

SAFETY DATA SHEET



ADVIA® Centaur FSH, 500 Test

SDS no.:

01360521

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

1.1 Product identifier

Product name : ADVIA® Centaur FSH, 500 Test
Product code : 01360521, 110756, 04912924, 110755, 10309973, 10309974, 118821, 10337964

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

Identified uses ADVIA® Centaur FSH ReadyPack Lite Reagent Diagnostic agents.
 ADVIA® Centaur FSH ReadyPack Solid Phase Diagnostic agents.

Restrictions on use For professional users only.

Supplier : Siemens Healthcare Diagnostics Limited
 Park View,
 Watchmoor Park,
 Camberley,
 Surrey,
 GU15 3YL
 United Kingdom

Phone: +44 (0) 345 600 1955

e-mail address of person responsible for this SDS : dx.msds.healthcare@siemens-healthineers.com

1.4 Emergency telephone number

CHEMTREC: +44 20 3807 3798

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : ADVIA® Centaur FSH ReadyPack Lite Reagent Mixture
 ADVIA® Centaur FSH ReadyPack Solid Phase Mixture

Classification according to UK CLP/GHS

Not classified.

The product is not classified as hazardous according to UK CLP Regulation SI 2019/720 as amended.
 See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Signal word : ADVIA® Centaur FSH ReadyPack Lite Reagent No signal word.
 ADVIA® Centaur FSH ReadyPack Solid Phase No signal word.

Hazard statements : ADVIA® Centaur FSH ReadyPack Lite Reagent No known significant effects or critical hazards.
 ADVIA® Centaur FSH ReadyPack Solid Phase No known significant effects or critical hazards.

Precautionary statements

SECTION 2: Hazards identification

| | | |
|---|---|--|
| Prevention | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not applicable. Not applicable. |
| Response | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not applicable. Not applicable. |
| Storage | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not applicable. Not applicable. |
| Disposal | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not applicable. Not applicable. |
| Supplemental label elements | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not applicable. Not applicable. |
| Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not applicable. Not applicable. |
| 2.3 Other hazards | | |
| Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB. |
| Other hazards which do not result in classification | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | None known. None known. |
| Additional information | : Not available. | Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. |

SECTION 3: Composition/information on ingredients

| | | |
|-----------------------|---|--------------------|
| 3.1 Substances | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Mixture Mixture |
|-----------------------|---|--------------------|

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

SECTION 4: First aid measures

4.1 Description of first aid measures

| | | |
|-----------------------------------|---|--|
| Eye contact | : ADVIA® Centaur FSH ReadyPack Lite Reagent | Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs. |
| Inhalation | : ADVIA® Centaur FSH ReadyPack Lite Reagent | Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. |
| Skin contact | : ADVIA® Centaur FSH ReadyPack Lite Reagent | Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. |
| Ingestion | : ADVIA® Centaur FSH ReadyPack Lite Reagent | Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur. |
| Protection of first-aiders | : ADVIA® Centaur FSH ReadyPack Lite Reagent | No action shall be taken involving any personal risk or without suitable training. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | No action shall be taken involving any personal risk or without suitable training. |

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

| | | |
|---------------------|---|-------------------|
| Eye contact | : ADVIA® Centaur FSH ReadyPack Lite Reagent | No specific data. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | No specific data. |
| Inhalation | : ADVIA® Centaur FSH ReadyPack Lite Reagent | No specific data. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | No specific data. |
| Skin contact | : ADVIA® Centaur FSH ReadyPack Lite Reagent | No specific data. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | No specific data. |

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SECTION 4: First aid measures

Ingestion : ADVIA® Centaur FSH ReadyPack Lite Reagent No specific data.
 ADVIA® Centaur FSH ReadyPack Solid Phase No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician : ADVIA® Centaur FSH ReadyPack Lite Reagent Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
 ADVIA® Centaur FSH ReadyPack Solid Phase Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments : ADVIA® Centaur FSH ReadyPack Lite Reagent No specific treatment.
 ADVIA® Centaur FSH ReadyPack Solid Phase No specific treatment.
 ADVIA® Centaur FSH ReadyPack Lite Reagent Not available.
 ADVIA® Centaur FSH ReadyPack Solid Phase Not available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous combustion products : No specific data.

