SAFETY DATA SHEET
PathDetect p53 cis Reporting System, Part Number 219083

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

1.1 Product identifier
Product name: PathDetect p53 cis Reporting System, Part Number 219083
Part no. (chemical kit): 219083
Part no.: p53-Luc Plasmid 219085-51
pFC-p53 Positive Control Plasmid 219083-52

1.2 Relevant identified uses of the substance or mixture and uses advised against
Material uses: Analytical reagent.
- p53-Luc Plasmid: 0.05 ml
- pFC-p53 Positive Control Plasmid: 0.2 ml (5 µg 25 ng/µl)

1.3 Details of the supplier of the safety data sheet
Agilent Technologies Manufacturing GmbH & Co. KG
Hewlett-Packard-Str. 8
76337 Waldbronn
Germany
0800 603 1000
E-mail address of person responsible for this SDS: pdl-msds_author@agilent.com

1.4 Emergency telephone number
Emergency telephone number (with hours of operation): CHEMTREC®: +(44)-870-8200418

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Product definition: p53-Luc Plasmid Mixture
pFC-p53 Positive Control Plasmid Mixture
Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]
Not classified.

See Section 16 for the full text of the H statements declared above.
See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements
Signal word: No signal word.
- p53-Luc Plasmid
- pFC-p53 Positive
- Control Plasmid

Hazard statements: No known significant effects or critical hazards.
- p53-Luc Plasmid
- pFC-p53 Positive
- Control Plasmid

Precautionary statements
PathDetect p53 cis Reporting System, Part Number 219083

SECTION 2: Hazards identification

Prevention: p53-Luc Plasmid Not applicable.
   pFC-p53 Positive Control Plasmid Not applicable.
Response: p53-Luc Plasmid Not applicable.
   pFC-p53 Positive Control Plasmid Not applicable.
Storage: p53-Luc Plasmid Not applicable.
   pFC-p53 Positive Control Plasmid Not applicable.
Disposal: p53-Luc Plasmid Not applicable.
   pFC-p53 Positive Control Plasmid Not applicable.
Supplemental label elements: p53-Luc Plasmid Not applicable.
   pFC-p53 Positive Control Plasmid Not applicable.
Annex XVII - Restrictions on the manufacture, placing on the market, and use of certain dangerous substances, mixtures and articles:
   p53-Luc Plasmid Not applicable.
   pFC-p53 Positive Control Plasmid Not applicable.

Special packaging requirements:
   Tactile warning of danger: p53-Luc Plasmid Not applicable.
   pFC-p53 Positive Control Plasmid Not applicable.

2.3 Other hazards:
   Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII:
   p53-Luc Plasmid This mixture does not contain any substances that are assessed to be a PBT or a vPvB.
   pFC-p53 Positive Control Plasmid 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:
   p53-Luc Plasmid None known.
   pFC-p53 Positive Control Plasmid None known.

SECTION 3: Composition/information on ingredients

3.1 Substances: p53-Luc Plasmid Mixture
   pFC-p53 Positive Control Plasmid 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.

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures:
   Eye contact: p53-Luc Plasmid 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.
   pFC-p53 Positive Control Plasmid Similarly as above.
### SECTION 4: First aid measures

#### Inhalation
- **p53-Luc Plasmid**: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
- **pFC-p53 Positive Control Plasmid**: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

#### Skin contact
- **p53-Luc Plasmid**: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. 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.
- **pFC-p53 Positive Control Plasmid**: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. 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.

#### Ingestion
- **p53-Luc Plasmid**: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. 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.
- **pFC-p53 Positive Control Plasmid**: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. 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
- **p53-Luc Plasmid**: No action shall be taken involving any personal risk or without suitable training.
- **pFC-p53 Positive Control Plasmid**: No action shall be taken involving any personal risk or without suitable training.

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

##### Potential acute health effects
- **Eye contact**
  - **p53-Luc Plasmid**: No known significant effects or critical hazards.
  - **pFC-p53 Positive Control Plasmid**: No known significant effects or critical hazards.

- **Inhalation**
  - **p53-Luc Plasmid**: No known significant effects or critical hazards.
  - **pFC-p53 Positive Control Plasmid**: No known significant effects or critical hazards.

