

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

1.1 Product identifier

Product code 3606
 Product name Premier® Substrate II
 Contains Methyl alcohol

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

Recommended Use In vitro diagnostic

1.3 Details of the supplier of the safety data sheet

Manufacturer
 Meridian Bioscience, Inc.
 3471 River Hills Drive
 Cincinnati, Ohio 45244
 (800) 343-3858

Authorized Representative
 Meridian Bioscience Europe
 Via del' Industria 7
 20020 Villa Cortese Milano, Italy

For further information, please contact:

E-mail Address www.meridianbioscience.com

1.4 Emergency telephone number

Emergency telephone Emergency telephone CHEMTREC (International) 1-703-527-3887 / For US 1-800-424-9300

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

REGULATION (EC) No 1272/2008

Acute oral toxicity	Category 4
Acute dermal toxicity	Category 4
Acute inhalation toxicity - gas	Category 2
Acute inhalation toxicity - dust/mist	Category 1
Serious eye damage/eye irritation	Category 2
Specific target organ toxicity (single exposure)	Category 1
Flammable liquids	Category 2

2.2 Label elements

**Signal Word**

Danger

Hazard Statements

H302 - Harmful if swallowed
 H312 - Harmful in contact with skin
 H319 - Causes serious eye irritation
 H330 - Fatal if inhaled
 H370 - Causes damage to organs
 H225 - Highly flammable liquid and vapor
 Contains Methyl alcohol
 EUH066 - Repeated exposure may cause skin dryness or cracking

Precautionary Statements - EU (§28, 1272/2008)

P310 - Immediately call a POISON CENTER or doctor/ physician
 P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing
 P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
 P307 + P311 - IF exposed: Call a POISON CENTER or doctor/ physician
 P260 - Do not breathe dust/fume/gas/mist/vapors/spray
 P309 - IF exposed or if you feel unwell:
 P370 + P378 - In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction
 P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking

2.3 Other information**SECTION 3: Composition/information on ingredients****3.1 Substances****3.2 Mixtures**

Chemical Name	EC-No	CAS-No	Weight %	Classification (Reg. 1272/2008)	REACH Registration Number
Acetone	Present	67-64-1	15	Eye Irrit. 2 (H319) STOT SE 3 (H336) Flam. Liq. 2 (H225) (EUH066)	no data available
Methyl alcohol	Present	67-56-1	10	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) STOT SE 1 (H370) Flam. Liq. 2 (H225)	no data available
Glycerin	Present	56-81-5	10	no data available	no data available

For the full text of the H-Statements mentioned in this Section, see Section 16.

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

Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Seek immediate medical attention/advice.
Skin contact	Wash off immediately with soap and plenty of water. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Call a physician or Poison Control Center immediately. Never give anything by mouth to an unconscious person.
Inhalation	Move to fresh air. Get medical attention immediately if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed**4.3 Indication of any immediate medical attention and special treatment needed**

Notes to physician Treat symptomatically.

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable Extinguishing Media**

CO₂, dry chemical, dry sand, alcohol-resistant foam.

Extinguishing media which shall not be used for safety reasons

No information available.

5.2 Special hazards arising from the substance or mixture

None.

5.3 Advice for firefighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Ensure adequate ventilation.

See Section 12 for additional Ecological Information.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so.

6.3 Methods and materials for containment and cleaning up**Methods for cleaning up**

Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal.

6.4 Reference to other sections

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Do not breathe vapors or spray mist. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Keep away from open flames, hot surfaces and sources of ignition.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/Storage conditions

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from open flames, hot surfaces and sources of ignition.

