

Safety Data Sheet

Section 1: Product and Company Identification

1.1 Product Identifiers:

Product Name: ABRAXIS[®] Patulin Plate Kit including TMB (Color Solution), Sulfuric Acid (Stop Solution), ABRAXIS[®] Patulin 1X6 Plate Kit including TMB (Color Solution), Sulfuric Acid (Stop Solution), ABRAXIS[®] Patulin Standard & Control Set and the ABRAXIS[®] Patulin Derivatization Set Product Code: 500106, 500110, 301102, 301103

1.2 Identified Use: Determination of Patulin in samples. Restrictions on Use: For research use only.

1.3 Company: Gold Standard Diagnostics, 795 Horsham Road, Horsham, PA 19044 USA, info.abraxis@us.goldstandarddiagnostics.com

+1(215) 357-3911, FAX +1(215) 357-5232

1.4 Emergency Telephone Number: +1(215) 357-3911

Section 2: Hazard(s) Identification

2.1 Classification of the mixture:

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) Flammable liquids (Category 4), H227 Combustible liquid HMIS Rating: Health hazard: 0, Chronic Health Hazard: *, Flammability: 2, Physical Hazard 0 NFPA Rating: Health hazard: 2, Fire Hazard: 3, Reactivity Hazard: 0 **2.2 GHS Label elements, including precautionary statements:** Pictogram(s):



Signal word(s): Warning Hazard statement(s): H227 Combustible liquid. Precautionary statement(s): P264 Wash skin thoroughly after handling. P280 Wear protective gloves/eye protection/face protection. P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish. P390 Absorb spillage to prevent material damage. P403 + P233 Store in a well-ventilated place. Keep container tightly closed. P501 Dispose of contents/ container to an approved waste disposal plant. **2.3 Hazards not otherwise classified (HNOC) or not covered by GHS:** Readily absorbed through skin **2.4 Unknown acute toxicity:** None known.

Section 3: Composition / Information on Ingredients

3.2 Mixtures: Mixture(s) of the hazardous substance(s) listed below, with nonhazardous additions. Hazardous component(s): Name and Synonym(s): DMSO, Dimethyl sulfoxide, Methyl sulfoxide Molecular weight: 78.13 g/mol Formula: C₂H₆OS CAS No.: 67-68-5 EC-No.: 200-664-3 Classification: Flammable Liquid 4; H227 Percentage in Mixture: 1.91-3.81 % Name and Synonym(s): Sulfuric Acid Formula: H₂SO₄ Molecular weight: 98.08 g/mol CAS No.: 7664-93-9 EC-No.: Classification: Acute Toxicity, 3; H311 Percentage in Mixture: 2% Name and Synonym(s): Sodium Azide Formula: NaN₃ Molecular weight: 65.01 g/mol CAS No.: 26628-22-8 EC-No.: 247-852-1 Classification: Acute Toxicity 3; H300, H400, H410 Percentage in Mixture: 0.05% For full text of H-Statements mentioned in this Section, see Section 2.

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. Move out of dangerous area. **If inhaled:** If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact: Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

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

If swallowed: Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician. 4.2 Most important symptoms and effects, both acute and delayed: The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed: No data available. Treat symptomatically.

Section 5: Fire-fighting Measures

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

5.2 Special hazards arising from the substance or mixture: Carbon oxides, Sulfur oxides

5.3 Advice for firefighters: Wear self-contained breathing apparatus for fire-fighting if necessary.

5.4 Further information: Use water spray to cool unopened containers.

Section 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures: Use personal protective equipment (see section 8). Avoid dust formation. Avoid breathing vapors, mist, dust, or gas. Ensure adequate ventilation. Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas. Remove all sources of ignition. Evacuate personnel to safe areas.

6.2 Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up: Contain spillage. Solids (if applicable): Pick up and arrange disposal without creating dust. Sweep up and shovel. Liquids (if applicable): Absorb with non-combustible liquid-binding material (sand, earth, diatomite, vermiculite). Keep in suitable, closed containers for disposal.