- **Skin contact**
  - **p53-Luc Plasmid**: No known significant effects or critical hazards.
  - **pFC-p53 Positive Control Plasmid**: No known significant effects or critical hazards.

- **Ingestion**
  - **p53-Luc Plasmid**: No known significant effects or critical hazards.
  - **pFC-p53 Positive Control Plasmid**: No known significant effects or critical hazards.

##### Over-exposure signs/symptoms
- **Eye contact**
  - **p53-Luc Plasmid**: No specific data.
  - **pFC-p53 Positive Control Plasmid**: No specific data.

- **Inhalation**
  - **p53-Luc Plasmid**: No specific data.
  - **pFC-p53 Positive Control Plasmid**: No specific data.

- **Skin contact**
  - **p53-Luc Plasmid**: No specific data.
  - **pFC-p53 Positive Control Plasmid**: No specific data.

- **Ingestion**
  - **p53-Luc Plasmid**: No specific data.
  - **pFC-p53 Positive Control Plasmid**: No specific data.

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

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*Date of previous issue*: 31/12/2017  
*Version*: 2  

*3/13*
SECTION 4: First aid measures

Notes to physician:
- **p53-Luc Plasmid**: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- **pFC-p53 Positive Control Plasmid**: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments:
- **p53-Luc Plasmid**: No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media
- **Suitable extinguishing media**:
  - **p53-Luc Plasmid**: Use an extinguishing agent suitable for the surrounding fire.
  - **pFC-p53 Positive Control Plasmid**: Use an extinguishing agent suitable for the surrounding fire.

- **Unsuitable extinguishing media**:
  - **p53-Luc Plasmid**: None known.
  - **pFC-p53 Positive Control Plasmid**: None known.

5.2 Special hazards arising from the substance or mixture
- **Hazards from the substance or mixture**:
  - **p53-Luc Plasmid**: In a fire or if heated, a pressure increase will occur and the container may burst.
  - **pFC-p53 Positive Control Plasmid**: In a fire or if heated, a pressure increase will occur and the container may burst.

- **Hazardous combustion products**:
  - **p53-Luc Plasmid**: No specific data.
  - **pFC-p53 Positive Control Plasmid**: No specific data.

5.3 Advice for firefighters
- **Special precautions for fire-fighters**:
  - **p53-Luc Plasmid**: 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.
  - **pFC-p53 Positive Control Plasmid**: 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**:
  - **p53-Luc Plasmid**: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.
  - **pFC-p53 Positive Control Plasmid**: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
- **For non-emergency personnel**:
  - **p53-Luc Plasmid**: 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.
  - **pFC-p53 Positive Control Plasmid**: 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.
SECTION 6: Accidental release measures

For emergency responders:
- p53-Luc Plasmid: 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".
- pFC-p53 Positive Control Plasmid: 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:
- p53-Luc Plasmid: 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).
- pFC-p53 Positive Control Plasmid: 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).

6.3 Methods and material for containment and cleaning up:
- Methods for cleaning up:
  - p53-Luc Plasmid: 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.
  - pFC-p53 Positive Control Plasmid: 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.

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:
  - p53-Luc Plasmid: Put on appropriate personal protective equipment (see Section 8).
  - pFC-p53 Positive Control Plasmid: Put on appropriate personal protective equipment (see Section 8).
- Advice on general occupational hygiene:
  - p53-Luc Plasmid: 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.
  - pFC-p53 Positive Control Plasmid: 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
SECTION 7: Handling and storage

| Storage | p53-Luc Plasmid | 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. |
| pFC-p53 Positive Control Plasmid | 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 | p53-Luc Plasmid | Industrial applications, Professional applications. |
| pFC-p53 Positive Control Plasmid | Industrial applications, Professional applications. |

| Industrial sector specific solutions | p53-Luc Plasmid | Not applicable. |
| pFC-p53 Positive Control Plasmid | Not applicable. |

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 monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) 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

Appropriate engineering controls

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

Individual protection measures


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SECTION 8: Exposure controls/personal protection

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

9.1 Information on basic physical and chemical properties

Appearance

<table>
<thead>
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<th>Physical state</th>
<th>p53-Luc Plasmid</th>
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<tbody>
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<td>pFC-p53 Positive Control Plasmid</td>
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</tr>
</tbody>
</table>
SECTION 9: Physical and chemical properties

Evaporation rate : p53-Luc Plasmid
                 pFC-p53 Positive Control Plasmid
                 Not available.

