1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product name
DIASOURCE 3α-DIOL G-RIA-CT kit

Catalog #
KIP0151

Kit components
Anti 3α-DIOL G
Coated tubes
\(^{125}\text{I} – \)labelled 3α-DIOL G
Standard 0
Standards 1 to 5
Controls 1 and 2
Washing Solution

1.2 Intended Use
In vitro diagnostic use

1.3 Company
DIAsource ImmunoAssays S.A.
Rue du Bosquet, 2
B-1348 Louvain-la-Neuve
Belgium
Tel. Nr. +32 (0)10/84.99.11
e-mail: tech.support@diasource.be

1.4 In emergencies
Call your local emergency centre

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

2.1.1 Classification according to Regulation (EC) no 1272/2008 (CLP)

\(^{125}\text{I} – \)labelled 3α-DIOL G
Aquatic acute cat. 1 – Aquatic chronic cat. 4

2.1.2 Classification according to Directive 1999/45/EC

\(^{125}\text{I} – \)labelled 3α-DIOL G
Dangerous for the environment

2.1.3 Additional Information
Classification according to radioprotection regulations.

\(^{125}\text{I} – \)labelled 3α-DIOL G
Contains radioactive material
2.2 Label elements:

2.2.1 Labeling according to Regulation (EC) no 1272/2008 (CLP)

No label required

2.2.2 Labeling according to radioprotection regulations

\[ ^{125} \text{I} – \text{labelled } 3\alpha-\text{DIOL G} \]

2.3 Other hazards:

\[ ^{125} \text{I} – \text{labelled } 3\alpha-\text{DIOL G} \]  
Contains material from bovine origin  
Contains material from rabbit origin  
Tracer: 185 kBq

Standard 0  
Contains material from bovine origin  
Standard 1 to 5  
Contains material from bovine origin  
Controls 1 and 2  
Contains material from human origin

Although these human materials have been tested for HBsAg, anti-HCV and anti-HIV-1/2 and have been found not reactive, they should be considered as potentially infectious.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous ingredients:

<table>
<thead>
<tr>
<th>Component</th>
<th>Classification</th>
<th>concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS-No. 26628-22-8</td>
<td>Aquatic Acute 1- Aquatic chronic 4,</td>
<td>&lt; 0.05%</td>
</tr>
<tr>
<td>EC-No. 247-852-1</td>
<td>H413</td>
<td></td>
</tr>
<tr>
<td>Index-No. 011-004-00-7</td>
<td>T+, N; R28, R50-53</td>
<td></td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

4.1 Description of first aid measures

All Kit Components

After skin contact: - Wash immediately with soap and plenty of water for at least 10 minutes.
                  - Consult a physician in case of inflammation.
                  - In the case of a wound or cut rinse with plenty of water, then dress the wound.

After eye contact: - Wash immediately with plenty of water for at least 15 minutes.
                  - Consult immediately a physician
                  - Do not apply neutralizing agents

After ingestion:  - Consult immediately a physician if ingested in large quantities

After inhalation: - Transfer the person to an open place.
                  - If he does not breathe, proceed to artificial respiration or provide oxygen.
                  - Consult a physician.

4.3 Indication of any immediate medical attention and special treatment needed
No data available.

5. FIRE FIGHTING MEASURES

All Kit Components

Suitable extinguishing media: - Powder, water, carbon dioxide, dry sand
Unsuitable extinguishing media: - No data available
Special exposure hazards:   - No generation of hazardous or toxic gases in dangerous quantities
Instructions:               - Due to small quantities: no special instructions apply
Special protective equipment for firefighters: - Wear a breathing apparatus and protective clothing to avoid all contact with the skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

All Kit Components

Personal protection: see 8

Environmental precautions:
- Prevent soil and water pollution
- Discharge according to local regulations

Clean-up:
- The radioactive material should be wiped up immediately.
- Take up liquid spill into absorbent material
- Discharge of absorbed material according to local regulations
- Clean contaminated surfaces with water
- Wash clothing according to radioprotection rules
7. HANDLING AND STORAGE

All Kit Components

Handling:
- Handle radioactive material according to radioprotection rules
- Observe normal hygiene standards
- Discharge according to local regulations
- Remove and clean contaminated clothing
- Handle and open the container with care

Storage:
- Keep container tightly closed
- Meet the legal requirements
- Keep away from: heat sources, combustible materials, acids, metals
- Storage temperature: see component label

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Component</th>
<th>No. Value</th>
<th>mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide</td>
<td>TLV-TWA</td>
<td>-</td>
</tr>
<tr>
<td>CAS 26628-22-8</td>
<td>TLV-STEL</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>TLV-Ceiling</td>
<td>0.29</td>
</tr>
<tr>
<td></td>
<td>OES-LTEL</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>OES-STEL</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>MAK</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>TRK</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MAC-TGG 8h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MAC-TGG 15min</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MAC-Ceiling</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>VMA 8h</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>VMA 15min</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>GWBB 8h</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>GWBB 15min</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Momentary value</td>
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</tr>
<tr>
<td></td>
<td>EC</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>EC-STEL</td>
<td>0.3</td>
</tr>
</tbody>
</table>

8.2 Exposure Controls

8.2.1 Appropriate engineering controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
8.2.2 Personal protection equipment

All Kit Components

Eye protection: - Safety goggles ($^{125}$I – labelled 3α-DIOL G)
- Face shield (Other components)

Hand protection: - Gloves

Suitable materials: - No data available

Skin protection: - Protective clothing

Operators handling radioactive material should be monitored according to local regulations regarding occupational medicine.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

