

DE 70% in WFI 4 x 5L (0.2 μ Filtered – Bio-Burden Reduced)

Packaging:

- All components are prepared in a controlled environment prior to Irradiating (Grade C - ISO Class 7).
- All components are gamma irradiated 25kGy – 45 kGy prior to filling.

Manufacturing Bulk Fluid:

- All bulk fluid is manufactured in a controlled environment.
- All bulk fluids are filtered to 0.2 μ at point of fill.
- All bulk fluids are manufactured using High Purity Water (WFI Quality) guaranteeing a low endotoxin level.

Filling Conditions:

- All containers are filled under Laminar Air Flow (Grade A) within a Grade C Clean Room.
- The product is filtered to 0.2 μ at point of fill.
- Finished product is double bagged in a Grade C Clean Room.





Product Specification

DE 70% WFI (Filtered - Bio Burden Reduced) - Specification
High Purity Water - WFI Grade - Specification



Product Specification

Date: Jun 16
Issue Number: 03
Review Date: Jun 18

Product	DE 70% in WFI / TSDA7 70% in WFI
Product Type	Liquid / Aerosol / Impregnant
Proportion	70:30 (v/v)
Alcohol Grade	95% Ethanol + 5% Propan-2-ol <i>Approved by HMRC for use in manufacture of disinfectants specifically for use in sterile environments E.g., places where pharmaceutical drugs are produced.</i>
Water Grade	WFI Quality Water
Filtration	0.2 micron Filtered
Appearance	Clear and Colourless Liquid
Odour	Characteristic
SG@20°C	0.880 – 0.888
pH	6.0 – 9.0
Refractive Index / Percentage Activity @20°C	1.360 – 1.370
Irradiation Dosage	25-45 kGy (Sterile Products)

Prepared by Name:	Nagadeepthi Ganta	Date:	30 Jun 2016
Position:	QC Technician		

The information contained in this data sheet is accurate to the best of our knowledge. No warranty is, however given or implied. Consult Agma Ltd concerning all non standard applications.

For health and safety and environmental information, please refer to the Agma Safety Data Sheet for this product. If you do not have this, we shall be pleased to send it on request

Product Specification

Date: Jun 16
Issue Number: 02
Review Date: Jun 18

Product Name	Highly Purified Water (HPW) Water For Injections-quality equivalent (WFI)
Product Type	Liquid
Process	Double-pass, reverse osmosis coupled with mixed bed deionisation, UV-sterilisation and microfiltration
Grade	Complies with Pharmacopoeial requirements of the USP and EP as specified for WFI water
Appearance	Clear, Colourless liquid
Conductivity ($\mu\text{S}/\text{cm}$)	≤ 2.1 *
Total Organic Carbon (TOC) (ppb)	≤ 500
Total Viable Aerobic Count (cfu/100ml)	≤ 10
Endotoxin (IU/ml)	< 0.25
Nitrates (ppm)	≤ 0.2

* Limit cited is for Stage 2 @25oC. Stage 1 limits are variable due to temperature dependence.

Prepared by Name:	D.C. Hagel	Date:	08 Jun 16
Position:	Technical and Regulatory Affairs Manager		

The information contained in this data sheet is accurate to the best of our knowledge. No warranty is, however given or implied. Consult Agma Ltd concerning all non-standard applications.

For health and safety and environmental information, please refer to the Agma Safety Data Sheet for this product. If you do not have this, we shall be pleased to send it on request.



MSDS

Sterile TSDA7 70% v/v WFI



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

1.1. Product identifier

Product name: DENATURED ETHANOL 70% V/V IN WFI

Synonyms: TSDA7 70% IN WFI
DE 70% IN WFI

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

Use of substance / mixture: Biocide - All Sectors

1.3. Details of the supplier of the safety data sheet

Company name: Agma Ltd
Gemini Works
Haltwhistle
Northumberland
NE49 9HA
UK

Tel: Tel: +44(0) 1434 320598

Fax: Fax: +44(0) 1434 321650

Email: sds@agma.co.uk

1.4. Emergency telephone number

Emergency tel: Tel: +44(0) 1434 320598
Monday - Thursday : 8:30 - 17:00 (GMT)
Friday: 8:30 - 14:30(GMT)
(office hours only)

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CHIP: F: R11

Classification under CLP: Flam. Liq. 1: H224

Most important adverse effects: Highly flammable.

2.2. Label elements

Label elements:

Hazard statements: H224: Extremely flammable liquid and vapour.