Flammability (solid, gas) : p53-Luc Plasmid
                            pFC-p53 Positive Control Plasmid
                            Not applicable.

Upper/lower flammability or explosive limits : p53-Luc Plasmid
                                             pFC-p53 Positive Control Plasmid
                                             Not available.

Vapour pressure : p53-Luc Plasmid
                 pFC-p53 Positive Control Plasmid
                 Not available.

Vapour density : p53-Luc Plasmid
                  pFC-p53 Positive Control Plasmid
                  Not available.

Relative density : p53-Luc Plasmid
                  pFC-p53 Positive Control Plasmid
                  Not available.

Solubility(ies) : p53-Luc Plasmid
                 pFC-p53 Positive Control Plasmid
                 Easily soluble in the following materials: cold water and hot water.

Partition coefficient: n-octanol/water : p53-Luc Plasmid
                                      pFC-p53 Positive Control Plasmid
                                      Not available.

Auto-ignition temperature : p53-Luc Plasmid
                           pFC-p53 Positive Control Plasmid
                           Not available.

Decomposition temperature : p53-Luc Plasmid
                            pFC-p53 Positive Control Plasmid
                            Not available.

Viscosity : p53-Luc Plasmid
            pFC-p53 Positive Control Plasmid
            Not available.

Explosive properties : p53-Luc Plasmid
                      pFC-p53 Positive Control Plasmid
                      Not available.

Oxidising properties : p53-Luc Plasmid
                       pFC-p53 Positive Control Plasmid
                       Not available.

9.2 Other information
No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity : p53-Luc Plasmid
                  pFC-p53 Positive Control Plasmid
                  No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability : p53-Luc Plasmid
                        pFC-p53 Positive Control Plasmid
                        The product is stable.
SECTION 10: Stability and reactivity

10.3 Possibility of hazardous reactions
- **p53-Luc Plasmid**: Under normal conditions of storage and use, hazardous reactions will not occur.
- **pFC-p53 Positive Control Plasmid**: Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid
- **p53-Luc Plasmid**: No specific data.
- **pFC-p53 Positive Control Plasmid**: No specific data.

10.5 Incompatible materials
- **p53-Luc Plasmid**: May react or be incompatible with oxidising materials.
- **pFC-p53 Positive Control Plasmid**: May react or be incompatible with oxidising materials.

10.6 Hazardous decomposition products
- **p53-Luc Plasmid**: Under normal conditions of storage and use, hazardous decomposition products should not be produced.
- **pFC-p53 Positive Control Plasmid**: 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**
Not available.

**Acute toxicity estimates**
N/A

**Irritation/Corrosion**
- **Conclusion/Summary**: Not available.

**Sensitiser**
- **Conclusion/Summary**: Not available.

**Mutagenicity**
- **Conclusion/Summary**: Not available.

**Carcinogenicity**
- **Conclusion/Summary**: Not available.

**Reproductive toxicity**
- **Conclusion/Summary**: Not available.

**Teratogenicity**
- **Conclusion/Summary**: Not available.

**Specific target organ toxicity (single exposure)**
Not available.

**Specific target organ toxicity (repeated exposure)**
Not available.

**Aspiration hazard**
Not available.

**Information on likely routes of exposure**
- **p53-Luc Plasmid**: Not available.
- **pFC-p53 Positive Control Plasmid**: Not available.

**Potential acute health effects**
- **Inhalation**
  - **p53-Luc Plasmid**: No known significant effects or critical hazards.
  - **pFC-p53 Positive Control Plasmid**: No known significant effects or critical hazards.
## SECTION 11: Toxicological information

### Potential chronic health effects

<table>
<thead>
<tr>
<th>Substance</th>
<th>General Description</th>
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<tbody>
<tr>
<td>p53-Luc Plasmid</td>
<td>No known significant effects or critical hazards. No known significant effects or critical hazards.</td>
</tr>
<tr>
<td>pFC-p53 Positive Control Plasmid</td>
<td>No known significant effects or critical hazards. No known significant effects or critical hazards.</td>
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</table>

