

SECTION 1: Identification**1.1. Identification**

Product form : Mixture
Product name : G6-PDH Substrate, P/N 345-8, 345-B

1.2. Recommended use and restrictions on use

Use of the substance/mixture : Medical Diagnostics
Restrictions on use : No additional information available

1.3. Supplier

Trinity Biotech
IDA Business Park
Southern Cross Road
Bray, Co. Wicklow - Ireland
T 00353 1 276 9800 (Technical Support Group)
www.trinitybiotech.com

1.4. Emergency telephone number

Emergency number : Contact your local Emergency Health Care Provider; Ireland-Technical Support Group 00353-1-276-9800 (operating hours 7:00-18:00)

SECTION 2: Hazard(s) identification**2.1. Classification of the substance or mixture****GHS-US classification**

Not classified

2.2. GHS Label elements, including precautionary statements**GHS US labelling**

No labelling applicable

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

1.32% of the mixture consists of ingredient(s) of unknown acute toxicity (Oral)
1.32% of the mixture consists of ingredient(s) of unknown acute toxicity (Dermal)
1.32% of the mixture consists of ingredient(s) of unknown acute toxicity (Inhalation (Dust/Mist))

SECTION 3: Composition/information on ingredients**3.1. Substances**

Not applicable

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of HazCom 2012

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

First-aid measures general : Never give anything by mouth to an unconscious person.
First-aid measures after inhalation : If inhaled and if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
First-aid measures after skin contact : Wash skin thoroughly with mild soap and water.
First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
First-aid measures after ingestion : Do NOT induce vomiting unless directed to do so by medical personnel.

4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects : No significant signs or symptoms indicative of any health hazard are expected to occur.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

G6-PDH Substrate, P/N 345-8, 345-B

Safety Data Sheet

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SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media : None known.

5.2. Specific hazards arising from the chemical

- Fire hazard : No particular fire or explosion hazard.

5.3. Special protective equipment and precautions for fire-fighters

- Firefighting instructions : Use extinguishing media appropriate for surrounding fire. Use water spray or fog for cooling exposed containers.
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection. Wear fire/flame resistant/retardant clothing. Wear a self contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid contact with skin, eyes and clothing. Avoid creating or spreading dust.

6.1.1. For non-emergency personnel

- Protective equipment : Refer to section 8.2.
Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Refer to section 8.2.
Emergency procedures : Ventilate area.

6.2. Environmental precautions

- Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- For containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.
Methods for cleaning up : Collect spillage. On land, sweep or shovel into suitable containers.

6.4. Reference to other sections

- Section 13: disposal information. Section 7: safe handling. Section 8: personal protective equipment.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Avoid contact with skin, eyes and clothing. Avoid creating or spreading dust. Handle and open container with care.
Hygiene measures : Take off immediately all contaminated clothing and wash it before reuse. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep only in the original container. Keep container tightly closed.
Incompatible products : Strong bases. Strong acids. Strong oxidizers.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

- No additional information available

8.2. Appropriate engineering controls

- Appropriate engineering controls : Avoid creating or spreading dust. Ensure good ventilation of the work station.
Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment:

- Avoid all unnecessary exposure.

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Hand protection:

Wear suitable gloves resistant to chemical penetration. Use rubber gloves.

Eye protection:

In case of dust production: protective goggles

Respiratory protection:

No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation

Other information:

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear.
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: 7.62 (7.57 - 7.67)
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive limits	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Heat.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizers.

G6-PDH Substrate, P/N 345-8, 345-B

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10.6. Hazardous decomposition products

None under normal use.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified

Acute toxicity (dermal) : Not classified

Acute toxicity (inhalation) : Not classified

Unknown acute toxicity (GHS US)	1.32% of the mixture consists of ingredient(s) of unknown acute toxicity (Oral) 1.32% of the mixture consists of ingredient(s) of unknown acute toxicity (Dermal) 1.32% of the mixture consists of ingredient(s) of unknown acute toxicity (Inhalation (Dust/Mist))
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Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

Viscosity, kinematic : No data available

Symptoms/effects : No significant signs or symptoms indicative of any health hazard are expected to occur.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

G6-PDH Substrate, P/N 345-8, 345-B	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

G6-PDH Substrate, P/N 345-8, 345-B	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

G6-PDH Substrate, P/N 345-8, 345-B	
Ecology - soil	Not established.