6.4 Reference to other sections: For information on safe handling see section 7. For information on personal protection see section 8. For information on disposal see section 13.

Section 7: Handling and Storage

7.1 Precautions for safe handling: See section 2. Avoid inhalation of vapors or mist, and avoid contact with skin and eyes. Wear appropriate personal protective equipment. Use explosion-proof equipment. Keep away from sources of ignition. Do not eat, drink, or smoke in work area. Take measures to prevent the buildup of electrostatic charge.

7.2 Precautions for safe storage: Keep container(s) tightly closed in a dry, well-ventilated place. Protect from physical damage. Opened containers must be carefully resealed and kept upright to prevent leakage. See label or product insert for appropriate storage temperature and additional specific information. Storage class (TRGS 510): Flammable liquids.

7.3 Specific end use(s): Other than use(s) specified in section 1, no other uses are stipulated.

Section 8: Exposure Controls / Personal Protection

8.1 Control parameters:

Component(s) with workplace control parameters

Dimethyl sulfoxide, CAS No. 67-68-5

Value		Control parameters	Basis
TWA		250.000000 ppm	USA. Workplace Environmental Exposure
			Levels (WEEL)
Sodium Azide			
Cas # 26628-22-8			
US OSHA None establ	ished		
ACGIH			
Sodium Azide	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid)		
(vapor)CAS # 26	5628-22-8		
DFG MAK			
Sodium Azide	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable		
fraction)CAS # 2	26628-22-8		
Ireland			
Sodium Azide	0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous		
absorption CAS	# 26628-22-8		
IOELVs			
Sodium Azide	Possibility of significant uptake through the skin; 0.1mg/m3 TWA; 0.3mg/m3		
STELCAS # 2662	28-22-8		
NOISH	None established		
Japan	None established		

8.2 Exposure controls:

Appropriate engineering controls: Provide adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Keep away from food and beverages.

Personal protective equipment

Eye protection: Use equipment for eye protection with side shields tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

Skin protection: Handle with chemical resistant 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: Do not breathe vapors. Use a chemical fume hood or approved respiratory protection equipment.

Body protection: Lightweight, protective clothing to prevent skin exposure.

Section 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties of mixture Appearance: Multiple Odor: Characteristic Odor Threshold: No data available pH: Multiple 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): No data available Upper/lower flammability or explosive limits No data available Vapor pressure: No data available Vapor density: No data available Relative density: No data available Water solubility: Various Partition coefficient: n-octanol/water: No data available Auto-ignition temperature: Not applicable Decomposition temperature: No data available Viscosity: No data available Explosive properties: No data available Corrosion: May be corrosive to metals Oxidizing 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 recommended storage conditions.

10.3 Possibility of hazardous reactions: This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the buildup of shock sensitive compounds, Sodium azide forms explosive compounds with heavy metals.

10.4 Conditions to avoid: Keep away from open flame, hot surfaces, heat sources, and sources of ignition.

10.5 Incompatible materials: Acid chlorides, phosphorus halides, strong acids, strong oxidizing agents, strong reducing agents, metals and metallic compounds.

10.6 Hazardous decomposition products: No data available. In the event of fire: see section 5.

Section 11: Toxicological Information

11.1 Information on toxicological effects

To the best of our knowledge, the chemical, physical, and toxicological properties of this product have not been thoroughly investigated. Acute toxicity (*Dimethyl sulfoxide, CAS No. 67-68-5*):

 $\label{eq:linkalation} LC50 Inhalation - Rat - 4 h - 40250 ppm \\ \mbox{Ingestion} LD50 Oral - Rat - 14,500 mg/kg \\ \mbox{Skin contact} LD50 Dermal - Rabbit - > 5,000 mg/kg; mild skin irritation; \\ \mbox{Eye contact} No data available \\ \mbox{Respiratory or skin sensitization} No data available; \\ \end{tabular}$

Aspiration hazard No data available

Mutagenicity (Dimethyl sulfoxide, CAS No. 67-68-5): Cytogenetic analysis (Mouse lymphocyte, Rat)--Result: mutation, DNA damage in mammalian somatic cells

