

Trade name: IDkit Hp™

SECTION 1: Identification

Product identifier used on the label:

Product Name: IDkit Hp™

Other means of identification:

Product Code Number: NDC#: 50402-100

Recommended use of the chemical and restrictions on use:

Recommended use: Diagnostic kit for detection of *Helicobacter pylori* bacterium in the stomach

Recommended restrictions: Uses other than as recommended above.

Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party:

Company Name: Meridian Bioscience Israel Ltd.
Company Address: 4 Ha'Maayan St. Modiin, Israel
Company Telephone: +972-8-9737500

Company Contact Name: Rinat Sack
Company Contact Email: rinat.sack@meridianbioscience.com

Emergency phone number: +1-888-392-5369

SECTION 2: Hazard(s) identification

Classification of the chemical in accordance with paragraph (d) of §1910.1200:

Physical hazards

No physical hazards

Health hazards

Eye damage/irritation, Category 2A

Environmental hazards

Not adopted under OSHA paragraph (d) of §1910.1200

GHS Signal word: WARNING

GHS Hazard statement(s): Causes serious eye irritation.

GHS Hazard symbol(s):



GHS Precautionary statement(s):

Prevention:

- Wash thoroughly after handling.
- Wear eye protection/face protection.

Response:

- If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- If eye irritation persists: Get medical advice/attention.

Storage:

- None required

Disposal:

- None required

Hazard(s) not otherwise

Classified (HNOC): None known.

Percentage of ingredient(s) of unknown acute toxicity:

93% of the Citrica powder consists of ingredients of unknown acute toxicity (inhalation).

SECTION 3: Composition/information on ingredients

Mixture:

Pouch 1 - Citrica powder is packaged into sachets, prepared using a high barrier film

| Chemical name | CAS# | Concentration (weight %) |
|-------------------------------|-------------|---------------------------------|
| Citric Acid anhydrous, USP/EP | 77-92-9 | 93% |

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Pouch 2 - C13 -Urea tablets packaged into 52mm x 65mm sachets, prepared using a high barrier film.

| Chemical name | CAS# | Concentration (weight %) |
|--|------|--------------------------|
| No hazardous ingredients at the concentrations present | | |

Note: The balance of the ingredients are not classified as hazardous or are below the concentration limit to be classified as hazardous, under the criteria of the Federal OSHA Hazard Communication Standard 29CFR 1910.1200.

SECTION 4: First-aid measures

Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion:

Inhalation: Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. If not breathing, give artificial respiration. Get medical attention if symptoms develop.

Skin contact: Wash with soap and water. Get medical attention if symptoms develop.

Eye contact: In case of eye contact, remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 mins. Get medical attention if symptoms develop.

Ingestion: None expected. Never give anything by mouth to an unconscious person. Get medical attention if symptoms develop.

Most important symptoms/effects, acute and delayed:

Causes serious eye irritation.

Indication of immediate medical attention and special treatment needed: If any symptoms are observed, contact a physician and give them this SDS sheet.

SECTION 5: Fire-fighting measures

Suitable (and unsuitable) extinguishing media:

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media: No information available.

Specific hazards arising from the chemical (e.g., nature of any hazardous combustion products): None known.

Hazardous combustion products: None known.

Special protective equipment and precautions for fire-fighters: Wear self-contained breathing apparatus and protective clothing. Fight fire from a protected location. Wear self-contained breathing apparatus and protective clothing. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8).

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures: Avoid contact with skin and eyes. Keep out of the reach of children.

Methods and materials for containment and cleaning up:
Collect spill and transfer to suitable properly labeled containers for recycling and/or disposal. Do not let product enter the drains.

SECTION 7: Handling and storage

Precautions for safe handling: Avoid contact with skin and eyes. Keep away from incompatibles such as oxidizing agents, bases, reducing agents. Keep away from children.

Conditions for safe storage, including any incompatibles: Keep pouches sealed until use. Store at 25°C (77°F). [See USP Controlled Room Temperature]

SECTION 8: Exposure controls/personal protection

OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available.

| US OSHA HAZARDOUS COMPONENTS (29 CFR 1910.1200) (Table Z-1 Limits for Air Contaminants): | | |
|---|-----------------------------|------------------------------|
| Substance | PEL-TWA (8 hour) | PEL-STEL (15 min) |
| Citric Acid | No data available | No data available |

| US ACGIH Threshold Limit Values | | |
|--|-----------------------------|------------------------------|
| Substance | TLV-TWA (8 hour) | TLV-STEL (15 min) |
| Citric Acid | No data available | No data available |

Appropriate engineering controls: During industrial use; use material in well-ventilated area only. Good general ventilation (typically 10 air changes per hour) should be sufficient in most

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cases. Ventilation rates should be matched to conditions. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Use appropriate personal protective equipment and clothing to avoid skin contact.

Individual protection measures, such as personal protective equipment:

Eye/face protection: During industrial use, wear safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US).

Skin and hand protection: During industrial use, 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.

Respiratory protection: For nuisance exposures use type P95 (US) particle respirator. For higher level protection use type OV/AG/P99 (US) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH.

General hygiene considerations: 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.

