



# STERILE ALCOHOL 5L BOTTLE.

## STERILE DE 70% IN WFI 2 X 5L PER CASE.

### ITEM NO. 0060

STERILE DE 70% WFI ARE A PROVEN MEANS FOR CONTINUAL DISINFECTION WITHIN PHARMACEUTICAL & HOSPITAL CLEANROOMS.

STERILE DE 70% IN WFI IS COMMONLY USED IN CLEANROOMS BOTH IN HOSPITALS AND PHARMACEUTICAL MANUFACTURING FACILITIES. THEY ARE A HIGH COST-EFFECTIVE MEANS OF ROUTINE DISINFECTION WHEN USED WITH STERILE DRY MOPS OR WIPES.

AS WELL AS A PROVEN DISINFECTANT DE 70% EVAPORATES FULLY LEAVING NO RESIDUES.

- EFFICACY INDEPENDENTLY VALIDATED.
- WFI QUALITY WATER – HIGH PURITY WATER.
- MANUFACTURED IN ISO CLASS 5 CLEANROOM.
- FULLY TRACEABILITY WITH SUPPORTING ANALYSIS.
- GAMMA IRRADIATED FOR STERILITY.
- 2-YEAR SHELF LIFE.
- DOUBLE BAGGED.
- AVAILABLE IN STERILE T/S & WET WIPE FORMATS.



#### DIRECTION FOR USE:

AGMA DE 70% IS MANUFACTURED FOR USE ON CLEANROOM CEILINGS, WALLS, FLOORS AND EQUIPMENT HARD SURFACES.

ENSURE COMPLETE WETTING OF THE SURFACE. DO NOT USE TO TREAT SURFACES THAT ARE PARTICULARLY SENSITIVE TO ALCOHOL SUCH AS ACRYLIC GLASS. ALWAYS CLOSE CONTAINER AFTER USE.

Use Biocides Safely. Always read the label and product information.

THE INFORMATION CONTAINED IN THIS DATA SHEET IS ACCURATE TO THE BEST OF OUR KNOWLEDGE AND BELIEF. NO WARRANTY IS, HOWEVER, GIVEN OR IMPLIED. CONSULT AGMA LTD CONCERNING ALL NON-STANDARD APPLICATIONS.

ISSUE NO. 1-03/23

## Product Specification

Date: Oct 17  
Issue Number: 04  
Review Date: Oct 19

<b>Product</b>	DE 70% in WFI / TSDA7 70% in WFI
<b>Product Type</b>	Liquid / Aerosol / Impregnant
<b>Proportion</b>	70:30 (v/v)
<b>Alcohol Grade</b>	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>
<b>Water Grade</b>	WFI Quality Water
<b>Filtration</b>	0.2 micron Filtered
<b>Appearance</b>	Clear and Colourless Liquid
<b>Odour</b>	Characteristic
<b>SG@20°C</b>	0.880 – 0.888
<b>pH (Non-Sterile Liquid Only)</b>	6.0 – 9.0
<b>Refractive Index / Percentage Activity @20°C</b>	1.360 – 1.370
<b>Irradiation Dosage (Sterile Products)</b>	25-45 kGy

Prepared by Name:	Nagadeepthi Ganta	Date:	17 Oct 2017
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

## CERTIFICATE OF ANALYSIS

<b>Product</b>	Sterile DE 70% in WFI – 2 X 5 L Per Case	<b>Certificate No.</b> 5989
<b>Product Code</b>	0060	
<b>Batch No.</b>	11868	
<b>Date of Manufacture</b>	17 June 2021	
<b>Date of Irradiation</b>	07 July 2021	
<b>Date of Expiry</b>	30 June 2023	
<b>TEST RESULTS</b>	<b>SPECIFICATION</b>	<b>PASS/FAIL (RESULTS)</b>
<b>Appearance</b>	Clear Colourless Liquid	Pass
<b>Odour</b>	Characteristic	Pass
<b>SG @ 20°C</b>	0.880 – 0.888	Pass(0.882)
<b>Refractive Index</b>	1.360 – 1.370	Pass(1.365)
<p><b>DECLARATION OF CONFORMITY</b>  It is hereby certified that the supplies detailed hereon have been inspected and are in compliance in all respects to the specification relevant thereto</p>		

<b>Irradiation Certificate No.</b>	2173-20749A	<b>Confirm irradiation dose complies with 25 – 45kGy:</b>	Complies	<b>Checked by:</b>	R.Dixon
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<b>Authorised Signatures</b>			<b>DATE</b>	14 July 2021
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It is hereby certified that above test results were carried out in accordance to procedures documented via a quality management system certified to BS ISO 9001: 2015 registration FM 13868

**Agma Ltd**, Gemini Works, Haltwhistle, Northumberland NE49 9HA Tel: # 44 1434 320598 Fax: #44 1434 321650 Email: [enquiries@agma.co.uk](mailto:enquiries@agma.co.uk)

# STERIS: Gamma Certificate Of Processing

Prepared for: AGMA LTD (8247)