5.3 Advice for firefighters

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment.

For emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

: Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

SECTION 6: Accidental release measures

6.3 Methods and material for containment and cleaning up

Small spill : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

6.4 Reference to other sections : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8).

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific solutions : Not available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to appropriate monitoring standards. Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

SECTION 8: Exposure controls/personal protection

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties

Appearance

| | | |
|--|---|-----------------------------|
| Physical state | : ADVIA® Centaur FSH ReadyPack Lite | Liquid. |
| | Reagent | |
| | ADVIA® Centaur FSH ReadyPack | Liquid. |
| Colour | Solid Phase | |
| | : ADVIA® Centaur FSH ReadyPack Lite | Colourless. |
| | Reagent | |
| Odour | ADVIA® Centaur FSH ReadyPack | Colourless to light yellow. |
| | Solid Phase | |
| | : ADVIA® Centaur FSH ReadyPack Lite | Odourless. |
| Odour threshold | Reagent | |
| | ADVIA® Centaur FSH ReadyPack | Odourless. |
| | Solid Phase | |
| Melting point/freezing point | : Not relevant/applicable due to nature of the product. | |
| Softening point | : Not relevant/applicable due to nature of the product. | |
| Sublimation temperature | : Not relevant/applicable due to nature of the product. | |
| Initial boiling point and boiling range | : ADVIA® Centaur FSH ReadyPack Lite | Not available. |
| | Reagent | |
| | ADVIA® Centaur FSH ReadyPack | Not available. |
| | Solid Phase | |

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SECTION 9: Physical and chemical properties

- Flammability (solid, gas)** : ADVIA® Centaur FSH ReadyPack Lite Reagent Not relevant/applicable due to nature of the product.
 ADVIA® Centaur FSH ReadyPack Solid Phase Not relevant/applicable due to nature of the product.
- Upper/lower flammability or explosive limits** : ADVIA® Centaur FSH ReadyPack Lite Reagent Not available.
 ADVIA® Centaur FSH ReadyPack Solid Phase Not available.
- Flash point** : ADVIA® Centaur FSH ReadyPack Lite Reagent [Product does not sustain combustion.]
 ADVIA® Centaur FSH ReadyPack Solid Phase [Product does not sustain combustion.]

Auto-ignition temperature :

| Ingredient name | °C | °F | Method |
|--|-----|-------|---------|
| ADVIA® Centaur FSH ReadyPack Lite Reagent sodium azide | 309 | 588.2 | EU A.16 |
| ADVIA® Centaur FSH ReadyPack Solid Phase sodium azide | 309 | 588.2 | EU A.16 |

Decomposition temperature : Not relevant/applicable due to nature of the product.

pH : ADVIA® Centaur FSH ReadyPack Lite Reagent 7.4
 ADVIA® Centaur FSH ReadyPack Solid Phase 7.4

Viscosity : ADVIA® Centaur FSH ReadyPack Lite Reagent Not available.
 ADVIA® Centaur FSH ReadyPack Solid Phase Not available.

Solubility(ies) :
 Not available.

Solubility in water : Not relevant/applicable due to nature of the product.

Miscible with water : Not relevant/applicable due to nature of the product.

Partition coefficient: n-octanol/ water : Not relevant/applicable due to nature of the product.

Vapour pressure :

| Ingredient name | Vapour Pressure at 20°C | | | Vapour pressure at 50°C | | |
|---|-------------------------|-----|--------|-------------------------|-----|--------|
| | mm Hg | kPa | Method | mm Hg | kPa | Method |
| ADVIA® Centaur FSH ReadyPack Lite Reagent water | 23.8 | 3.2 | | | | |
| ADVIA® Centaur FSH ReadyPack Solid Phase water | 23.8 | 3.2 | | | | |

Evaporation rate : Not relevant/applicable due to nature of the product.

Relative density : ADVIA® Centaur FSH ReadyPack Lite Reagent 1
 ADVIA® Centaur FSH ReadyPack Solid Phase >1

Density : ADVIA® Centaur FSH ReadyPack Lite Reagent Not available.
 ADVIA® Centaur FSH ReadyPack Solid Phase Not available.