Carcinogenicity:

(Dimethyl sulfoxide, CAS No. 67-68-5): Rat (oral)—Tumorigenic: Equivocal tumorigenic agent by RTECS criteria. Skin and Appendages: Other: Tumors. Mouse (oral)--Tumorigenic: Equivocal tumorigenic agent by RTECS criteria. Leukemia Skin and Appendages: Other: Tumors. IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Teratogenicity: No data available

Reproductive/fertility toxicity:

(Dimethyl sulfoxide, CAS No. 67-68-5): Reproductive toxicity (Rat, intraperitoneal and subcutaneous)--Effects on Fertility: Abortion; postimplantation mortality (e.g., dead and/or resorbed implants per total number of implants); litter size (e.g.; # fetuses per litter; measured before birth). Reproductive toxicity (Mouse, oral)--Effects on Fertility: Pre-implantation mortality (e.g., reduction in number of implants per female; total number of implants per corpora lutea). Effects on Embryo or Fetus: Fetotoxicity (except death, e.g., stunted fetus). Specific Developmental Abnormalities: Musculoskeletal system.

Developmental Toxicity (Mouse, intraperitoneal)--Effects on Embryo or Fetus: Fetotoxicity (except death, e.g., stunted fetus). Specific Developmental Abnormalities: Musculoskeletal system.

Specific target organ toxicity, single exposure (Dimethyl sulfoxide, CAS No. 67-68-5): No data available

Specific target organ toxicity, repeated exposure: The substance or mixture is not classified as specific target organ toxicant, repeated exposure. Additional information (*Dimethyl sulfoxide, CAS No. 67-68-5*): RTECS: PV6210000 Exposure to large amounts can cause redness of skin, itching, burning, sedation, headache, nausea, dizziness. Eyes - Eye disease - Based on Human Evidence

Acute toxicity (Sodium azide, CAS No. 26628-22-8):

Inhalation: No data available

Ingestion: Oral LD50 Rat 27 mg/kg

Skin contact: Dermal LD50 Rat 50mg/kg

Eye contact: May cause eye irritation in susceptible persons.

Respiratory or skin sensitization: No data available

Aspiration hazard: No data available Mutagenicity: No data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed humancarcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Teratogenicity: No data available Reproductive/fertility toxicity: No data available

Specific target organ toxicity, single exposure: No data available

Specific target organ toxicity, repeated exposure: No data available

Section 12: Ecological Information

12.1 Toxicity: (*Dimethyl sulfoxide, CAS No. 67-68-5*) Toxicity to fish LC50 - Pimephales promelas (fathead minnow) - 34,000 mg/l - 96 h; LC50 - Oncorhynchus mykiss (rainbow trout) - 35,000 mg/l - 96 h. Toxicity to daphnia and other aquatic invertebrates EC50 - Daphnia magna (Water flea) - 24,600 mg/l - 48 h (OECD Test Guideline 202). Toxicity to algae EC50 - Pseudokirchneriella subcapitata (green algae) - 17,000 mg/l - 72 h (OECD Test Guideline 201)

(Sodium Azide, CAS No. 26628-22-8) Toxicity to fish LC50 - Pimephales promelas (fathead minnow) – 0.7 mg/l - 96 h; LC50 - Oncorhynchus mykiss (rainbow trout) – 0.8 mg/l - 96 h.

12.2 Persistence and degradability: Dimethyl sulfoxide result: 31 %, not readily biodegradable (OECD Test Guideline 301D)

12.3 Bioaccumulative potential: No data available

12.4 Mobility in soil: No data available

12.5 Results of PBT and vPvB assessment: No data available

12.6 Other adverse effects: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Section 13: Disposal Considerations

13.1 Waste treatment methods

Product: All waste must be handled and disposed according to local, state, and federal regulations. Avoid disposing large volumes in sewer. **Contaminated packaging:** All waste must be handled and disposed according to local, state, and federal regulations. Refer to sections 7 and 8 for safe handling guidance.

