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Revision Number 1

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product Code(s)	OCDUS6901861/707930/719220/707910/6901862
Product Name	AFFIRMAGEN, AFFIRMAGEN 4, ORTHO A2 Cells
Synonyms	6901861/707930 AFFIRMAGEN 719220/707910 AFFIRMAGEN 4 6901862 ORTHO A2 Cells

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

Recommended use	In vitro diagnostic
Uses advised against	No information available.

1.3. Details of the supplier of the safety data sheet

Importer Ortho-Clinical Diagnostics 1500 Boulevard Sébastien Brant B.P. 30335 67411 Illkirch CEDEX, France	Supplier Ortho-Clinical Diagnostics, Inc. 1001 US Highway 202 Raritan, NJ 08869
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For further information, please contact

E-mail address	UK and Irish Republic - ukhotline@orthoclinicaldiagnostics.com France - hotlinefrance@orthoclinicaldiagnostics.com Germany - ocdtechsupport-de@orthoclinicaldiagnostics.com Italy - italianhl@orthoclinicaldiagnostics.com Nordic - nordichotline@orthoclinicaldiagnostics.com Poland - service_pl@pl.diasorin.com Portugal - port_ocdhotline@orthoclinicaldiagnostics.com Spain - spanishhotline@orthoclinicaldiagnostics.com
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1.4. Emergency telephone number

Emergency Telephone	Transportation Emergencies: US Telephone Number: (800) 424-9300 International and Maritime Telephone Number: +1 (703) 527-3887 US: (800) 421-3311
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Emergency Telephone - §45 - (EC)1272/2008	
Europe	UK and Irish Republic 0 800 895963

	France 03 88 65 47 33 Germany 0 800 181 48 97 Italy 800 87 06 55 Nordic 00 800 08372560 Poland 48 (22) 223 62 65 Portugal 0 800 833143 Spain 900 97 33 25
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For further contact details please refer to the Ortho SDS Contact Details Document available at <https://www.orthoclinicaldiagnostics.com/en-us/home/technical-documents>

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

Hazard statements

Not classified

2.3. Other hazards

This product contains human blood derivatives. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. Therefore, all blood derivatives should be considered potentially infectious. It is recommended that these reagents be handled using established good laboratory working practices.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

The product contains no substances which at their given concentration, are considered to be hazardous to health

Full text of H- and EUH-phrases: see section 16

Acute toxicity estimate

No information available

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

Remove to fresh air.

Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Rinse mouth. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Call a physician.

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

Symptoms No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical No information available.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. Handle all blood and materials in contact with blood as if capable of transmitting infectious agents. It is recommended that blood and materials in contact with blood be handled using established good laboratory practices.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Ensure adequate ventilation.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place. Store according to label instructions.

7.3. Specific end use(s)

Specific use(s). No information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.
Environmental exposure controls	No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Red/clear suspension
Color	Red
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	6.8 - 7.4	None known
pH (as aqueous solution)	No data available	None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapor pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Vapor density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

9.2.1. Information with regard to physical hazard classes
 Not applicable

9.2.2. Other safety characteristics
 No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity None under normal use conditions.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid Heat.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Based on available data, the classification criteria are not met

Acute toxicity Based on available data, the classification criteria are not met

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	Contains no ingredients above reportable quantities listed as a carcinogen.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity .

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

12.7. Other adverse effects

Other adverse effects No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

Waste codes / waste designations according to EWC / AVV According to the European Waste Catalog, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

SECTION 14: Transport information

IATA

14.1 UN number or ID number Not regulated

14.2 Extended Proper Shipping Name Not regulated

14.3 Transport hazard class(es) Not regulated

14.4 Packing group Not regulated

14.5 Environmental hazards Not applicable

14.6 Special precautions for user
Special Provisions None

IMDG

14.1 UN number or ID number Not regulated

14.2 Extended Proper Shipping Name Not regulated

14.3 Transport hazard class(es) Not regulated

14.4 Packing group Not regulated

14.5 Marine pollutant Not applicable

14.6 Special precautions for user
Special Provisions None

14.7 Maritime transport in bulk according to IMO instruments No information available

RID

14.1 UN number Not regulated

14.2 Extended Proper Shipping Name Not regulated

14.3 Transport hazard class(es) Not regulated

14.4 Packing group Not regulated

14.5 Environmental hazards Not applicable

14.6 Special precautions for user
Special Provisions None

ADR

14.1 UN number or ID number Not regulated

14.2 UN proper shipping name Not regulated

14.3 Transport hazard class(es) Not regulated

14.4 Packing group Not regulated

14.5 Environmental hazards Not applicable

14.6 Special precautions for user
Special Provisions None

SECTION 15: Regulatory information

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

National regulations

Germany

Water hazard class (WGK) slightly hazardous to water (WGK 1)

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV).
 This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII).

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

15.2. Chemical safety assessment

Chemical Safety Report No information available

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)
 Ceiling Maximum limit value * Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method

STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
 U.S. Environmental Protection Agency ChemView Database
 European Food Safety Authority (EFSA)
 EPA (Environmental Protection Agency)
 Acute Exposure Guideline Level(s) (AEGL(s))
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
 U.S. Environmental Protection Agency High Production Volume Chemicals
 Food Research Journal
 Hazardous Substance Database
 International Uniform Chemical Information Database (IUCLID)
 Japan GHS Classification
 Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
 NIOSH (National Institute for Occupational Safety and Health)
 National Library of Medicine's ChemID Plus (NLM CIP)
 National Library of Medicine's PubMed database (NLM PUBMED)
 National Toxicology Program (NTP)
 New Zealand's Chemical Classification and Information Database (CCID)
 Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
 Organization for Economic Co-operation and Development High Production Volume Chemicals Program
 Organization for Economic Co-operation and Development Screening Information Data Set
 World Health Organization

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Disclaimer

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End of Safety Data Sheet