, dry receptacle.
2. Label the sample collection tube with the specimen's ID number (patient ID sticker). Open the sample collection tube by unscrewing the top and use the collection stick to randomly pierce the stool sample in 2-5 different sites, twisting the collection stick into the stool specimen to help collection is necessary. Do not scoop stool sample as this may lead to an invalid test result.
3. Ensure that all inner grooves of the collection stick are filled with stool sample. Excess stool sample on the outside of the grooves should be scraped off. Incorrect sampling may lead to an erroneous test result.
4. Replace the collection stick and tighten securely to close the sample collection tube.
5. Shake the sample collection tube vigorously.



The specimen is now ready for testing, transportation or storage.

Procedure B: Watery stool samples

1. Collect a random stool sample in a clean, dry receptacle.
2. Label the sample collection tube with the specimen's ID number (patient ID sticker). Open the sample collection tube by unscrewing the top.
3. Fill the plastic dropper with the sample; dispense 2 drops (70-85µL) into the sample collection tube.
4. Replace the collection stick and tighten securely to close the sample collection tube.
5. Shake the sample collection tube vigorously.



The specimen is now ready for testing, transportation or storage.

Note: Specimens extracted may be stored at 2°C-8°C or at room temperature up to 37°C for 10 days. For longer storage, the extracted specimen may be frozen at -20°C. Avoid multiple free-thaw cycles.

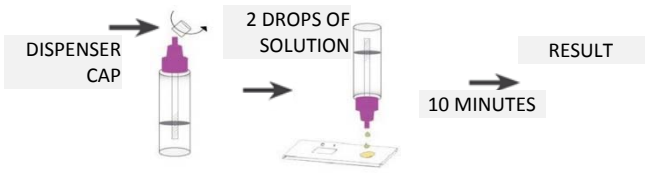
Test Procedure

Step 1 Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2 When ready to test, open the pouch at the notch and remove the test device. Place the test device on a clean, flat surface.

Step 3 Shake the sample collection tube vigorously to ensure a homogenous liquid suspension.

Step 4 Position the sample collection tube upright and twist off the dispenser cap. Dispense 2 drops (70-90µl) of the solution into the sample well of the cassette. Do not overload the solution.



Step 5 Set up the timer.

Step 6 Results can be read 10 minutes after adding the specimen. Positive results can be visible in a time period as short as 1 minute. Negative results must be confirmed at the end of the 15 minutes only. However, any results interpreted outside of the 10-15 minute window should be considered invalid and must be repeated. Discard used device after interpreting the result following local requirements governing the disposal of device.

Quality Control

1. Internal Control: This test contains a built-in control feature, the C band. The C band develops after adding specimen extract. If the C band does not develop, review the entire procedure and repeat the test with a new device.
2. External Control: Good Laboratory Practice recommends using external positive and negative controls to assure the proper performance of the assay, particularly under the following circumstances:
   a. A new operator uses the kit, prior to performing testing of specimens.
   b. A new lot of test kits is used.
   c. A new shipment of kits is used.
   d. The temperature during storage of the kit falls outside of 2 - 30°C.
   e. The temperature of the test area falls outside of 15 - 30°C.
   f. To verify a higher than expected frequency of positive or negative results.
   g. To investigate the cause of repeated invalid results.

Interpretation of Assay Result

1. **Negative Result:** If only the C band is developed, the test indicates that no detectable H. pylori antigen is present in the specimen. The result is negative or non-reactive.

2. **Positive Result:** If both C and T bands develop, the test indicates the presence of H. pylori antigen in the specimen. The result is positive or reactive.

3. **Invalid:** If no C band develops, the assay is invalid regardless of any colour development on the T band as indicated below. Repeat the assay with a new test device. Excess faecal specimen can lead to invalid test results; if this is the cause, re-sample and re-test (see instructions for collection of specimen).