Signal words: Danger

Hazard pictograms: GHS02: Flame



SAFETY DATA SHEET

DENATURED ETHANOL 70% V/V IN WFI

Page: 2

Precautionary statements: P243: Take precautionary measures against static discharge.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P303+361+353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P370+378: In case of fire: Use alcohol resistant foam, dry chemical powder or sand to extinguish.
P403+235: Store in a well-ventilated place. Keep cool.
P501: Dispose of contents to a container and dispose in accordance with applicable local, state and federal regulations.

Label elements under CHIP:

Hazard symbols: Highly flammable.



Risk phrases: R11: Highly flammable.

2.3. Other hazards

Other hazards: In use, may form flammable / explosive vapour-air mixture.

PBT: This product is not identified as a PBT/vPvB substance.

Section 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients:

ETHANOL

EINECS	CAS	CHIP Classification	CLP Classification	Percent
200-578-6	64-17-5	F: R11 Substance with a Community workplace exposure limit.	Flam. Liq. 2: H225	50-70%

PROPAN-2-OL

200-661-7	67-63-0	F: R11; Xi: R36; -: R67	Flam. Liq. 2: H225; Eye Irrit. 2: H319; STOT SE 3: H336	1-10%
-----------	---------	-------------------------	--	-------

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Remove all contaminated clothes and footwear immediately unless stuck to skin. Wash immediately with plenty of soap and water. Seek medical aid if irritation or discomfort persists.

Eye contact: Promptly wash eyes with plenty of water while lifting the eye lids. Remove any contact lenses from the eyes. Continue to rinse for at least 15 minutes. Obtain medical attention if any discomfort continues.

[cont...]

SAFETY DATA SHEET

DENATURED ETHANOL 70% V/V IN WFI

Page: 3

Ingestion: Wash out mouth with water. Do not induce vomiting. If patient is conscious, give water to drink. If patient feels unwell seek medical attention.

Inhalation: If liquid has entered the lungs, consult a doctor immediately. Irritating to respiratory system. Vapour may effect central nervous system and cause headache, discomfort, vomiting or intoxication

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

Skin contact: There may be mild irritation at the site of contact.

Eye contact: There may be irritation and redness. Prolonged contact may lead to corneal damage.

Ingestion: There may be irritation of the throat. Gastrointestinal symptoms, including upset stomach. May cause nausea, headache, dizziness and intoxication. Narcotic effect. Chronic intoxication may damage the optic nerve, kidneys, liver, heart muscle and brain, and may lead to death.

Inhalation: Irritating to respiratory system. Vapour may affect central nervous system and cause headache, discomfort, vomiting or intoxication.

Delayed / immediate effects: No data available.

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

Immediate / special treatment: No recommendation given, but first aid may still be required in case of accidental exposure, inhalation or ingestion of this product. If in doubt, GET MEDICAL ATTENTION PROMPTLY.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Suitable - Carbon dioxide, dry powder, alcohol resistant foam. Fight larger fires with alcohol resistant foam. Use water spray only to cool containers in the event of fire. Do NOT use - Water jet, as burning product will float and spread.

5.2. Special hazards arising from the substance or mixture

Exposure hazards: In combustion emits toxic fumes of carbon dioxide / carbon monoxide.

5.3. Advice for fire-fighters

Advice for fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Refer to section 8 of SDS for personal protection details. Turn leaking containers leak-side up to prevent the escape of liquid. Eliminate all sources of ignition.

6.2. Environmental precautions

Environmental precautions: Do not allow to enter drains, sewers or watercourses. Spillages or uncontrolled discharges into watercourses must be alerted to the appropriate regulatory body. Contain the spillage using bunding.

[cont...]

SAFETY DATA SHEET
DENATURED ETHANOL 70% V/V IN WFI

6.3. Methods and material for containment and cleaning up

Clean-up procedures: Absorb into dry earth or sand. Transfer to a closable, labelled salvage container for disposal by an appropriate method. Do not use equipment in clean-up procedure which may produce sparks.

6.4. Reference to other sections

Reference to other sections: Refer to section 13 of SDS.

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements: Keep away from heat, sparks and open flame. Avoid spilling, skin and eye contact. Earth any equipment used in handling. Ensure there is sufficient ventilation of the area. Avoid the formation or spread of mists in the air. Unsuitable containers: aluminium.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in a cool, well ventilated area. Keep container tightly closed. Keep away from sources of ignition. Prevent the build up of electrostatic charge in the immediate area. Ensure lighting and electrical equipment are not a source of ignition.

Suitable packaging: Must only be kept in original packaging.

