SAFETY DATA SHEET
Fecal Occult Blood Rapid Test

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03

1. Identification includes product identifier

Identification of the substance or preparation

Trade name: Fecal Occult Blood Rapid Test

Reference No.: **CS425**

Use of the substance/preparation: In vitro diagnostic medical device.

Company/undertaking identification:

Jant Pharmacal Corporation
16530 Ventura Blvd., Encino California 91436, USA
Tel: (800)676-5565 , (818)986-8530
Fax: (818)986-0235
Web:http://www.jantdx.com
E-mail: info@jantdx.com

Further information obtainable from: For further information, contact your local distributor/supplier.

2. Hazard(s) identification includes all hazards regarding the chemical

Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:

As an article, the device is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200.
This substance is classified according to the Globally Harmonized System

Label elements

GHS label elements: Non-regulated GHS label on the concentration of 0.02%
Hazard pictograms: Non-regulated material on the concentration of 0.02%
Signal word: No signal word, non-regulated material on the concentration of 0.02%

Other hazards

Other hazards: None known

3. Composition/information on ingredients

Chemical characterisation

Description:

In vitro diagnostics medical device. Test strip impregnated with dried chemical / biochemical reagents.

Dangerous components:

Component	CAS No.	EINECS No.	Classification according to GHS	Concentration

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Sodium azide	26628-22-8	247-852-1	Acute Tox. 2; Acute Tox. 1; Aquatic Acute 1; Aquatic Chronic 1; H300 + H310, H410, EUH032	0.02%
Other products ingredients	Not specified in GHS	Not specified in GHS	Not specified in GHS	Not specified in GHS

Additional information:
Each device is packaged in a foil pouch.
For the wording of the listed risk phrases refer to section 16.

4. First-aid measures

General Information:
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.
After skin contact:
Wash with soap and water and rinse thoroughly.
After eye contact:
Rinse opened eye for several minutes under running water.
After ingestion:
If desiccant or other components are swallowed seek medical attention.

5. Fire-fighting measures

Suitable extinguishing agents:
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire-extinguishing methods suitable to surrounding conditions.
Special hazards caused by the substance, its products of combustion or resulting gases:
In case of fire, the following can be released: Hazardous fumes and vapours, Carbon oxides (CO_x), Nitrogen oxides (NO_x),
Protective equipment:
Wear full protective suit and self-contained respiratory protective device when extinguishing fires.
Additional information:
The device contains combustible materials.

6. Accidental release measures

Person-related safety precautions:
Refer to Section 8 for protective measures when handling the spillage.
Measures for environmental protection:
Avoid release to the environment.
Measures for cleaning/collecting:
Collect material and dispose of as waste according to Section 13.

7. Handling and storage

Information for safe handling:
Keep out of reach of children.

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Storage:
Store in the original container at 2-30°C.
Requirements to be met by storerooms and receptacles:
No special requirements.

8. Exposure controls/personal protection

Ingredients with limit values that require monitoring in the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

Additional information:
The lists valid during the creation of this SDS were used as a basis for this assessment.

Personal protective equipment:
General protective and hygienic measures:
Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54/EC or US Regulation 29 CFR 1910.1030 for information on handling biohazardous materials.
Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.
Respiratory protection:
Required, if there is a risk of splashing or aerosol generation during sample handling
Protection of hands:
Disposable gloves (for sample handling)
Material of gloves: Latex/natural rubber.
Penetration time of glove material: Glove resistance is not critical as the gloves are intended to provide protection against the sample material.
Eye protection:
Safety glasses or face shield, where there is a risk of splashing during sample handling
Body protection:
Lab coat

9. Physical and chemical properties

General Information
Form: The device is an article containing solid components
Appearance: Laminated test strip, which may be housed in a plastic holder.
Odour: Odourless
Flash point: Not applicable.
Self-igniting: Product is not self-igniting.
Danger of explosion: Product does not present an explosion hazard.

10. Stability and reactivity

Stability: The product is stable in accordance with the recommended storage conditions.
Materials to be avoided: None
Hazardous reactions: No dangerous reactions known.
Hazardous decomposition products: No dangerous decomposition products known.

11. Toxicological information

Acute toxicity:
Quantitative data on the toxic effects of this product is not available.

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Primary effects:
After skin contact: No irritating effects anticipated.
After eye contact: Contact with the chemicals impregnated in the test strip may cause mild irritation.
Sensitisation: No sensitising effects known.

12. Ecological information

Environmental Toxicity:
Quantitative data on the toxic effects of this product is not available.

Persistence and Degradability:
The device contains plastic and other components that are not readily degradable.

13. Disposal considerations

Product:
Used devices and other contaminated materials should be disposed of as potentially biohazardous waste.
To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

European waste catalogue:
18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.

Packaging:
Disposal must be made in accordance with local waste management regulations.
Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

14. Transport information

Land transport ADR/RID (cross-border)
Not regulated for transport.

US DOT Transport Regulations:
Not regulated for transport.

Maritime transport IMDG:
Not regulated for transport.
Marine pollutant: No

Air transport ICAO-TI and IATA-DGR:
Not regulated for transport.

15. Regulatory information

Labelling according to EU guidelines:
Safety data sheet available for professional user on request.

Note:
The preparation is exempt from the above labelling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

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US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:
Not required.

Chemical inventory listings relevant to US regulations:

Carcinogen listings

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):	None of the ingredients is listed.
Section 313 (specific toxic chemical listings):	None of the ingredients is listed.

Label elements

GHS label elements:	Non-regulated material
Hazard pictograms:	Non-regulated material
Signal word:	No single word, non-regulated material

16. Other 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.