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SECTION 9: Physical and chemical properties

| | | |
|-----------------------------|---|----------------|
| Vapour density | : ADVIA® Centaur FSH ReadyPack Lite Reagent | Not available. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. |
| Explosive properties | : ADVIA® Centaur FSH ReadyPack Lite Reagent | Not available. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. |
| Oxidising properties | : ADVIA® Centaur FSH ReadyPack Lite Reagent | Not available. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. |

Particle characteristics

Median particle size : Not applicable.

9.2 Other information

| | | |
|-------------------------------------|---|----------------|
| Fire point | : ADVIA® Centaur FSH ReadyPack Lite Reagent | Not available. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. |
| Burning time | : Not relevant/applicable due to nature of the product. | |
| Fundamental burning velocity | : Not relevant/applicable due to nature of the product. | |
| Burning rate | : Not relevant/applicable due to nature of the product. | |
| SADT | : Not relevant/applicable due to nature of the product. | |
| SAPT | : Not relevant/applicable due to nature of the product. | |
| Heat of reaction | : Not relevant/applicable due to nature of the product. | |
| Heat of combustion | : Not relevant/applicable due to nature of the product. | |
| Flow time (ISO 2431) | : Not relevant/applicable due to nature of the product. | |
| Molecular weight | : Not relevant/applicable due to nature of the product. | |

SECTION 10: Stability and reactivity

| | |
|--|--|
| 10.1 Reactivity | : No specific test data related to reactivity available for this product or its ingredients. |
| 10.2 Chemical stability | : The product is stable. |
| 10.3 Possibility of hazardous reactions | : Under normal conditions of storage and use, hazardous reactions will not occur. |
| 10.4 Conditions to avoid | : No specific data. |
| 10.5 Incompatible materials | : No specific data. |
| 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

| | | |
|---------------------------|---|----------------|
| Conclusion/Summary | : ADVIA® Centaur FSH ReadyPack Lite Reagent | Not available. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. |

Acute toxicity estimates

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SECTION 11: Toxicological information

| Product/ingredient name | Oral (mg/kg) | Dermal (mg/kg) | Inhalation (gases) (ppm) | Inhalation (vapours) (mg/l) | Inhalation (dusts and mists) (mg/l) |
|---|--------------|----------------|--------------------------|-----------------------------|-------------------------------------|
| ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Lite Reagent | 27015.9 | 20011.8 | N/A | N/A | N/A |
| ADVIA® Centaur FSH ReadyPack Solid Phase ADVIA® Centaur FSH ReadyPack Solid Phase | 27018.6 | 20013.8 | N/A | N/A | N/A |

Irritation/Corrosion

Conclusion/Summary

| | | |
|--------------------|---|----------------------------------|
| Skin | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
| Eyes | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
| Respiratory | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |

Sensitisation

Conclusion/Summary

| | | |
|--------------------|---|----------------------------------|
| Skin | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
| Respiratory | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |

Mutagenicity

Conclusion/Summary

| | | |
|---------------------------|---|----------------------------------|
| Conclusion/Summary | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
|---------------------------|---|----------------------------------|

Carcinogenicity

Conclusion/Summary

| | | |
|---------------------------|---|----------------------------------|
| Conclusion/Summary | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
|---------------------------|---|----------------------------------|

Reproductive toxicity

Conclusion/Summary

| | | |
|---------------------------|---|----------------------------------|
| Conclusion/Summary | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
|---------------------------|---|----------------------------------|

Teratogenicity

Conclusion/Summary

| | | |
|---------------------------|---|----------------------------------|
| Conclusion/Summary | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
|---------------------------|---|----------------------------------|

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

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Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure : ADVIA® Centaur FSH ReadyPack Lite Reagent Not available.
 ADVIA® Centaur FSH ReadyPack Solid Phase Not available.

Potential acute health effects

Eye contact : ADVIA® Centaur FSH ReadyPack Lite Reagent No known significant effects or critical hazards.
 ADVIA® Centaur FSH ReadyPack Solid Phase No known significant effects or critical hazards.

Inhalation : ADVIA® Centaur FSH ReadyPack Lite Reagent No known significant effects or critical hazards.
 ADVIA® Centaur FSH ReadyPack Solid Phase No known significant effects or critical hazards.

Skin contact : ADVIA® Centaur FSH ReadyPack Lite Reagent No known significant effects or critical hazards.
 ADVIA® Centaur FSH ReadyPack Solid Phase No known significant effects or critical hazards.