### Symptoms related to the physical, chemical and toxicological characteristics

<table>
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<th>Inhalation Description</th>
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<td>p53-Luc Plasmid</td>
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<td>pFC-p53 Positive Control Plasmid</td>
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### Delayed and immediate effects as well as chronic effects from short and long-term exposure

#### Short term exposure

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<th>Immediate effects Description</th>
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<td>pFC-p53 Positive Control Plasmid</td>
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<thead>
<tr>
<th>Substances</th>
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<thead>
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<th>Substances</th>
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<td>pFC-p53 Positive Control Plasmid</td>
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## Note

- **Date of issue/Date of revision**: 23/12/2019
- **Date of previous issue**: 31/12/2017
- **Version**: 2
SECTION 12: Ecological information

12.1 Toxicity
   Conclusion/Summary : Not available.

12.2 Persistence and degradability
   Not available.

12.3 Bioaccumulative potential
   Not available.

12.4 Mobility in soil
   Soil/water partition coefficient (K_{OC}) : Not available.
   Mobility : 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.

   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.

SECTION 14: Transport information

<table>
<thead>
<tr>
<th></th>
<th>ADR/RID</th>
<th>IMDG</th>
<th>IATA</th>
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<td>shipping name</td>
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<tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.4 Packing</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>group</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**SECTION 14: Transport information**

14.5 Environmental hazards

<table>
<thead>
<tr>
<th>Environmental hazards</th>
<th>No.</th>
<th>No.</th>
<th>No.</th>
</tr>
</thead>
</table>

Additional information

14.6 Special precautions for user

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 Annex II of Marpol and the IBC Code

Not available.

**SECTION 15: Regulatory information**

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

**EU Regulation (EC) No. 1907/2006 (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.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

<table>
<thead>
<tr>
<th>Restriction</th>
<th>Substance</th>
<th>EU Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>p53-Luc Plasmid</td>
<td>Not applicable.</td>
<td></td>
</tr>
<tr>
<td>pFC-p53 Positive Control Plasmid</td>
<td>Not applicable.</td>
<td></td>
</tr>
</tbody>
</table>

**Other EU regulations**

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol (Annexes A, B, C, E)

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.

Inventory list

<table>
<thead>
<tr>
<th>Country</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>All components are listed or exempted.</td>
</tr>
<tr>
<td>Canada</td>
<td>All components are listed or exempted.</td>
</tr>
</tbody>
</table>

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12/13
SECTION 15: Regulatory information

<table>
<thead>
<tr>
<th>Country</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>All components are listed or exempted.</td>
</tr>
<tr>
<td>Europe</td>
<td>All components are listed or exempted.</td>
</tr>
<tr>
<td>Japan</td>
<td>Japan inventory (ENCS): All components are listed or exempted. Japan inventory (ISHL): All components are listed or exempted.</td>
</tr>
<tr>
<td>New Zealand</td>
<td>All components are listed or exempted.</td>
</tr>
<tr>
<td>Philippines</td>
<td>All components are listed or exempted.</td>
</tr>
<tr>
<td>Republic of Korea</td>
<td>All components are listed or exempted.</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Thailand</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Turkey</td>
<td>Not determined.</td>
</tr>
<tr>
<td>United States</td>
<td>All components are listed or exempted.</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>All components are listed or exempted.</td>
</tr>
</tbody>
</table>

15.2 Chemical safety assessment: This product contains substances for which Chemical Safety Assessments might still be required.

SECTION 16: Other information

Indicates information that has changed from previously issued version.

Abbreviations and acronyms:
- ATE = Acute Toxicity Estimate
- CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
- DMEL = Derived Minimal Effect Level
- DNEL = Derived No Effect Level
- EUH statement = CLP-specific Hazard statement
- N/A = Not available
- PBT = Persistent, Bioaccumulative and Toxic
- PNEC = Predicted No Effect Concentration
- RRN = REACH Registration Number
- vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

<table>
<thead>
<tr>
<th>Classification</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not classified.</td>
<td></td>
</tr>
</tbody>
</table>

Full text of abbreviated H statements
Not applicable.

Full text of classifications [CLP/GHS]
Not applicable.

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