7.3 Specific end uses

Other Guidelines

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Exposure limits

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

Chemical Name	European Union	The United Kingdom	France	Spain	Germany
Acetone 67-64-1	TWA 500 ppm TWA 1210 mg/m ³	STEL: 1500 ppm STEL: 3620 mg/m ³ TWA: 500 ppm TWA: 1210 mg/m ³	TWA: 500 ppm TWA: 1210 mg/m ³ STEL: 1000 ppm STEL: 2420 mg/m ³	TWA: 500 ppm TWA: 1210 mg/m ³	TWA: 500 ppm TWA: 1200 mg/m ³ Ceiling / Peak: 1000 ppm Ceiling / Peak: 2400 mg/m ³
Methyl alcohol 67-56-1	TWA: 200 ppm TWA: 260 mg/m ³ Skin	STEL: 250 ppm STEL: 333 mg/m ³ TWA: 200 ppm TWA: 266 mg/m ³ Skin	TWA: 200 ppm TWA: 260 mg/m ³ STEL: 1000 ppm STEL: 1300 mg/m ³	S* TWA: 200 ppm TWA: 266 mg/m ³	TWA: 200 ppm TWA: 270 mg/m ³ Ceiling / Peak: 800 ppm Ceiling / Peak: 1080 mg/m ³ Skin
Glycerin 56-81-5		STEL: 30 mg/m ³ TWA: 10 mg/m ³	TWA: 10 mg/m ³	TWA: 10 mg/m ³	TWA: 50 mg/m ³ Ceiling / Peak: 100 mg/m ³
Component	Italy	Portugal	The Netherlands	Finland	Denmark
Acetone 67-64-1 (10)	TWA: 500 ppm TWA: 1210 mg/m ³	STEL: 750 ppm TWA: 500 ppm TWA: 1210 mg/m ³	STEL: 2420 mg/m ³ TWA: 1210 mg/m ³	TWA: 500 ppm TWA: 1200 mg/m ³ STEL: 630 ppm STEL: 1500 mg/m ³	TWA: 250 ppm TWA: 600 mg/m ³
Methyl alcohol 67-56-1 (10)	TWA: 200 ppm TWA: 260 mg/m ³ Skin	STEL: 250 ppm TWA: 200 ppm TWA: 260 mg/m ³	Skin TWA: 133 mg/m ³ TWA: 100 ppm	TWA: 200 ppm TWA: 270 mg/m ³ STEL: 250 ppm STEL: 330 mg/m ³ Skin	TWA: 200 ppm TWA: 260 mg/m ³ Skin
Glycerin 56-81-5 (10)		TWA: 10 mg/m ³		TWA: 20 mg/m ³	
Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
Acetone 67-64-1	STEL 2000 ppm STEL 4800 mg/m ³ TWA: 500 ppm TWA: 1200 mg/m ³	STEL: 1000 ppm STEL: 2400 mg/m ³ TWA: 500 ppm TWA: 1200 mg/m ³	STEL: 1800 mg/m ³ TWA: 600 mg/m ³	TWA: 125 ppm TWA: 295 mg/m ³ STEL: 156.25 ppm STEL: 368.75 mg/m ³	TWA: 500 ppm TWA: 1210 mg/m ³
Methyl alcohol 67-56-1	Skin STEL 800 ppm	Skin STEL: 800 ppm	STEL: 300 mg/m ³ TWA: 100 mg/m ³	TWA: 100 ppm TWA: 130 mg/m ³	TWA: 200 ppm TWA: 260 mg/m ³

	STEL: 1040 mg/m ³ TWA: 200 ppm TWA: 260 mg/m ³	STEL: 1040 mg/m ³ TWA: 200 ppm TWA: 260 mg/m ³		Skin STEL: 150 ppm STEL: 162.5 mg/m ³	STEL: 600 ppm STEL: 780 mg/m ³ Skin
Glycerin 56-81-5		STEL: 100 mg/m ³ TWA: 50 mg/m ³	TWA: 10 mg/m ³		TWA: 10 mg/m ³ STEL: 30 mg/m ³

Derived No Effect Level (DNEL) No information available

Predicted No Effect Concentration (PNEC) No information available

8.2 Exposure controls

Engineering Measures Ensure adequate ventilation, especially in confined areas. Apply technical measures to comply with the occupational exposure limits.

Personal protective equipment

Eye Protection Tightly fitting safety goggles.
Hand Protection Protective gloves.
Skin and body protection Wear impervious gloves and/or clothing if needed to prevent contact with the material.
Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Hygiene measures Handle in accordance with good industrial hygiene and safety practice.

Environmental Exposure Controls No information available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid	Odor	Alcohol
Appearance	No information available	Odor Threshold	No information available
Color	Clear straw-bluish liquid		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH		No information available
Melting/freezing point		No information available
Boiling point/boiling range	76 °C / 169 °F	not applicable
Flash Point	9 °C / 48 °F	No information available
Evaporation rate		No information available
Flammability (solid, gas)		No information available
Flammability Limits in Air		No information available
upper flammability limit		
lower flammability limit		
Vapor pressure		No information available
Vapor density		No information available
Specific Gravity		No information available
Water solubility		No information available
Solubility in other solvents VALUE		No information available
Partition coefficient: n-octanol/water		No information available
Autoignition temperature		No information available
Decomposition temperature		No information available
Viscosity, kinematic		No information available
Viscosity, dynamic		No information available
Explosive properties	No information available	
Oxidizing Properties	No information available	

9.2 Other information

Softening point	No information available
Molecular Weight	No information available
VOC Content(%)	No information available
Density VALUE	No information available
Bulk Density VALUE	No information available

SECTION 10: Stability and reactivity

10.1 Reactivity

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

10.4 Conditions to Avoid

Extremes of temperature and direct sunlight. Heat, flames and sparks.