12.5. Other adverse effects

Other information : No additional information available.

SECTION 13: Disposal considerations

13.1. Disposal methods

Sewage disposal recommendations : Do not dispose of waste into sewer.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not regulated.

G6-PDH Substrate, P/N 345-8, 345-B

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Transport by sea

Not regulated.

Air transport

Not regulated.

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

National regulations

No additional information available

15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Data sources : ACGIH (American Conference of Government Industrial Hygienists). European Chemicals Agency (ECHA) C&L Inventory database. Accessed at <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>. Krister Forsberg and S.Z. Mansdorf, "Quick Selection Guide to Chemical Protective Clothing", Fifth Edition. National Fire Protection Association. Fire Protection Guide to Hazardous Materials; 10th edition. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. United Nations Economic Commission for Europe: About the GHS. Accessed at http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.

Other information : None.

Abbreviations and acronyms:

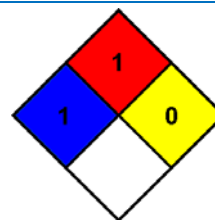
	ATE: Acute Toxicity Estimate
	CAS (Chemical Abstracts Service) number
	CLP: Classification, Labelling, Packaging.
	EC50: Environmental Concentration associated with a response by 50% of the test population.
	GHS: Globally Harmonized System (of Classification and Labeling of Chemicals).
	LD50: Lethal Dose for 50% of the test population
	STEL: Short Term Exposure Limits
	TWA: Time Weighted Average
	WEL: Workplace Exposure Limit
	European List of Waste (LoW) code

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NFPA health hazard	: 1 - Materials that, under emergency conditions, can cause significant irritation.
NFPA fire hazard	: 1 - Materials that must be preheated before ignition can occur.
NFPA reactivity	: 0 - Normally stable, even under fire exposure conditions, and not reactive with water.



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

SECTION 1: Identification

1.1. Identification

Product form : Mixture
Product name : G6-PDH Reagent, P/N 345-5, 345-B

1.2. Recommended use and restrictions on use

Use of the substance/mixture : Medical Diagnostics
Restrictions on use : No additional information available

1.3. Supplier

Trinity Biotech
IDA Business Park
Southern Cross Road
Bray, Co. Wicklow - Ireland
T 00353 1 276 9800 (Technical Support Group)
www.trinitybiotech.com

1.4. Emergency telephone number

Emergency number : Contact your local Emergency Health Care Provider; Ireland-Technical Support Group 00353-1-276-9800 (operating hours 7:00-18:00)

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Skin Sens. 1 H317 May cause an allergic skin reaction.
Full text of hazard classes and H-statements : see section 16

2.2. GHS Label elements, including precautionary statements

GHS US labelling

Hazard pictograms (GHS US) :



Signal word (GHS US) : Warning
Hazard statements (GHS US) : H317 - May cause an allergic skin reaction.
Precautionary statements (GHS US) : P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 - If on skin: Wash with plenty of water/...
P321 - Specific treatment (see supplemental first aid instruction on this label)
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P363 - Wash contaminated clothing before reuse.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS-US classification
maleimide	(CAS-No.) 541-59-3	0.1 - 0.5	Acute Tox. 3 (Oral), H301 Skin Corr. 1B, H314 Skin Sens. 1, H317

G6-PDH Reagent, P/N 345-5, 345-B

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*Chemical name, CAS number and/or exact concentration have been withheld as a trade secret

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person.
- First-aid measures after inhalation : If inhaled and if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
- First-aid measures after skin contact : Wash skin thoroughly with mild soap and water.
- First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- First-aid measures after ingestion : Do NOT induce vomiting unless directed to do so by medical personnel.

4.2. Most important symptoms and effects (acute and delayed)

- Symptoms/effects after skin contact : May cause an allergic skin reaction.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media : None known.

5.2. Specific hazards arising from the chemical

- Fire hazard : No particular fire or explosion hazard.

5.3. Special protective equipment and precautions for fire-fighters

- Firefighting instructions : Use extinguishing media appropriate for surrounding fire. Use water spray or fog for cooling exposed containers.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection. Wear fire/flammable resistant/retardant clothing. Wear a self contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid contact with skin, eyes and clothing. Avoid creating or spreading dust.