Ingestion : ADVIA® Centaur FSH ReadyPack Lite Reagent No known significant effects or critical hazards.
 ADVIA® Centaur FSH ReadyPack Solid Phase No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : ADVIA® Centaur FSH ReadyPack Lite Reagent No specific data.
 ADVIA® Centaur FSH ReadyPack Solid Phase No specific data.

Inhalation : ADVIA® Centaur FSH ReadyPack Lite Reagent No specific data.
 ADVIA® Centaur FSH ReadyPack Solid Phase No specific data.

Skin contact : ADVIA® Centaur FSH ReadyPack Lite Reagent No specific data.
 ADVIA® Centaur FSH ReadyPack Solid Phase No specific data.

Ingestion : ADVIA® Centaur FSH ReadyPack Lite Reagent No specific data.
 ADVIA® Centaur FSH ReadyPack Solid Phase No specific data.

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

Short term exposure

Potential immediate effects : ADVIA® Centaur FSH ReadyPack Lite Reagent Not available.
 ADVIA® Centaur FSH ReadyPack Solid Phase Not available.

Potential delayed effects : ADVIA® Centaur FSH ReadyPack Lite Reagent Not available.
 ADVIA® Centaur FSH ReadyPack Solid Phase Not available.

Long term exposure

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SECTION 11: Toxicological information

| | | |
|--|---|--|
| Potential immediate effects | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
| Potential delayed effects | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
| <u>Potential chronic health effects</u> | | |
| Not available. | | |
| Conclusion/Summary | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
| General | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | No known significant effects or critical hazards. No known significant effects or critical hazards. |
| Carcinogenicity | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | No known significant effects or critical hazards. No known significant effects or critical hazards. |
| Mutagenicity | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | No known significant effects or critical hazards. No known significant effects or critical hazards. |
| Reproductive toxicity | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | No known significant effects or critical hazards. No known significant effects or critical hazards. |
| Interactive effects | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
| <u>Toxicokinetics</u> | | |
| Absorption | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
| Distribution | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
| Metabolism | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
| Elimination | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |
| Other information | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. Not available. |

SECTION 12: Ecological information

12.1 Toxicity

| | | |
|---------------------------|---|----------------|
| Conclusion/Summary | : ADVIA® Centaur FSH ReadyPack Lite Reagent | Not available. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. |

12.2 Persistence and degradability

| | | |
|---------------------------|---|----------------|
| Conclusion/Summary | : ADVIA® Centaur FSH ReadyPack Lite Reagent | Not available. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. |

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

| | | |
|--|---|----------------|
| Soil/water partition coefficient (K_{oc}) | : ADVIA® Centaur FSH ReadyPack Lite Reagent | Not available. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. |
| Mobility | : ADVIA® Centaur FSH ReadyPack Lite Reagent | Not available. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Not available. |

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

| | |
|----------------------------|---|
| Methods of disposal | : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. |
| Hazardous waste | : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. |

Packaging

| | |
|----------------------------|---|
| Methods of disposal | : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. |
| Special precautions | : This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. |

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SECTION 14: Transport information

ADR/RID

| | | |
|--|---|----------------|
| 14.1 UN number | ADVIA® Centaur FSH ReadyPack Lite Reagent | Not regulated. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Not regulated. |
| 14.2 UN proper shipping name | ADVIA® Centaur FSH ReadyPack Lite Reagent | - |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |
| 14.3 Transport hazard class(es) | ADVIA® Centaur FSH ReadyPack Lite Reagent | - |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |
| 14.4 Packing group | ADVIA® Centaur FSH ReadyPack Lite Reagent | - |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |
| 14.5 Environmental hazards | ADVIA® Centaur FSH ReadyPack Lite Reagent | No. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | No. |
| Additional information | ADVIA® Centaur FSH ReadyPack Lite Reagent | - |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |

ADN

| | | |
|--|---|----------------|
| 14.1 UN number | ADVIA® Centaur FSH ReadyPack Lite Reagent | Not regulated. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Not regulated. |
| 14.2 UN proper shipping name | ADVIA® Centaur FSH ReadyPack Lite Reagent | - |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |
| 14.3 Transport hazard class(es) | ADVIA® Centaur FSH ReadyPack Lite Reagent | - |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |
| 14.4 Packing group | ADVIA® Centaur FSH ReadyPack Lite Reagent | - |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |
| 14.5 Environmental hazards | ADVIA® Centaur FSH ReadyPack Lite Reagent | No. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | No. |
| Additional information | ADVIA® Centaur FSH ReadyPack Lite Reagent | - |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |

IMDG

| | | |
|--|---|----------------|
| 14.1 UN number | ADVIA® Centaur FSH ReadyPack Lite Reagent | Not regulated. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Not regulated. |
| 14.2 UN proper shipping name | ADVIA® Centaur FSH ReadyPack Lite Reagent | - |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |
| 14.3 Transport hazard class(es) | ADVIA® Centaur FSH ReadyPack Lite Reagent | - |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |

ADVIA® Centaur FSH, 500 Test

SECTION 14: Transport information

| | | |
|-----------------------------------|--|-----|
| 14.4 Packing group | ADVIA® Centaur FSH ReadyPack Lite | - |
| | Reagent | |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |
| 14.5 Environmental hazards | ADVIA® Centaur FSH ReadyPack Lite | No. |
| | Reagent | |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | No. |
| Additional information | ADVIA® Centaur FSH ReadyPack Lite | - |
| | Reagent | |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |

IATA

| | | |
|--|--|----------------|
| 14.1 UN number | ADVIA® Centaur FSH ReadyPack Lite | Not regulated. |
| | Reagent | |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | Not regulated. |
| 14.2 UN proper shipping name | ADVIA® Centaur FSH ReadyPack Lite | - |
| | Reagent | |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |
| 14.3 Transport hazard class(es) | ADVIA® Centaur FSH ReadyPack Lite | - |
| | Reagent | |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |

| | | |
|-----------------------------------|---|-----|
| 14.4 Packing group | ADVIA® Centaur FSH ReadyPack Lite | - |
| | Reagent | |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |
| 14.5 Environmental hazards | ADVIA® Centaur FSH ReadyPack Lite Reagent | No. |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | No. |
| | | |
| Additional information | ADVIA® Centaur FSH ReadyPack Lite | - |
| | Reagent | |
| | ADVIA® Centaur FSH ReadyPack Solid Phase | - |

14.6 Special precautions for user : ADVIA® Centaur FSH ReadyPack Lite Reagent

Transport within user's premises:
always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

ADVIA® Centaur FSH ReadyPack Solid Phase

Transport within user's premises:
always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to IMO instruments : Not applicable.

SECTION 15: Regulatory information

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

UK (GB) /REACH

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Ozone depleting substances

Not listed.

Prior Informed Consent (PIC)

Not listed.

Persistent Organic Pollutants

Not listed.

| | | |
|---|---|------------------------------------|
| Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not applicable. Not applicable. |
|---|---|------------------------------------|

Seveso Directive

This product is not controlled under the Seveso Directive.

EU regulations

| | | |
|---|---|--------------------------|
| Industrial emissions (integrated pollution prevention and control) - Air | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not listed Not listed |
| Industrial emissions (integrated pollution prevention and control) - Water | : ADVIA® Centaur FSH ReadyPack Lite Reagent ADVIA® Centaur FSH ReadyPack Solid Phase | Not listed Not listed |

International regulations

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

15.2 Chemical safety assessment : Not applicable.

SECTION 16: Other information

✔ Indicates information that has changed from previously issued version.

Abbreviations and acronyms

- : ATE = Acute Toxicity Estimate
- GB CLP = UK CLP (EC No 1272/2008) on the Classification, Labelling and Packaging of Substances and Mixtures as amended by (EU Exit) Regulations 2019 No. 720 and amendments
- DMEL = Derived Minimal Effect Level
- DNEL = Derived No Effect Level
- EUH statement = GB CLP-specific Hazard statement
- N/A = Not available
- PBT = Persistent, Bioaccumulative and Toxic
- PNEC = Predicted No Effect Concentration
- RRN = REACH Registration Number
- SGG = Segregation Group
- vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification

Not classified.

Full text of abbreviated H statements

Not applicable.

Full text of classifications

Not applicable.

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Date of previous issue : No previous validation

Version : 1

Notice to reader

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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.