7.3. Specific end use(s)

Specific end use(s): The identified uses for this product are detailed in section 1.2

Section 8: Exposure controls/personal protection

8.1. Control parameters

Hazardous ingredients:

ETHANOL

Workplace exposure limits:

Respirable dust

State	8 hour TWA	15 min. STEL	8 hour TWA	15 min. STEL
UK	1920 mg/m ³	-	-	-

PROPAN-2-OL

UK	999 mg/m ³	1250 mg/m ³	-	-
----	-----------------------	------------------------	---	---

DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

Engineering measures: Ensure there is sufficient ventilation of the area. Ensure lighting and electrical equipment are not a source of ignition.

Respiratory protection: Self-contained breathing apparatus must be available in case of emergency.

Hand protection: Protective gloves.

SAFETY DATA SHEET
DENATURED ETHANOL 70% V/V IN WFI

Page: 5

Eye protection: Safety glasses. Ensure eye bath is to hand.

Skin protection: Protective clothing.

Environmental: Wash hands at the end of each work shift and before eating, smoking and using the toilet. When using do not eat, drink or smoke.

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

State: Liquid

Colour: Colourless

Odour: Alcoholic

Solubility in water: Soluble

Flash point°C: 20.5

Relative density: 0.880 - 0.888

9.2. Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2. Chemical stability

Chemical stability: Stable under normal conditions. Stable at room temperature.

10.3. Possibility of hazardous reactions

Hazardous reactions: None Known.

10.4. Conditions to avoid

Conditions to avoid: Heat. Hot surfaces. Sources of ignition. Flames.

10.5. Incompatible materials

Materials to avoid: Strong oxidising agents. Strong acids.

10.6. Hazardous decomposition products

Haz. decomp. products: In combustion emits toxic fumes.

Section 11: Toxicological information

11.1. Information on toxicological effects

Hazardous ingredients:

ETHANOL

IVN	RAT	LD50	1440	mg/kg
-----	-----	------	------	-------

[cont...]

SAFETY DATA SHEET
DENATURED ETHANOL 70% V/V IN WFI

Page: 6

ORL	MUS	LD50	3450	mg/kg
ORL	RAT	LD50	7060	mg/kg

PROPAN-2-OL

Acute dermal toxicity	RBT	LD50	>2000	mg/kg
Acute inhalation toxicity	RAT	8H LC50	>20	mg/l
Acute oral toxicity	RAT	LD50	>2000	mg/kg

Toxicity values: No data available.

Symptoms / routes of exposure

Skin contact: There may be mild irritation at the site of contact.

Eye contact: There may be irritation and redness. Prolonged contact may lead to corneal damage.

Ingestion: There may be irritation of the throat. Gastrointestinal symptoms, including upset stomach. May cause nausea, headache, dizziness and intoxication. Narcotic effect. Chronic intoxication may damage the optic nerve, kidneys, liver, heart muscle and brain, and may lead to death.

Inhalation: Irritating to respiratory system. Vapour may affect central nervous system and cause headache, discomfort, vomiting or intoxication.

Delayed / immediate effects: No data available.

Section 12: Ecological information

12.1. Toxicity

Hazardous ingredients:

PROPAN-2-OL

Leuciscus idus melanotus	48H LC50	>100	mg/l
Scenedesmus subspicatus	72H EC50	>100	mg/l
Daphnia magna	48H EC50	>100	mg/l

12.2. Persistence and degradability

Persistence and degradability: Biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential: No bioaccumulation potential.

12.4. Mobility in soil

Mobility: Soluble in water.

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT/vPvB substance.

[cont...]

SAFETY DATA SHEET
DENATURED ETHANOL 70% V/V IN WFI

Page: 7

12.6. Other adverse effects

Other adverse effects: Negligible ecotoxicity.

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations: Dispose of waste and residues in accordance with local authority requirements. Do not puncture or incinerate even when empty. When handling waste, consideration should be made to the safety precautions applying to handling of the product.

Recovery operations: Not applicable.

Disposal of packaging: Empty contaminated packagings thoroughly. They can be recycled after thorough and proper cleaning. Packagings that cannot be cleaned are to be disposed of in the same manner as the product.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Section 14: Transport information

* See section 16, Other Information for IATA Transport Information

14.1. UN number

UN number: UN1170

14.2. UN proper shipping name

Shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

14.3. Transport hazard class(es)

Transport class: 3

14.4. Packing group

Packing group: II

14.5. Environmental hazards

Environmentally hazardous: No

Marine pollutant: No

14.6. Special precautions for user

Special precautions: This Product, unopened and in original packaging is classified as Limited Quantity for the purpose of transport and does not require a UN number on the packaging. Limited Quantity for this product is 1 L.