$^{125}$I

Half-life: 59.9 days
Specific activity: $6.4 \times 10^{14}$ Bq.g$^{-1}$

Coated Tubes: Tubes

Controls 1 and 2, Standard 0, Standards 1 to 5: Lyophilized, soluble in water

Washing Solution, $^{125}$I – labelled 3α-DIOL G: Liquid

9.2 Other Information

No data available

10. STABILITY AND REACTIVITY

All Kit Components

Stability: All components are stable until expiry date if stored in specified conditions (see label)

Reactivity/Hazardous decomposition products: No hazardous decomposition products are formed in high quantities

Conditions/Materials to avoid: Keep away from metals and acids (Azide containing components)

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

$^{125}$I labeled component(s):

Chronic and acute effects: Radioactivity related adverse effects are only observed at exposure levels that are very much higher than those experienced with the reagents in this kit.

Sodium azide:

Acute oral toxicity: LD50 rat: 27 mg/kg (RTECS)

Absorption symptoms: Irritations of mucous membranes in the mouth, pharynx, oesophagus
MATERIAL SAFETY DATA SHEET
(According to regulation (EC) 1907/2006 and amendments)
Product name: DIASOURCE 3α-DIOL G-RIA-CT kit
Catalog #: KIP0151

Acute inhalation toxicity
Symptoms: Irritation symptoms in the respiratory tract. Inhalation may lead to the formation of oedemas in the respiratory tract. Symptoms may be delayed.

Acute dermal toxicity
LD50 rabbit: 20 mg/kg (RTECS) (Regulation (EC) No 1272/2008, Annex VI)
Skin irritation
Possible damages: slight irritation
Eye irritation
Possible damages: slight irritation
Sensitisation
This information is not available.
Germ cell mutagenicity
This information is not available.
Carcinogenicity
This information is not available.
Reproductive toxicity
This information is not available.
Teratogenicity
This information is not available.
Specific target organ toxicity - single exposure
This information is not available.
Specific target organ toxicity - repeated exposure
This information is not available.
Aspiration hazard
This information is not available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity
Aquatic toxicity
Sodium azide:
LC50 Lepomis macrochirus (Bluegill sunfish): 0.7 mg/l; 96 h (ECOTOX Database)
EC50 Daphnia pulex (Water flea): 4.2 mg/l; 48 h (ECOTOX Database)
IC50 mixed culture of green algae: 272 mg/l(Lit.)
EC50 Photobacterium phosphoreum: 38.5 mg/l(Lit.)

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
Sodium azide:
Partition coefficient: n-octanol/water: log Pow: 0.3
OECD Test Guideline 117
Bioaccumulation is not expected.

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
No data available

12.6 Other adverse effects
Sodium azide:
Forms toxic mixtures in water, dilution measures notwithstanding.
Herbicide
Nematocidal effect.
Discharge into the environment must be avoided.
13. DISPOSAL CONSIDERATIONS


Disposal methods:
- Radioactive material should be disposed of following local regulations regarding radioactive waste.
- Patient samples, $^{125}$I – labelled 3α-DIOL G, Standard 0, Standards 1 to 5, Controls 1 and 2 are potentially infectious. They should be disposed of following established safety procedures and local regulations.
- All the kit components must be considered as hazardous waste. They should be disposed of following local regulations.
- Sodium azide reacts with lead and copper plumbing forming highly explosive metal azides.

14. TRANSPORT INFORMATION

Radioactive material, N.O.S., UN 2910 - except package

Land transport AIEA/ADR/RID regulation (Class 7, fiche 1 - ADR)
Sea transport IMDG regulation
Air transport OACI/IATA regulation

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.1 Safety, health and environmental regulations/legislation specific for the mixture
no data available

15.2 Chemical Safety assessment
no data available

16. OTHER INFORMATION

16.1 Indication of changes
v1: SDS changes as required by current REACH regulation (as amended by 453/2010).
Classification and labeling according to CLP added.

16.2 Abbreviations and acronyms
T+ Very toxic
N Dangerous for the environment
16.3 Key literature references and sources for data
SDS sheets provided by suppliers of raw materials.

16.4 Classification and procedure used to derive the classification for mixtures according to regulation EC 1272/2008 – CLP

Classification of mixtures is based on the calculation method.

16.5 Relevant R-phrases and/or H-P statements

R28 Very toxic if swallowed
R50 Very toxic to aquatic organisms
R53 May cause long term adverse effects in the aquatic environment

H413 May cause long lasting harmful effects to aquatic life

P273 Avoid release to the environment
P391 Collect spillage
P501 Dispose of contents/container to …

16.7 Training advice
This product is designed for use by professionals.

16.8 Further information

NOTE: The safety analysis of the lyophilized components in this kit has been performed on the reconstituted components. Therefore, the information in this MSDS and product labeling relates to the components as they will be used, i.e. after reconstitution.

The human blood components included in this kit have been tested by European approved and/or FDA approved methods and found negative for HBsAg, anti-HCV and anti-HIV-1 and 2. No known method can offer complete assurance that human blood derivatives will not transmit hepatitis, AIDS or other infections. Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

All animal products and derivatives have been collected from healthy animals. Bovine components originate from countries where BSE has not been reported.

This MSDS assumes that radioprotection principles and applicable regulations are known by the user.

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

It remains the user’s own responsibility to make sure that the information is appropriate and complete for his specific use of this product. The user is also responsible for observing any laws and applicable guidelines.

MSDS established : 2015-05-08
Revision number : 2