

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

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

1.1 Product identifier

Trade name

Jant Pharmacal/Accutest Drugs of Abuse, Strips-Devices, Dip Cards & Cups (Amphetamines, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Methamphetamine, MDMA, Morphine, Methadone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants, Marijuana)

Reference No.

Strips: DS78,
Devices: DS1105, DS135, DS3155, DS51, DS55, DS56, DS71
Dip Cards: DS01AC425, DS100, DS106, DS110AC225, DS111 AC225, DS1124, DS112 AC225, DS113AC225, DS114AC225, DS115AC225, DS116AC225, DS117AC225, DS118AC225, DS119AC225, DS120AC225, DS130AC225, DS134AC425, DS220AC225, DS60AC425, DS61AC425, DS64AC425, DS73AC425, DS74AC425,
SplitCups: DS012, DS02AC625, DS03AC625, DS07AC625, DS08AC625, DS09AC625, DS103AC625, DS106, DS208, DS2167, DUD15702319
Drug Test Cups: DS84, DS93S625

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

Identified use(s)

In vitro diagnostic reagent. For professional use only.

1.3 Details of the supplier of the safety data sheet

Company Identification

Jant Pharmacal Corporation.
16530 Ventura Blvd., # 512
Encino, CA 91436, USA
1-818-986-8530
info@accutest.net

Telephone

E-Mail (competent person)

1.4 Emergency telephone number

Emergency Phone No.

Free phone (North America only): 1-(800)-676-5565

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture Regulation (EC) No. 1272/2008 (CLP)

Hazard statement(s)

Repr. 1B

H360: May damage fertility or the unborn child.

Version 3

Directive 67/548/EEC & Directive 1999/45/EC
Risk Phrases

Repr. Cat. 2

R60: May impair fertility.

R61: May cause harm to the unborn child.

OSHA Hazard Communication Standard 29
CFR 1910.1200 (HazCom 2012) / GHS

Repr. 1B Hazard statement(s) H360: May damage fertility or the unborn child.

- 2.2 Label elements** No measures required. The product is placed on the market in the form of an article, which contains insignificant quantities of hazardous chemicals that are not intended to be released from the device.
- 2.3 Other hazards** None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: In vitro diagnostic reagent test device. Preparation. Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.

Dangerous components:
EC Classification No. 1272/2008 / GHS

Hazardous ingredient(s)	%W/W	EC No.	CAS No.	Classification code: Hazard statement(s)
Sodium tetraborate	5 - 30	215-540-4	1330-43-4	Repr. 1B; H360
Tris (hydroxymethyl) aminomethane	2 - 10	201-064-4	77-86-1	Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335
Sodium azide	< 0.1	247-852-1	26628-22-8	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	%W/W	EC No.	CAS No.	EC Classification and Risk Phrases
Sodium tetraborate	5 - 30	215-540-4	1330-43-4	Repr. Cat. 2; R60-61
Tris (hydroxymethyl) aminomethane	2 - 10	201-064-4	77-86-1	Xi, R36/37/38
Sodium azide	< 0.1	247-852-1	26628-22-8	T+, N; R28-32-50/53

- 3.3 Additional Information** For full text of R/H phrases see section 16. Each device is packaged in a foil pouch.

SECTION 4: FIRST AID MEASURES



- 4.1 Description of first aid measures**
General information

Inhalation
Skin Contact

Eye Contact

Ingestion
 - 4.2 Most important symptoms and effects, both**
- The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.
Supply fresh air; consult doctor in case of complaint.
Wash skin with soap and water. If exposed or concerned: Get medical advice/attention.
Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.
Wash out mouth with water. Consult a doctor.
None.

Version 3

acute and delayed

- 4.3 Indication of the immediate medical attention and special treatment needed** None.

SECTION 5: FIRE-FIGHTING MEASURES

- 5.1 Extinguishing media**
Suitable Extinguishing Media CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- 5.2 Special hazards arising from the substance or mixture** In case of fire, the following can be released: Hazardous fumes, Carbon oxides (COx), nitrogen oxides (NOx).
- 5.3 Advice for fire-fighters** Use fire-extinguishing methods suitable to surrounding conditions.
Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.


SECTION 6: ACCIDENTAL RELEASE MEASURES

- 6.1 Personal precautions, protective equipment and emergency procedures** Refer to Section 8 for protective measures when handling the spillage.
- 6.2 Environmental precautions** Avoid release to the environment.
- 6.3 Methods and material for containment and cleaning up** Collect material and dispose of as waste according to Section 13.
- 6.4 Reference to other sections** 8, 13

SECTION 7: HANDLING AND STORAGE

- 7.1 Precautions for safe handling** Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54EC or US regulation 29 CFR 1910.1030 for information on handling biohazardous materials.
Avoid contact with the eyes, skin and mucous membranes.
Keep out of reach of children.
Wash hands before breaks and after work.
Clean work areas with hypochlorite or other disinfecting agent.
- 7.2 Conditions for safe storage, including any incompatibilities** Store in the original container at 2 to 30°C.
- 7.3 Specific end use(s)** Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 Control parameters**
- 8.1.1 Occupational Exposure Limits** The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- 8.2 Exposure controls**
- 8.2.1 Appropriate engineering controls** Not relevant for this material.
- 8.2.2 Personal protection equipment**
- Eye/face protection Safety glasses recommended. (EN166)
- Hand protection Disposable gloves. (EN374).
-  Material of gloves: Latex / natural rubber, Nitrile rubber.
Penetration time of glove material: Gloves resistance is not critical when the product is handled according to the instructions for use.