SECTION 9: Physical and chemical properties

Appearance (physical state, color, etc.):

| | |
|---|--|
| Physical state: | Pouch 1 – powder. Pouch 2 – Solid tablet |
| Color: | White |
| Odor: | Pouch 1 – Tutti Fruity. Pouch 2 - None |
| Odor threshold: | No data available |
| pH: | No data available |
| Melting point/freezing point: | No data available |
| Initial boiling point and boiling range: | No data available |
| Flash point: | No data available |
| Evaporation rate: | No data available |
| Flammability (solid, gas): | Not applicable |
| Upper/lower flammability or explosive limits | |
| Flammability limit – lower (%): | No data available |
| Flammability limit – upper (%): | No data available |
| Explosive limit – lower (%): | No data available |
| Explosive limit – upper (%): | No data available |
| Vapor pressure: | No data available |
| Vapor density: | No data available |
| Relative density: | No data available |

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Solubility (ies): No data available
Partition coefficient (n-octanol/water): No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity (dynamic): No data available

SECTION 10: Stability and reactivity

Reactivity: No data available
Chemical stability: Material is normally stable under recommended storage conditions.
Possibility of hazardous reactions: None known.
Conditions to avoid: None known.
Incompatible materials: Avoid contact with oxidizing agents, bases, reducing agents.
Hazardous decomposition Products: None known.

SECTION 11: Toxicological information

Information on likely routes of exposure:

Inhalation: Expected to be a route of entry.
Ingestion: Expected to be a route of entry.
Skin: Expected to be a route of entry.
Eyes: Expected to be a route of entry.

Symptoms related to the physical, chemical, and toxicological characteristics:

Causes serious eye irritation.

Delayed and immediate effects and chronic effects from short or long-term exposure:

Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

Numerical measures of toxicity (such as acute toxicity estimates):

Ingredient Information:

| Substance | Test Type (species) | Value |
|-------------|-----------------------------------|-------------------|
| Citric acid | LD ₅₀ Oral (Rat) | 5400 mg/kg |
| | LD ₅₀ Dermal (Rat) | > 2000 mg/kg |
| | LC ₅₀ Inhalation (Rat) | No data available |

Skin corrosion/irritation: Not expected to cause skin corrosion or irritation.

Serious eye damage/eye irritation: Based on data from components this product causes severe eye irritation.

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| | |
|---|--|
| Respiratory sensitization: | Not expected to cause respiratory sensitization. |
| Skin sensitization: | Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals. |
| Germ cell mutagenicity: | No information available on the mixture, however none of the components have been classified for germ cell mutagenicity (or are below the concentration threshold for classification). |
| Carcinogenicity: | Not expected to cause cancer. |
| Reproductive toxicity: | Not expected to cause reproductive toxicity. |
| Specific target organ toxicity- Single exposure: | The substance or mixture is not expected to cause specific target organ toxicity after a single exposure. |
| Specific target organ toxicity- Repeat exposure: | The substance or mixture is not expected to cause specific target organ toxicity after repeated exposure. |
| Aspiration hazard: | This product is not anticipated to be an aspiration hazard if swallowed. |

SECTION 12: Ecological information

Ecotoxicity (aquatic and terrestrial, where available):

Product data: No data available.

Ingredient Information:

| Substance | Test Type | Species | Value |
|-------------|---------------------|--------------------------------------|-------------------|
| Citric acid | LC ₅₀ | Fish <i>Leuciscus idus melanotus</i> | 440 mg/l - 48 h |
| | EC ₅₀ | <i>Daphnia magna</i> (Water flea) | 1,535 mg/l - 24 h |
| | EC/LC ₅₀ | Algae | No data available |

| | |
|--|--------------------|
| Persistence and Degradability: | No data available. |
| Bioaccumulative Potential: | No data available. |
| Mobility in Soil: | No data available. |
| Other adverse effects (such as hazardous to the ozone layer): | No data available. |

SECTION 13: Disposal considerations

Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.

All disposal methods must be in compliance with all federal, state/provincial and local laws and regulations. Waste characteristics and compliance with applicable laws are the responsibility solely of the waste generator.

Contaminated packaging: Contaminated packaging may contain traces of the product and therefore should be disposed of in the same way as product.

SECTION 14: Transport Information

US Department of Transportation Classification (49CFR)

Not regulated as hazardous for transport under DOT

IMDG (Transport by sea)

Not regulated as hazardous for transport under IMDG

IATA (Country variations may apply)

Not regulated as hazardous for transport under IATA

Environmental hazards

Marine pollutant: No

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)

No further relevant information available.

Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises.

No data available.

SECTION 15: Regulatory Information

USA:

United States Federal Regulations: This SDS complies with the OSHA, 29 CFR 1910.1200. The product is classified as hazardous under OSHA.

Toxic Substances Control Act (TSCA) – All of the ingredients are listed on the U.S. EPA TSCA Inventory List.

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None listed

SARA HAZARD DESIGNATION SECTIONS 311/312 (40 CFR 370):

| | |
|-----------------------------------|-----|
| Acute Health Hazard | YES |
| Chronic Health Hazard | NO |
| Fire Hazard | NO |
| Reactivity Hazard | NO |
| Sudden Release of Pressure Hazard | NO |

Section 313 Toxic Chemicals (40 CFR 372.65): None listed

STATE REGULATIONS:

This SDS contains specific health and safety data is applicable for state requirements. For details on your regulatory requirements you should contact the appropriate agency in your state.

California Proposition 65 (California Safe Drinking Water and Toxic Enforcement Act of 1986):

None listed

Massachusetts Right to Know: None listed

New Jersey Right to Know: Citric acid is listed on the New Jersey Right to Know list.

Pennsylvania Right to Know: Citric acid is listed on the Pennsylvania Right to Know List.

SECTION 16: Other Information

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DISCLAIMER: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 1910.1200. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.