Tunnel code: D/E

Transport category: 2

Section 15: Regulatory information

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

Specific regulations: Approved Code Of Practice : Safety Data Sheets for Substances and Preparations. Classification and Labelling of Substances and Preparations Dangerous for Supply.

[cont...]

SAFETY DATA SHEET
DENATURED ETHANOL 70% V/V IN WFI

Page: 8

15.2. Chemical Safety Assessment

Chemical safety assessment: A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

Section 16: Other information

Other information

Other information: The information in this Safety Data Sheet is based on data provided by chemical Suppliers/Manufacturers and the use of Lycos SDS-generating program. This information is based on our current level of knowledge and relates to the product in the state in which it is delivered. It is intended to describe our product in the view of safety requirements and does not guarantee any particular properties.

*** IATA - Transport by Air:** UN no: 1170
Class: 3
Label: 3
Shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

Phrases used in s.2 and s.3: H224: Extremely flammable liquid and vapour.
H225: Highly flammable liquid and vapour.
H319: Causes serious eye irritation.
H336: May cause drowsiness or dizziness.
R11: Highly flammable.
R36: Irritating to eyes.
R67: Vapours may cause drowsiness and dizziness.

Legal 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. This company shall not be held liable for any damage resulting from handling or from contact with the above product.



Micro Efficacy Data Summary

Sterile TSDA7 70% v/v WFI



Vallensbækvej 18, 2605 Brøndby, +45 3645 4591, mail: sales@imtex.dk, www.imtex.dk

TSDA 7 70% in WFI

STANDARD /PROTOCOL	METHOD	CHALLENGE ORGANISM	CONTACT TIME (minutes)	LOG REDUCTION PASS CRITERIA	METHOD VALIDATION	LOG REDUCTION ACHIEVED	RESULT
EN 1040 @20°C	QST,N, 1	<i>S. aureus</i>	5	5.0	PASS	> 5.23	PASS
EN 1040 @20°C	QST,N, 1	<i>Ps. aeruginosa</i>	5	5.0	PASS	> 5.43	PASS
EN 1275 @20°C	QST,N, 1	<i>C. albicans</i>	15	4.0	PASS	> 4.24	PASS
EN 1275 @20°C	QST,N, 1	<i>A. niger</i>	15	4.0	PASS	> 4.30	PASS
EN 1276 @20°C	QST,N, 1	<i>S. aureus</i>	5	5.0	PASS	> 5.23	PASS
EN 1276 @20°C	QST,N, 1	<i>E. coli</i>	5	5.0	PASS	> 5.43	PASS
EN 1276 @20°C	QST,N, 1	<i>Ps. aeruginosa</i>	5	5.0	PASS	> 5.43	PASS
EN 1276 @20°C	QST,N, 1	<i>Ent. hirae</i>	5	5.0	PASS	> 5.41	PASS
EN 1650 @20°C	QST,N, 1	<i>C. albicans</i>	15	4.0	PASS	> 4.24	PASS
EN 1650 @20°C	QST,N, 1	<i>A. niger</i>	15	4.0	PASS	> 4.30	PASS
EN 13697 @20°C	ST, 2	<i>S. aureus</i>	5	4.0	PASS	> 5.7	PASS
EN 13697 @20°C	ST, 2	<i>Ps. aeruginosa</i>	5	4.0	PASS	> 4.7	PASS
EN 13697 @20°C	ST, 2	<i>E. coli</i>	5	4.0	PASS	> 5.1	PASS
EN 13697 @20°C	ST, 2	<i>Ent. hirae</i>	5	4.0	PASS	> 5.6	PASS
EN 13697 @20°C	ST, 2	<i>C. albicans</i>	15	3.0	PASS	> 3.9	PASS
EN 13697 @20°C	ST, 2	<i>A. niger</i>	15	3.0	PASS	3.1	PASS

Analysed in accordance with CEN 216

KEY

- QST: Quantitative suspension test
- N: Neutralisation method employed
- ST: Surface quantitative test
- 1: Result derived when product is analysed under 'clean' conditions
- 2: Surface tested; stainless steel Grade 304

Agma Ltd, Gemini Works, Haltwhistle, Northumberland, NE49 9HA T: +44 (0)1434 320598 F: + 44 (0)1434 321650
 Email: enquiries@agma.co.uk Website: www.agma.co.uk

This data remains the property of AGMA and relates only to the AGMA branded product tested. Use of this data with any other product is misrepresentation, strictly forbidden and may result in legal action being taken. This document must not be reproduced except in full, without written approval of AGMA.