Performance Characteristics

Clinical Performance

A total of 157 faecal specimens were collected from symptomatic patients and healthy individuals. Specimens were tested with the H. pylori Ag Rapydtest®. The urea breath test (UBT) gold standard is used as the reference test method. Comparison for all subjects is shown in the following table:

	H. pylori Ag Rapydtest®		
UBT	Positive	Negative	Total
Positive	58	2	60
Negative	6	91	97
Total	64	93	157

Relative Sensitivity: 96.7%, Relative Specificity: 93.8%, Overall Agreement: 94.9%

Analytic Sensitivity

Six groups of faecal specimen extracts from 20 healthy individuals were spiked with H. pylori lysate antigen (Strain 43504) at concentrations of 0, 0.25, 0.5, 0.75, 1, and 2ng/mL, respectively, and tested with the H. pylori Ag Rapydtest®. The results are showed in the following table. The detection limit of the H. pylori Ag Rapydtest® as defined as the level of ≥95% positive detection is 1ng/mL of H. pylori lysate antigen.

H. pylori lysate ng/ml	0	0.25	0.5	0.75	1	2
Positive	0	0	0	9	20	20
Negative	20	20	20	11	0	0
Detection Rate %	0	0	0	45	100	100

n=20, relative sensitivity at 1ng/mL is 100%

Cross-Reactivity

The organisms listed below were tested for cross-reactivity with the H. pylori Ag Rapydtest®. No cross-reactivity was observed on the organisms at ≥ 1 x 108 org/ml.

Acinetobacter calcoaceticus
Adenovirus
Enterococcus faecalis
Escherichia coli
Gardnerella vaginalis
Geotrichum candidum
Haemophilus influenza
α-haemolytics streptococcus
B-haemolytic streptococcus
Klebsiella pneumonia
Moraxella catarrhalis
Neisseria gonorrheae
Neisseria meningitides
Proteus mirabilis
Proteus vulgaris Hauser
Pseudomonas aeruginosa
Rotavirus
Salmonella Paratyphi A
Salmonella Paratyphi B
Salmonella Paratyphi C
Salmonella typhi

Interference

The following common and potentially interfering substances may affect the performance of the H. pylori Ag Rapydtest®. This was studied by spiking these substances into negative and positive faecal specimens, respectively. The results demonstrate, at the concentrations tested, the substances studied do not affect the performance of the H. pylori Ag Rapydtest®.

List of potentially interfering substances and concentrations tested:

Tums® Antacid	5mg/ml	Pepto-Bismol® Antacid	1:20
Tagamet® Antacid	5mg/ml	Barium sulfate	5%
Prilosec® Antacid	5mg/ml	Haemoglobin (tarry stool)	12.5%
Mylanta® Antacid	1:20		

Limitations

1. The Test Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of H. pylori antigen in faeces. **Failure to follow the procedure, particularly the Specimen Collection and Handling procedure, may lead to inaccurate results.**
2. The H. pylori Ag Rapydtest® is limited to the qualitative detection of H. pylori antigen in human faecal specimen. The intensity of the test band does not have linear correlation with antigen titer in the specimen.
3. A negative or non-reactive result indicates the absence of detectable H. pylori antigen. However, a negative test result does not preclude the possibility of infection with H. pylori.
4. A negative or non-reactive result can occur if the quantity of the H. pylori antigen present in the specimen is below the detection limits of the assay or if the antigens that are detected are not present in the faecal specimen collected.
5. It is reported that the seroprevalence of H. pylori in specimens with positive faecal occult blood (FOB) test results is approximately 39.3%[10]. Therefore a specimen that tests positive with an FOB test may also be tested positive with the H. pylori Ag Rapydtest®.
6. If symptoms persist and the result from the H. pylori Ag Rapydtest® is negative or non-reactive, it is recommended to test with alternative test methods.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