Section 14: Transport Information

DOT, Land Transport ADR/RID (cross-border), Maritime Transport IMDG, Air Transport ICAO-TI and IATA-DGR UN Number: 3316; 1830 UN Proper shipping name: Chemical Kit, (contains DMSO) Transport hazard class(es): 9 Packing group: III Environmental hazard: See section 12 Bulk transport: Excepted/Limited quantity Special considerations: See section 7 for handling

Section 15: Regulatory Information

EU Regulations, Hazard Symbol(s): Dimethyl sulfoxide: Xi (Irritant)

Safety Phrases: Dimethyl sulfoxide: S 24/25 Avoid contact with skin and eyes

SARA Title III, Section 302 Components: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302. SARA Title III, Section 313 Components: This material does not contain any chemical components with known CAS numbers that exceed the threshold (DeMinimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards: Dimethyl sulfoxide, CAS No. 67-68-5: Fire Hazard, Chronic Health Hazard State Right-to-Know

Massachusetts: No components are subject to the Massachusetts Right to Know Act.

Pennsylvania: Dimethyl sulfoxide, CAS No. 67-68-5

New Jersey: Dimethyl sulfoxide, CAS No. 67-68-5

California Prop. 65 Components: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any

other reproductive harm.

EU Regulations, Hazard Symbol(s): Sodium azide

SARA 313 is subject to reporting requirements of section 313, title III of SARA. 1.0% DeMinimis concentration

CERCLA RG's, 40 CFR 302.4	Sodium azide is listed
CA Prop 65	No ingredients listed
MA MSL	Sodium azide is listed
NJ Dept. Health RTK List	Sodium azide is listed
PA RTK	Sodium azide is listed

United Nations

According to the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Section 1.5.3.1.1, "an SDS should be provided based on the generic cut-off values/concentration limits indicated in" the following table:

Hazard class	Cut-off value/concentration limit	
Acute toxicity	≥ 1.0%	
Skin corrosion/irritation	≥ 1.0%	
Serious eye damage/eye irritation	≥ 1.0%	
Respiratory/Skin sensitization	≥0.1%	
Germ cell mutagenicity (Category 1)	≥0.1%	
Germ Cell mutagenicity (Category 2)	≥ 1.0%	
Carcinogenicity	≥0.1%	
Reproductive toxicity	≥0.1%	
Specific target organ toxicity (single exposure)	≥ 1.0%	
Specific target organ toxicity (repeated exposure)	≥ 1.0%	
Aspiration hazard (Category 1)	≥ 10% of Category 1 ingredient(s) and kinematic viscosity ≤ 20.5 mm ² /s at 40°C	
Aspiration hazard (Category 2)	≥ 10% of Category 2 ingredient(s) and kinematic viscosity ≤ 14 mm ² /s at 40°C	
Hazardous to the aquatic environment	≥ 1.0%	

Unless otherwise specified, if the concentration of a specific material of this kit is not declared by this SDS, it is at a concentration that is below the cut-off for its specific hazard class(es).

Section 16: Other information

This information is based on our present knowledge. While Gold Standard Diagnostics believes that the data contained herein are factual and the opinions expressed represent a best effort to present accurate information, the data are not to be taken as a warranty or representation for which Gold Standard Diagnostics assumes legal responsibility. The information shall not be taken as being all-inclusive and is to be used only as a guide. The data are offered solely for the user's consideration, investigation, and verification. These suggestions should not be confused with either state, municipal, or insurance requirements, or with national safety codes and constitute no warranty. Any use of these data and information must be determined by the user to be in accordance with applicable federal, state, and local regulations.

All materials and mixtures may present unknown hazards and should be used with caution. Since Gold Standard Diagnostics cannot control the methods, volumes, or conditions of use of this product, Gold Standard Diagnostics shall not be held liable for any damages or losses resulting from the handling or from contact with the product as described herein. An individual technically qualified to handle potentially hazardous chemicals must supervise the use of this material. This product is sold for research use only. It is not for any human or animal therapeutic or clinical diagnostic use.

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