

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
 Product name : ADEXUSDx[®] hCG Control Set
 Product code : 401.009

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For in vitro diagnostic use

1.2.2. Uses advised against

Restrictions on use : Professional Use of Medical Devices

1.3. Details of the supplier of the safety data sheet

Manufacturer

NOWDiagnostics, Inc.
 1200 Stewart Pl.
 Springdale, AR 72764
www.nowdx.com
techsupport@nowdx.com
 T 479.966.4530 - F 479.927.6383

1.4. Emergency telephone number

Emergency number : 1.800.424.8802 National Response Center

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Components	CLP classification
hCG Plasma Control, Absent	Skin Sens. 1, H317
hCG Plasma Control, Present	Skin Sens. 1, H317



Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

2.2. Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
hCG Plasma Control, Absent		Warning	H317 - May cause an allergic skin reaction.	P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P302+P352 - IF ON SKIN: Wash with plenty of water. P321 - Specific treatment (see ... on this label).
hCG Plasma Control, Present		Warning	H317 - May cause an allergic skin reaction.	P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P302+P352 - IF ON SKIN: Wash with plenty of water. P321 - Specific treatment (see ... on this label).

2.3. Other hazards

No additional information available

SECTION 3: Composition/Information on ingredients
3.1. Substances

Not applicable

3.2. Mixtures

Name	Chemical name	CAS-No. EC-No.	%	CLP classification
hCG Plasma Control, Absent	ProClin 300	96118-96-6	0.1	Acute Tox. 4 (Oral), H302 Acute Tox 4 (Inhalation) H332 Acute Tox 5 (Dermal) H313 Skin Corrosion 1B H314 Respiratory Sensitization H334 Aquatic Acute 1, H400
hCG Plasma Control, Present	ProClin 300	96118-96-6	0.1	Acute Tox. 4 (Oral), H302 Acute Tox 4 (Inhalation) H332 Acute Tox 5 (Dermal) H313 Skin Corrosion 1B H314 Respiratory Sensitization H334 Aquatic Acute 1, H400

Full text of H-phrases: see section 16

SECTION 4: First aid measures
4.1. Description of first aid measures

First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center/doctor/physician if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
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4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures
5.1. Extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Foam.
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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released.
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5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
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SECTION 6: Accidental release measures
6.1. Personal precautions, protective equipment and emergency procedures
6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapors/spray.
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6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Mechanically recover the product.
 Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray. Wear personal protective equipment.
 Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Materials for protective clothing:

Lab coat
 Gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s):



Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
 Appearance : Clear fluid
 Color : Colorless
 Odor : Odorless.
 Odor threshold : No data available

pH	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosion limits	: Not applicable

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations
13.1. Waste treatment methods

Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
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SECTION 14: Transport information

In accordance with ADR / IATA

14.1. UN number

UN-No. (ADR)	: Not regulated
UN-No. (IATA)	: Not regulated

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not regulated
Proper Shipping Name (IATA)	: Not regulated

14.3. Transport hazard class(es)

ADR	: Not regulated
Transport hazard class(es) (ADR)	
IATA	: Not regulated
Transport hazard class(es) (IATA)	

14.4. Packing group

Packing group (ADR)	: Not regulated
Packing group (IATA)	: Not regulated

14.5. Environmental hazards

Dangerous for the environment	: No
Other information	: No supplementary information available

14.6. Special precautions for user

Overland transport
Not regulated

Air transport
Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
15.1.1. EU-Regulations

Contains no REACH candidate substance

15.1.2. National regulations

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Classification according to Regulation (EC) No. 1272/2008 [CLP]:	
Skin Sens. 1	H317

Full text of H- and EUH-phrases:	
Skin Sens. 1	Skin sensitization, Category 1
H317	May cause an allergic skin reaction.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.