10.5 Incompatible Materials

Acids.

10.6 Hazardous Decomposition Products

None under normal use conditions.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product Information Product does not present an acute toxicity hazard based on known or supplied information.

Inhalation There is no data available for this product.

Eye contact There is no data available for this product.

Skin contact There is no data available for this product.

Ingestion There is no data available for this product.

Acute toxicity 75% of the mixture consists of ingredient(s) of unknown toxicity.

The following values are calculated based on chapter 3.1 of the GHS document:

Oral	341.00 mg/kg
Dermal	1,050.00 mg/kg
Inhalation	
Gas	350.04 mg/l
Mist	0.02 mg/l
Vapor	99,999.00 mg/l

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Acetone	5800 mg/kg (Rat)		50100 mg/m ³ (Rat) 8 h
Methyl alcohol	6200 mg/kg (Rat)	15800 mg/kg (Rabbit)	22500 ppm (Rat) 8 h 64000 ppm (Rat) 4 h
Glycerin	12600 mg/kg (Rat)	10 g/kg (Rabbit)	570 mg/m ³ (Rat) 1 h

Skin corrosion/irritation No information available.

Eye damage/irritation No information available.

Sensitization No information available.

Germ Cell Mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
Specific target organ systemic toxicity (single exposure)	No information available.
Specific target organ systemic toxicity (repeated exposure)	No information available.
Aspiration hazard	No information available.

SECTION 12: Ecological information

12.1 Toxicity

Ecotoxicity effects Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to daphnia and other aquatic invertebrates
Acetone		4.74 - 6.33: 96 h Oncorhynchus mykiss mL/L LC50 6210 - 8120: 96 h Pimephales promelas mg/L LC50 static 8300: 96 h Lepomis macrochirus mg/L LC50	10294 - 17704: 48 h Daphnia magna mg/L EC50 Static 12600 - 12700: 48 h Daphnia magna mg/L EC50
Methyl alcohol		28200: 96 h Pimephales promelas mg/L LC50 flow-through 100: 96 h Pimephales promelas mg/L LC50 static 19500 - 20700: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 18 - 20: 96 h Oncorhynchus mykiss mL/L LC50 static 13500 - 17600: 96 h Lepomis macrochirus mg/L LC50 flow-through	
Glycerin		51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static	500: 24 h Daphnia magna mg/L EC50

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

Chemical Name	log Pow
Acetone	-0.24
Methyl alcohol	-0.77
Glycerin	-1.76

12.4 Mobility in soil

Mobility

No information available.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste from residues / unused products	Dispose of in accordance with all federal, state, and local regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information

IATA/DOT

14.1. UN/ID No	3316
14.2. Technical Name	Chemical Kit
14.3. Hazard class	9
14.4. Description	Premier® Substrate II
14.5. IATA Note	Note: Per IATA 2.6, when shipping 30 mL or less per inner package, volume of outer package cannot exceed 500 mL.
14.6. DOT Note	Note: Per 49 CFR - When Shipping 30 mL or less per inner packaging and the gross weight does not exceed 64 lbs. use the 173.4 small quantity exception

SECTION 15: Regulatory information

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

Chemical Name	French RG number
Acetone	RG 84
Methyl alcohol	RG 84

International Inventories

TSCA	Complies
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
IECSC	-
AICS	-
KECL	-

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

15.2 Chemical Safety Report

No information available

SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3

H301 - Toxic if swallowed
H311 - Toxic in contact with skin
H331 - Toxic if inhaled
H370 - Causes damage to organs (a,b,c) if inhaled
H225 - Highly flammable liquid and vapor
H319 - Causes serious eye irritation
H336 - May cause drowsiness or dizziness
EUH066 - Repeated exposure may cause skin dryness or cracking
H302 - Harmful if swallowed
H312 - Harmful in contact with skin
H319 - Causes serious eye irritation
H330 - Fatal if inhaled
H370 - Causes damage to organs

Issuing date	13-Oct-2016
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Revision Note	not applicable.

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

Disclaimer

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.