References

1. Fashner J, Gitu AC. Diagnosis and Treatment of Peptic Ulcer Disease and H.pylori infection. Am Fam Physician. 2015 Feb 15;91(4):236-42
2. Asaka M, Kato M, Takahashi S, et al. Guidelines for the management of Helicobacter pylori infection in Japan: 2009 revised edition. Helicobacter 2010; 15:1–20.
3. Fischbach W, Malfertheiner P, Hoffmann JC, et al. S3-guideline "helicobacter pylori and gastroduodenal ulcer disease" of the German society for digestive and metabolic diseases (DGVS) in cooperation with the German society for hygiene and microbiology, society for pediatric gastroenterology and nutrition e. V., German society for rheumatology, AWMF-registration-no.021/001. Z Gastroenterol 2009;47:1230–63.
4. Fock KM, Talley N, Moayyedi P, et al. Asia-Pacific consensus guidelines on gastric cancer prevention. JGastroenterolHepatol 2008;23:351–65.
5. Malfertheiner P, Bornschein J, Selgrad M. Role of Helicobacter pylori infection in gastric cancer pathogenesis: a chance for prevention. J Dig Dis 2010;11:2–11.
6. Polk DB, Peek RM Jr. Helicobacter pylori: gastric cancer and beyond. Nat Rev Cancer 2010;10:403–14.
7. Malfertheiner P, Megraud F, O'Morain CA, et al. European Helicobacter Study Group. Management of Helicobacter pylori infection—the Maastricht IV/ Florence Consensus Report. Gut 2012;61:646–64.
8. Shimoyama T, Kato T, Kodama M, et al. Applicability of a monoclonal antibody-based stool antigen test to evaluate the results of Helicobacter pylori eradication therapy. Jpn J Infect Dis 2009. 62(3):225-7.
9. Peter M, Francis M, Colm AO, et al. Management of Helicobacter pylori infection-the Maastricht IV/ Florence Consensus Report. Gut. 2012 May;61(5):646-64.
10. Ugwuja E, Ugwu N. An Assessment of Faecal Occult Blood Test and H. pylori infection in Patients with Uninvestigated Dyspepsia in Primary Health Cares in Abakaliki, Nigeria. The Internet J of laboratory Medicine 2003 V3 No. 1.

Ordering Information

PRODUCT	PACK SIZE	CODE
H. pylori Ag Rapydtest®	25	1632

Products can be ordered direct from Apacor or from an appointed distributor

Visit our website for all the latest information www.apacor.com or e-mail on: orders@apacor.com

APACOR

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30175 Hanover
Germany

IVD

APA125 – V4.4 01/2021

SAFETY DATASHEET
SAMPLE EXTRACTION BUFFER – H.PYLORI AG RAPYDTEST®

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:** 1632 Sample Extraction Buffer H.pylori Ag Rapydtest®

1.2 **Relevant identified uses of the substance or mixture and uses advised against:** Lateral flow immunochromatographic assay for the qualitative detection of antigen in human faecal specimens. These tests are for in vitro use only.

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]: Not classified as hazardous in concentration of <0.1% (Sodium Azide).

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]: The product does not contain a hazardous ingredient in an amount that requires identification and labelling according to the concentration limit/cut-off values of EC directives. This product contains no hazardous constituents, or the concentration of all chemical constituents is below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200 and the European Directive 91/155/EEC, 93/112/EC and (EC) 1272/2008 (CLP).
Pictogram: None
Signal Word: -
Hazard statement(s): -
Precautionary statements:-

2.3 Other hazards

Bio-hazards: All the biological substances are derived from in vitro culture system or animal materials which are free of known-pathogens for human. Thus, no bio-hazardous can be claimed in the product.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous ingredients according to Regulation (EC) No 1272/2008
Substance Name: Sodium Azide
CAS #: 26628-22-8
Index No: -
EC Number: 247-852-1
Classification: Acute Tox. 2 (H300), Aquatic Acute 1 (H400), Aquatic Chronic 1 H410, EUH032
Amount: 0.09%
See Section 16 for the full text of H-Statements mentioned in this Section.

Note: The strip is composed of nitrocellulose membrane, vinyl matte adhesive, fibre absorbent pad, fibre sample pad, fibre conjugate pad. The nitrocellulose membrane and the fibre conjugate pad contain dried biological substances preserved by sodium azide. The identity of each biological substance is confidential.

