

Date prepared:	2007-07-10
Version No:	3.0
Page No:	Page 1 of 8

Material Safety Data Sheet

1. PRODUCT & COMPANY IDENTIFICATION

Product Name: affigene® DNA extraction Kit

Description: *In vitro* Diagnostic Reagent

Code Numbers: Article nr: 71000942

MANUFACTURER/SUPPLIER	EMERGENCY PHONE
Cepheid AB P.O.Box 20045, SE-161 02 Bromma, Sweden Visiting address: Bällstavägen 34-36, Bromma-Sthlm, Sweden Phone: +46-8-555 20 400	Phone 1: 112 Phone 2: Dial local emergency number!

2. COMPOSITION / INFORMATION ON INGREDIENTS

This Material Safety Data Sheet covers the affigene® DNA extraction Kit. The Extraction Kit contains six solutions and one lyophilized component.

Component 1: Lysis buffer 1; Code: 71000966

<u>Chemical Name</u>	<u>Wt. %</u>	<u>CAS#</u>	<u>Classification</u>
Guanidiniumchloride solution	< 45%	50-01-1	Xn Label not necessary if quantity below 125 g or mL according to 67/548/EEC Art. 25, 1999/45/EC Art. 12)

Date prepared:	2007-07-10
Version No:	3.0
Page No:	Page 2 of 8

Water and other constituents. Each of the other constituents are present in less than 1% concentration or less than 0,1% for potential carcinogens, reproductive toxins, respiratory tract sensitizers and mutagens.	Balance	N/A	None of the other constituents in this mixture contribute significantly to the hazards associated with this component. All hazard information pertinent to this product has been provided in this MSDS per the requirements and in compliance with EC Directive 91/155/EEC and EC Directive 1999/45/EC (preparations).
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Component 2: Lysis buffer 2; Code: 71000999

<u>Chemical Name</u>	<u>Wt.%</u>	<u>CAS#</u>	<u>Classification</u>
Water and other constituents. Each of the other constituents are present in less than 1% concentration or less than 0,1% for potential carcinogens, reproductive toxins, respiratory tract sensitizers and mutagens.	Balance	N/A	None of the other constituents in this mixture contribute significantly to the hazards associated with this component. All hazard information pertinent to this product has been provided in this MSDS, per the requirements and in compliance with EC Directive 91/155/EEC and EC Directive 1999/45/EC (preparations).

Component 3:Proteinas K; Code: 71001008

<u>Chemical Name</u>	<u>Wt.%</u>	<u>CAS#</u>	<u>Classification</u>
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Date prepared:	2007-07-10
Version No:	3.0
Page No:	Page 3 of 8

Proteinas K, lyophilized		39450-01-6	Xn, Xi Label not necessary if quantity below 125 g or mL according to 67/548/EEC Art. 25, 1999/45/EC Art. 12)
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Component 4: Proteinas K buffer; Code: 71000968

<u>Chemical Name</u>	<u>Wt. %</u>	<u>CAS#</u>	<u>Classification</u>
Water and other constituents. Each of the other constituents are present in less than 1% concentration or less than 0,1% for potential carcinogens, reproductive toxins, respiratory tract sensitizers and mutagens.	Balance	N/A	None of the other constituents in this mixture contribute significantly to the hazards associated with this component. All hazard information pertinent to this pro-duct has been provided in this MSDS, per the requirements and in compliance with EC Directive 91/155/EEC and EC Directive 1999/45/EC (preparations).