6.1.1. For non-emergency personnel

- Protective equipment : Refer to section 8.2.
- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Refer to section 8.2.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- For containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.
- Methods for cleaning up : Collect spillage. On land, sweep or shovel into suitable containers.

6.4. Reference to other sections

Section 13: disposal information. Section 7: safe handling. Section 8: personal protective equipment.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Avoid contact with skin, eyes and clothing. Avoid creating or spreading dust. Handle and open container with care.
- Hygiene measures : Take off immediately all contaminated clothing and wash it before reuse. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product.

G6-PDH Reagent, P/N 345-5, 345-B

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in the original container. Keep container tightly closed.
Incompatible products : Strong bases. Strong acids. Strong oxidizers.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

maleimide (541-59-3)
Not applicable

8.2. Appropriate engineering controls

Appropriate engineering controls : Avoid creating or spreading dust. Ensure good ventilation of the work station.
Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

Wear suitable gloves resistant to chemical penetration. Use rubber gloves.

Eye protection:

In case of dust production: protective goggles

Respiratory protection:

No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation

Other information:

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : Lyophilized powder / cake.
Colour : white Yellow
Odour : No data available
Odour threshold : No data available
pH : 7.62 (7.57 - 7.67)
Melting point : No data available
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Relative evaporation rate (butylacetate=1) : No data available
Flammability (solid, gas) : No data available
Vapour pressure : No data available
Relative vapour density at 20 °C : No data available
Relative density : No data available
Solubility : No data available
Log Pow : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive limits : No data available
Explosive properties : No data available

G6-PDH Reagent, P/N 345-5, 345-B

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according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Oxidising properties : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Heat.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous decomposition products

None under normal use.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified

Acute toxicity (dermal) : Not classified

Acute toxicity (inhalation) : Not classified

maleimide (541-59-3)	
ATE US (oral)	100 mg/kg bodyweight
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Viscosity, kinematic	: No data available
Symptoms/effects after skin contact	: May cause an allergic skin reaction.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

G6-PDH Reagent, P/N 345-5, 345-B	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

G6-PDH Reagent, P/N 345-5, 345-B	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

G6-PDH Reagent, P/N 345-5, 345-B	
Ecology - soil	Not established.

G6-PDH Reagent, P/N 345-5, 345-B

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12.5. Other adverse effects

Other information : No additional information available.

SECTION 13: Disposal considerations

13.1. Disposal methods

Sewage disposal recommendations : Do not dispose of waste into sewer.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

15.2. International regulations

CANADA

maleimide (541-59-3)

Listed on the Canadian DSL (Domestic Substances List) inventory.

EU-Regulations

No additional information available

National regulations

No additional information available

15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Data sources

: ACGIH (American Conference of Government Industrial Hygienists). European Chemicals Agency (ECHA) C&L Inventory database. Accessed at <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>. Krister Forsberg and S.Z. Mansdorf, "Quick Selection Guide to Chemical Protective Clothing", Fifth Edition. National Fire Protection Association. Fire Protection Guide to Hazardous Materials; 10th edition. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. United Nations Economic Commission for Europe: About the GHS. Accessed at http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.

Other information

: None.

G6-PDH Reagent, P/N 345-5, 345-B

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Full text of H-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Sens. 1	Skin sensitisation, Category 1
H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.

Abbreviations and acronyms:

	ATE: Acute Toxicity Estimate
	CAS (Chemical Abstracts Service) number
	CLP: Classification, Labelling, Packaging.
	EC50: Environmental Concentration associated with a response by 50% of the test population.
	GHS: Globally Harmonized System (of Classification and Labeling of Chemicals).
	LD50: Lethal Dose for 50% of the test population
	STEL: Short Term Exposure Limits
	TWA: Time Weighted Average
	WEL: Workplace Exposure Limit
	European List of Waste (LoW) code

NFPA health hazard

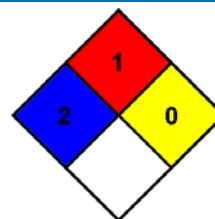
: 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.

NFPA fire hazard

: 1 - Materials that must be preheated before ignition can occur.

NFPA reactivity

: 0 - Normally stable, even under fire exposure conditions, and not reactive with water.



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