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.
If inhaled: Inhalation of any component in this kit is unlikely. If a component of this kit is inhaled and causes discomfort, move exposed individual to fresh air. Seek medical attention if breathing is difficult or symptoms persist.
In case of skin contact: The Sample Extraction Buffer is not likely to be hazardous by skin contact. However, in case of contact, immediately clean skin with plenty of water. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. The animal proteins and dried reagents absorbed into the nitrocellulose membrane and the fibre conjugate pad are very unlikely to be hazardous by skin contact, but cleaning the skin after use is advisable.
If swallowed: Ingestion of small amounts of the Sample Extraction Buffer should not be toxic, however, a physician should be consulted immediately. The animal proteins and dried reagents absorbed into the nitrocellulose membrane and the fibre conjugate pad are very unlikely to be ingested or be hazardous by ingestion. However, a physician should be consulted should ingestion occur.
In case of eye contact: The test device is very unlikely to come into contact with the eye, however, a physician should be consulted should contact occur. In case of contact with the Sample Extraction Buffer, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.
Aggravating Condition: Repeated or prolonged exposure is not known to aggravate medical conditions.

4.2 Most important symptoms and effects, both acute and delayed

The most important known 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

No data available.

SECTION 5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

For small fires, use dry chemical, carbon dioxide, or alcohol-resistant foam. No direct contact with water.

5.2 Special hazards arising from the substance or mixture

This material will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the surrounding fire. Utilize proper personal protective equipment when responding to any fire. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-

Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

5.3 Advice for firefighters
When involved in a fire, this material can decompose and produce irritating fumes and toxic gases (e.g., carbon monoxide, carbon dioxide, sulfuric dioxide). Explosion Sensitivity to Mechanical Impact: Not sensitive under normal conditions. Explosion Sensitivity to Static Discharge: Not sensitive under normal conditions.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Lab coat and gloves.

6.2 Environmental precautions
No data available.

6.3 Methods and material for containment and cleaning up
Use absorbent paper towel or cloth to absorb the spill solution and dispose or clean the contaminated surface in accordance with local procedures or appropriate standards

6.4 Reference to other sections
For disposal, see Section 13.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling
Do not eat, drink, smoke or apply cosmetics in laboratory area. Use the product according to the product insert.

7.2 Conditions for safe storage, including any incompatibilities
Keep container tightly closed. Keep product at 2-30°C. Do not freeze or expose to temperature higher than 30°C. Keep away from children.

7.3 Specific end use(s)
No other specific uses are specified apart from those listed in Section 1.2.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

CAS #	Chemical Name	OSHA (PEL)	ACGIH (TLV)*	MAK
26628-22-8	Sodium Azide	0.3mg/m³	0.29mg/m³	0.2mg/m³

Biological Exposure Index (ACGIH)
Other exposure limits for potential decomposition products: None.

8.2 Exposure controls
Engineering Control: Eye bath. Use adequate ventilation to keep airborne concentrations low.
Hygiene Measures: Wash hands after handling compounds and before eating, smoking, using lavatory, and at the end of the day.
Personal Protective Equipment:
Respiratory Protection: None needed under normal conditions of use.
Skin and Body: Lab coat as indicated by general lab practice guidelines.
Eyes: Safety glasses or face shield are recommended to prevent eye contact.
Hand: Compatible chemical resistant gloves.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance Form: liquid

b) Odour odourless

c) Odour threshold no data available

d) pH no data available

e) Melting point / freezing point 275

f) Initial boiling point and boiling range no data available

g) Flash point non-combustible

h) Evaporation rate no data available

i) Flammability (solid, gas) no data available

j) Upper/lower flammability or explosive limits not applicable

k) Vapour pressure no data available

l) Vapour density 2.2

m) Relative density no data available

n) Solubility (ies) 42% at 17°C (water)

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

p) Auto-ignition temperature not applicable

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
No data available.

10.2 Chemical stability
Stable under normal storage conditions.

10.3 Possibility of hazardous reactions
Acids, metals, caustics, acid chlorides, peroxides and hydroperoxides, and oxidizing agents.