Component 5: Wash 1; Code: 71000971

<u>Chemical Name</u>	<u>Wt. %</u>	<u>CAS#</u>	<u>Classification</u>
Guanidiniumchloride solution	< 45%	50-01-1	Xn Label not necessary if quantity below 125 g or mL according to 67/548/EEC Art. 25, 1999/45/EC Art. 12)
Water and other constituents. Each of the other	Balance	N/A	None of the other constituents in this mixture contribute

Date prepared:	2007-07-10
Version No:	3.0
Page No:	Page 4 of 8

constituents are present in less than 1% concentration or less than 0,1% for potential carcinogens, reproductive toxins, respiratory tract sensitizers and mutagens.			significantly to the hazards associated with this component. All hazard information pertinent to this product has been provided in this MSDS per the requirements and in compliance with EC Directive 91/155/EEC and EC Directive 1999/45/EC (preparations).
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Component 6: Wash 2; Code: 71000973

<u>Chemical Name</u>	<u>Wt. %</u>	<u>CAS#</u>	<u>Classification</u>
Water and other constituents. Each of the other constituents are present in less than 1% concentration or less than 0,1% for potential carcinogens, reproductive toxins, respiratory tract sensitizers and mutagens.	Balance	N/A	None of the other constituents in this mixture contribute significantly to the hazards associated with this component. All hazard information pertinent to this product has been provided in this MSDS, per the requirements and in compliance with EC Directive 91/155/EEC and EC Directive 1999/45/EC (preparations).

Component 7: Eluent; Code: 71000975

<u>Chemical Name</u>	<u>Wt. %</u>	<u>CAS#</u>	<u>Classification</u>
Water and other constituents. Each of the other constituents are present in less than 1% concentration or less than 0,1% for	Balance	N/A	None of the other constituents in this mixture contribute significantly to the hazards associated with this component. All hazard

Date prepared:	2007-07-10
Version No:	3.0
Page No:	Page 5 of 8

potential carcinogens, reproductive toxins, respiratory tract sensitizers and mutagens.			information pertinent to this product has been provided in this MSDS, per the requirements and in compliance with EC Directive 91/155/EEC and EC Directive 1999/45/EC (preparations).
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3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

PHYSICAL APPEARANCE:

All components are colourless and odourless liquids except 3 which is lyophilised white solid.

POTENTIAL HEALTH EFFECTS

Components 1, 3 and 5 can cause slight to severe impairments of health due to swallowing or breathing in vapours or direct skin contact depending on the amount which has been ingested. It can accumulate within the body.

All other components are considered to be non hazardous products as specified in EC Directive 1999/45/EC (preparations)

COMMENTS ON HEALTH

All work should apply to Good Laboratory Practice (GLP) and as such any potential risks involved in using the kit are at a minimum.

4. FIRST AID MEASURES

Components 1, 3 and 5:

EYES: Rinse out with plenty of water with the eye-lid open for min. 10 minutes. Before (if possible) apply eye drops Proxymetacaine 0.5%, if the opening of the eyelid is painful. Then apply a loose bandage. Further treatment to be carried out by an eye specialist.

SKIN: Wash off with plenty of water. Remove contaminated clothing.

INGESTION: Make victim drink plenty of water with activated charcoal supplement and immediately induce vomiting.

INHALATION: Fresh air should be inhaled, keeping the airways clear. Administrate Dexamethasone spray as soon as possible. Ensure quiet, warmth and provide resuscitation if necessary.

Date prepared:	2007-07-10
Version No:	3.0
Page No:	Page 6 of 8

5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

CO₂, powder, foam, (water)

FIRE FIGHTING PROCEDURES

Due to the relatively small amounts of the preparations present, fire fighting is primarily to be focused and adapted towards materials stored in close proximity.

SPECIAL RISKS

Possible development of hazardous gases and vapours in the event of fire.

SPECIAL PROTECTIVE EQUIPMENT

Use only acid –resistant safety equipment. Do not stay in dangerous zone without suitable chemical protection clothing and self-contained breathing apparatus.

ADDITIONAL INFORMATION

The substance itself is not flammable. Product package burns like paper or plastic. Cool any undamaged container in water and remove from danger zone if possible. Heating will lead to an increase in pressure and a danger of bursting. Spray any vapours released with water. The extinguishing water may cause an acid or alkaline reaction. Only use equipment which is resistant to chemicals.