Gamma Process Run ID: 2173-20749A

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<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
IPA 70% IN WFI DV5764	DE 70% B/N 11868	504	Case

Validation Reference Number: 5764

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Processing Run Start Date: 05-Jul-2021 4:03 PM

Processing Run End Date: 07-Jul-2021 12:50 PM

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Specified Dose Range (kGy):	20.0 - 45.0	Calculated Min Dose (kGy):	25.8
Reference Dose Range (kGy):	26.6 - 41.2	Calculated Max Dose (kGy):	39.1

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PO Number: 10318

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

## Signature Manifest

Reviewed and E-Signed By: **Nelia Dias (Quality Engineer)**

Date/Time E-Signed: 07-Jul-2021 1:30 PM

Document Content Revision: 1

Operating facilities are in compliance with applicable regulations providing services under a certified ISO 13485 quality system and processing in accordance with STERIS practices and procedures.

## Processing Location

Synergy Health Sterilisation UK  
Limited, a STERIS Company  
Brunel Close  
Drayton Fields Industrial Estate  
Daventry  
Northants  
NN11 8RB  
Phone: + 44(0) 1327 706 111



## External Subcontractor Results Report

### 1. Product details

<b>Product</b>	<b>AGMA- produced HPW / WFI</b>
<b>Sampling Date</b>	<b>15 June 2021</b>
<b>Date Tested</b>	<b>16 June 2021</b>
<b>Date Results Received</b>	<b>30 June 2021</b>
<b>External Subcontractor Laboratory</b>	<b>HGL</b>
<b>External Report Reference</b>	<b>AGMA 16Jun22</b>


### 2. Specification and results

<b>Parameter</b>	<b>Specification</b>	<b>Pass / Fail / Comment</b>
<b>Appearance</b>	Clear, Colourless Liquid	PASS
<b>Conductivity (<math>\mu\text{S}/\text{cm}</math>)</b>	$\leq 2.1$ *	PASS
<b>Total Organic Carbon (TOC) (<math>\mu\text{g C}/\text{L}</math>, ppb)</b>	$\leq 500$	PASS
<b>Bacteria (cfu/100mL)</b>	$\leq 10$	PASS
<b>Endotoxin (EU/mL)</b>	$< 0.25$	PASS
<b>Nitrates (ppm)</b>	$\leq 0.2$	PASS
<b><i>Results confirm compliance with the current specification as required by Highly Purified Water (HPW) (Water For Injections-quality equivalent; (WFI)) and conform to the Pharmacopoeial requirements of the USP and the EP as specified for WFI quality water</i></b>		PASS
<b>Product release status:</b>	Released	

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

### 3. Signatures – **QUALITY CONTROL / QUALITY ASSURANCE ONLY PERMITTED**

<b>Author / Reviewer Name:</b>	Halima Nasir
<b>Position:</b>	QA Technician
<b>Signature and Date:</b>	

<b>Report Approver Name:</b>	James Pahamtang
<b>Position:</b>	QC Chemist
<b>Signature and Date:</b>	





**RECONCILIATION WORKSHEET**

Reference: AS.LP003

Client Name

AGMA Ltd  
(AHN)

Worksheet Number:

278165  
(278165)

Issued By:

CB

Worksheet Number From:	Worksheet Number To:	Issued By:	Date Issued:	Reconciled By:	Date Reconciled:
278164	278165	CB	15 June 21	J	30 Jun 2021
278166	278167	CB	15 June 21	J	30 Jun 2021
278168	278169	CB	15 June 21	J	30 Jun 2021
/	/	/	/	/	/
/	/	/	/	/	/
/	/	/	/	/	/
/	/	/	/	/	/

**Worksheets Issued for HGL Use Only**

278170	N/A	CB	15 June 21	J	30 Jun 2021
/	/	/	/	/	/
/	/	/	/	/	/
/	/	/	/	/	/
/	/	/	/	/	/

**Additional Report Details**

Report Reference:	Recorded By & Date:	No. of Pages:		Reconciled By:	Date Reconciled:
		HGL	Client		
/	/	/	/	/	/
/	/	/	/	/	/
/	/	/	/	/	/
/	/	/	/	/	/

Comments: N/A = Not Applicable

Results Approved For Release:

Jiny

Date:

30 Jun 2021


Worksheet Ref: WS061

Version Number: 006

Written By: [Signature]

Authorised By: [Signature]

Date Issued: 22 Jun 21

	Client Name:	AGMA Ltd	HGL Code:	From:	666/82/m
	Water Type:	Water For Injection		To:	N/A
	Worksheet Number:	273166 (278160)	Issued By:	CB	

**Total Viable Count (TVC) by Membrane Filtration (Procedure Ref: AS-MEP002)**

Analysis Request Submitted By/Date:	ANB	16 JUN 21
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Equipment Details			
LAF Cabinet Ref.:	① 348 120	Membrane Filter Ref.:	210600847
Incubator Ref.:	210		

Reagent References			
500ml PBS Ref.:	m/21/088	Expiry Date:	13 SEP 21.