10.4 Conditions to avoid
Contact with acids, metals, caustics, acid chlorides, peroxides and hydroperoxides, and oxidizing agents.

10.5 Incompatible materials
>250°C

10.6 Hazardous decomposition products
Nitrogen oxides, nitrogen, hydrazoic acid

SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information of toxicological effects
No adverse effects on the health are expected from the components of the product. There is no aquatic toxicity data

for this product at this time. Individual aquatic toxicity studies have been completed for the below listed chemicals.

Sodium Azide RTECS Number: VYB050000
Acute toxicity: no data available
Skin corrosion/irritation: no data available
Serious eye damage/eye irritation: no data available
Respiratory or skin sensitisation: no data available
Germ cell mutagenicity: no data available
Carcinogenicity: IARC: no component of this product present at levels greater than 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
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

Additional Information

Sodium Azide	**Toxicity Data & References:**	**Toxicology Review Reference FNSCA6 2:67, 1973**
	Orl; hmn: TDLo: 710 µg/kg	JCPAAK 28:350, 1975.
	Orl; man: LDLo: 143 mg/kg	JTCTDW 24:339, 1986.
	Orl; wmn: LDLo: 14 mg/kg	Arrythmias JFSCAS 35: 193, 1990.
	ipr; rat: LdLo: 30mg/kg	PHRPA6 58:607, 1943.
	Genetic Data & References:	
	Fbr; hmn: Dose: 50mg/L DNA inhibition STBIBN 78: 165, 1980.	
	Lvr; rat; Dose: 1 mmol/L Mutations in mammalian somatic cells MUREAV 77:293, 1980.	
	Tumorigenic Data References:	
	Orl; rat; Dose: 2730 mg/kg/ 78W-C Skin, appendage and endocrine system tumours. JJIND8 67:75, 1981.	
	Orl; rat; Dose: 5460 mg/kg/ 78W-C Skin, appendage and endocrine system tumours. JJIND8 67:75, 1981.	

Refer to the Registry of Toxic Effects of Chemical Substances (RTECS) for definitions of abbreviations used in the above text and for additional information. This report contains only selected information from the RTECS.

SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity
Dangerous to the environment. Very toxic to aquatic organisms; may cause long term adverse effects in the aquatic environment. Freshwater Fish Species Data:
96 Hr LC50 Oncorhynchus mykiss: 0.8 mg/L;
96 Hr LC50 Lepomis macrochirus: 0.7 mg/L;
96 Hr LC50 Pimephales promelas: 5.46 mg/L [flow-through]

12.2 Persistence and degradability
When released into the soil, this material is not expected to biodegrade. When released into the soil, this material is expected to leach into groundwater. When released into the air, this material may be moderately degraded by photolysis.

12.3 Bioaccumulative potential
No data available.

12.4 Mobility in soil
No data available.

12.5 Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects
No data available.

12.7 Additional information
There is limited potential for the components within this product to accumulate in plant or animal systems.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
Waste must be disposed of in accordance with federal, state and local environmental control regulations. *This product is not considered a RCRA hazardous waste*.
Accumulation of sodium azide in the sink may form highly explosive metal azides. Do not dispose the solid product into the sink.

SECTION 14 TRANSPORT INFORMATION

14.1 UN number none

14.2 UN proper shipping name none

14.3 Transport hazard class(es) This substance is considered to be non-hazardous for transport.

14.4 Packing group none

14.5 Environmental hazards Do not discharge effluent containing this kit into streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact the appropriate environmental agency.

14.6 Special precautions for user no data available

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Not intended to be transported in bulk.

SECTION 15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/ legislation specific for the substance or mixture
No data available.

15.2 Chemical Safety Assessment
No chemical safety assessment has been carried out for this product.

SECTION 16 OTHER INFORMATION

Full text of H-Statements referred to in Sections 2 and 3
H300 Fatal if swallowed.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long-lasting effects.
EUH032 Contact with acids liberates very toxic gas.

The information supplied in this SDS is correct to the best of our knowledge. We do not accept any liability for loss, injury or damage, which may result from its use.

EC REP
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