Version 3

Body protection
Respiratory protection

Laboratory coat.
Not normally required.

8.2.3 Environmental Exposure Controls

No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Laminated test strip, which may be housed in a plastic holder.
Colour	Variable depending on product.
Odour	No odour.
Odour Threshold (ppm)	Not applicable.
pH (Value)	Not determined.
Melting Point (°C) / Freezing Point (°C)	Not determined.
Boiling point/boiling range (°C):	Not determined.
Flash Point (°C)	Not applicable.
Evaporation rate (BA = 1)	Not applicable.
Flammability (solid, gas)	Not determined.
Explosive limit ranges	Not applicable.
Vapour Pressure (mm Hg)	Not applicable.
Vapour Density (Air=1)	Not applicable.
Density (g/ml)	Not applicable.
Solubility (Water)	Not determined.
Solubility (Other)	Not determined.
Partition Coefficient (n-Octanol/water)	Not determined.
Auto Ignition Temperature (°C)	Not determined.
Decomposition Temperature (°C)	Not determined.
Viscosity (mPa.s)	Not applicable.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising
9.2 Other information	Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	None known.
10.2 Chemical stability	The product is stable in accordance with the recommended storage conditions.
10.3 Possibility of hazardous reactions	Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerisation will not occur.
10.4 Conditions to avoid	None
10.5 Incompatible materials	Strong acids, strong bases, strong oxidizing agents.
10.6 Hazardous Decomposition Product(s)	None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Irritation	Based upon the available data, the classification criteria are not met.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitisation	Based upon the available data, the classification criteria are not met.
Repeated dose toxicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.

Version 3

Mutagenicity	Based upon the available data, the classification criteria are not met.
Toxicity for reproduction STOT-single exposure	Repr. 1B. May damage fertility or the unborn child. Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

11.2 Other information Not applicable

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2 Persistence and degradability	The device contains plastic and other components that are not readily degradable.
12.3 Bioaccumulative potential	None anticipated.
12.4 Mobility in soil	The product is predicted to have low mobility in soil.
12.5 Results of PBT and vPvB assessment	Not applicable.
12.6 Other adverse effects	Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. Disposal should be in accordance with local, state or national legislation. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Product:	
European waste catalogue:	
Packaging:	Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number	Not applicable
14.2 UN Proper Shipping Name	Not applicable
14.3 Transport hazard class(es)	Not classified as dangerous for transport.
14.4 Packing Group	Not applicable
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	Not applicable
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

SECTION 15: REGULATORY INFORMATION

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

In Vitro diagnostics medical devices directive 98/79/EC. OSHA Hazard Communication Standard 29 CFR 1910.1200
Consumer Product Safety Regulations 16 CFR 1600Version 3

Carcinogen listings

IVD Product Labelling 21 CFR 809

IARC:	None of the ingredients is listed.
NTP:	None of the ingredients is listed.
ACGIH:	None of the ingredients is listed.
OSHA:	None of the ingredients is listed.
EPA:	None of the ingredients is listed.

Californian Proposition 65

Chemicals known to cause cancer:	None of the ingredients is listed.
Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.

SARA

Section 355 (extremely hazardous substances):	Sodium azide (trace).
Section 313 (specific toxic chemical listings):	Sodium azide (trace).

15.2 Chemical Safety Assessment Not applicable.

SECTION 16: OTHER INFORMATION**LEGEND**

STOT Specific Target Organ Toxicity

Classification code:

Repr. 1B	Toxic for reproduction: Category 1B
Acute Tox. 2	Acute toxicity: Category 2
Skin Irrit. 2	Skin Irritant. Category 2
Eye Irrit. 2	Eye Irritant. Category 2
Aquatic Acute 1	Acute Aquatic toxicity: Category 1
Aquatic Chronic 1	Chronic Aquatic toxicity: Category 1
Repr. Cat. 2	Toxic for reproduction: Category 2
Xi	Irritant
T+	Very toxic.
N	Dangerous for the environment.

Hazard statement(s) H300:

Fatal if swallowed. H315:
Causes skin irritation.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H360: May damage fertility or the unborn child.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
EUH032: Contact with acids liberates very toxic gas.

Risk Phrases

R28: Very toxic if swallowed.
R32: Contact with acids liberates very toxic gas.
R36/37/38: Irritating to eyes, respiratory system and skin.
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R60: May impair fertility.
R61: May cause harm to the unborn child.

References:

Raw material safety data sheets.

Additional Information

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 the accuracy or 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.