6. ACCIDENTAL RELEASE MEASURES

GENERAL PROCEDURES

Regular staff training is necessary indicating hazards and precautions on the basis of operation instructions.

PROCEDURES FOR CLEANING / ABSORPTION

Take up with liquid-absorbent material (e.g. Chemisorb®). Forward for disposal. Clean up affected area.

7. HANDLING AND STORAGE

HANDLING

In accordance with the instructions. Use before expiration date as printed on box! Always apply Good Laboratory Practice (GLP).

STORAGE

Store all components in box, dry and well ventilated place at maximum 25°C.

They spin columns **must** be stored at 2-8°C . Accessible for authorized personnel only.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

PERSONAL PROTECTION

Date prepared:	2007-07-10
Version No:	3.0
Page No:	Page 7 of 8

Good ventilation and extraction system in the room. Floor resistant to chemicals with floor drainage and washing facilities.

Due to the nature of the components in the assembled kit and its intended use we recommend wearing protective lab-coats and disposable laboratory gloves, with frequent changes, at all times.

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

EYES: Yes, safety glasses

RESPIRATORY: Not required unless aerosols and/or vapours are generated.

SKIN: Required

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE & APPEARANCE:

FORM: All components except 3 are liquids. Component 3 is lyophilized.

ODOURS: All components are virtually odourless.

pH: aqueous solution of compound 1 and 5 the pH is 5.

SOLUBILITY: Soluble (in water)

SPECIFIC GRAVITY: Not available

VISCOSITY: Not available

10. STABILITY AND REACTIVITY

Decomposition is not observed during the expiration period when stored in the original package under recommended condition.

11. TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: The acute and chronic toxic effects of harmful substances can differ markedly. They can have toxic respiratory effect and irritant effect on the skin and the mucous membranes, they can damage the skin, have narcotic effect, be central stimulation and in particular have damaging effect on the organs or lead to super-sensitisation. Cardiovascular system disorders, respiratory system lung disorders and gastro- intestinal disturbance can be the result. The symptoms are reddening of skin, unusually dry or moist, warm or cool skin, oedemas, blisters, exsiccosis, bleeding and sloughs.

Carcerogen/mutagen effects:

Components 1 and 5:

LD₅₀ (oral ratt): 475 mg/kg

LC₅₀ (ihll ratt):5,3 mg/l/4h

Date prepared:	2007-07-10
Version No:	3.0
Page No:	Page 8 of 8

LD₅₀ (drm rbt): >2000 mg/kg
Components 2,6 and 7:
LD₅₀ (oral ratt): >2000 mg/kg
Components 3: none

12. ECOLOGICAL INFORMATION

ECOLOGIC DATA:

The potential effects of a single package on the environment are considerably low. Hazard to drinking water only if large amounts enter the subsoil and waters.

13. DISPOSAL CONSIDERATIONS

PRODUCT DISPOSAL: Chemicals must be disposed of in compliance with the respective national regulations. *PACKAGING:* All packaging must be disposed of in compliance with country-specific regulations or must be passed to packaging return system.

14. TRANSPORT INFORMATION

Component 1 and 5:
Shipping name: Toxic liquid, organic, n.o.s (guanidium salts)
UN No: 2810
Class:6.1
Packaging group:III
Commercial transport: Classcode T1, LQ 19= 3L/30 kg
Maritime transport : F-A, S-B
Air transport : PAX 611 CAO 618
Other components no restrictions.

15. REGULATORY INFORMATION

LABELLING ACCORDING TO EC DIRECTIVES:

Symbol: R-phrases: S-phrases: For classification of individual components, see chapter 2.

16. OTHER INFORMATION

REGIONAL REPRESENTATION: Cepheid AB, P.O.Box 20045, SE-161 02 Bromma, Sweden, Tel: +46-8-555 20 400Fax: +46-8-555 20 499, e-mail: info@cepheid.se

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.