Media References					
Media Type:	R2A	Media Batch No.:	4315364	Expiry Date:	26 JULY 21
Media QC Satisfactory?	YES/NO* ② ③				

Sample Analysis Details			
Volume of Sample to be Analysed:	Plate 1 (ml)		Plate 2 (ml)
	200		200
Incubator Temperature:	30-35°C	Incubation Period:	5-7 Days

Test Details Checked & Approved By:	AJT
Date & Time: (Must be approved prior to performing Analysis)	09:45 16 JUN 2021

**Comments:** \* = Delete as applicable, N/A = Not Applicable, PBS = Phosphate Buffered Saline

① incorrect entry ANB 16 JUN 21.

② media still undergoing QC results held until QC is completed ANB 16 JUN 21.

③ Media passed QC as of 18 Jun 21 DW 22 Jun 21

Results Approved For Release:	<i>Ying</i>	Date:	22 JUN 2021
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<b>Client Name:</b> AGMA Ltd	<b>Water Type:</b> Water For Injection
<b>Worksheet Number:</b> 273167 (278167)	<b>Issued By:</b> CB

<b>Total Viable Count (TVC) by Membrane Filtration (Procedure Ref: ANS-MLR002)</b>									
<b>Analysed By:</b> ANB	<b>Date of Analysis:</b> 16 JUN 21	<b>Time of Analysis:</b> 10:35	<b>Incubation start Time:</b>		11:05				
<b>Incubation Media:</b>	<b>By:</b> AM	<b>Date:</b> 21 JUN 21	<b>Time:</b> 12:45	<b>Plate Reading:</b>	<b>By:</b> AM	<b>Date:</b> 21 JUN 21	<b>Time:</b> 12:45		


<b>Specifications</b>		
<b>(T) Target Level (cfu/ml)</b> (If Target Level exceeded record Sentence as "Pass (T)")	<b>(A) Alert Level (cfu/ml)</b> (If Alert Level exceeded record Sentence as "Pass (A)")	<b>Action Level (cfu/100ml)</b> (If Action Level exceeded record Sentence as "Fail")
N/A	N/A	10cfu/100ml

Sample Details					TVC Results					
Sample ID	Sample Date	Sample Time	Samplers Initials	HGL Code	Plate 1 (Refer to Page 1 for volume)	Plate 2 (Refer to Page 1 for volume)	Final TVC (cfu/100ml)	Sentence	Checked: By: Date:	
Jun 15 21	15 June 21	10:45	DS	666/82/m	NIL	NIL	ND	PASS	AM	22 Jun 21
/										
<b>Negative Controls</b>		<b>Settle Plate (cfu)</b>	NIL / NIL	<b>Satis / Unsatis*</b>	<b>Client Informed of</b>			N/A		
		<b>PBS (cfu/100ml)</b>	NIL	<b>Satis / Unsatis*</b>	<b>Investigation Required?</b>			N/A		
					<b>ID Required?</b>			N/A		

**Comments:** \* Delete as Applicable, N/A = Not Applicable, FIO = For Information Only, OOS = Out of Specification, OOT = Out Of Trend, ND = None Detected, TNTC = Too Numerous To Count

<b>Results Approved For Release:</b> Jing	<b>Date:</b> 22 Jun 2021
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<b>Worksheet Number:</b> MWS122	<b>Page</b> of	<b>Version Number:</b> 004
<b>Written By:</b> S.A. E...	<b>Authorised By:</b> J...	<b>Date Issued:</b>


 Pharmaceutical Process Support	Client Name:	AGMA Ltd		Sample ID:	Jun1521	
	Sampled By:	DS	Sample Date:	15 June 21	HGL Code:	734/126k
	Water Type:	WFI	Worksheet Number:	278168 (278168)	Issued By:	CB

Appearance (EP) and Conductivity - WFI (EP) (Method AS AM001)	
<b>Appearance (EP) Result</b>	
Appearance	COMPRES
Specification	Clear, colourless liquid
Sentence:	PASS
<b>Conductivity Result</b>	
Conductivity	0.6 µS/cm at 19 °C
Stage 1 Specification	≤ 1.0 µS/cm (Refer to EP table 1)
Sentence:	PASS
Stage 2 (µS/cm @ 25 ± 1 °C)	Initial result = ..... µS/cm After 5 minutes = ..... µS/cm After 10 minutes = ..... µS/cm Final result = ..... µS/cm
Specification	≤ 2.1 µS/cm @ 25 ± 1 °C
Sentence:	
Stage 3 (pH 5.0 - 7.0)	pH .....
Specification	Limit at above pH ..... µS/cm
Sentence:	
Analysis Checked By: <i>AL</i> Date: 22 June 2021	

Nitrate (EP) (Method AS AM001)		
2ppm Nitrate Standard Ref.:	770/037/A	Result
10%w/v Potassium Chloride Ref.:	666/099/A	
Diphenylamine Solution Ref.:	770/007/F	Nitrate
Sulphuric Acid Ref.:	770/037/A	Specification
Water Bath Ref.:	403	≤ 0.2ppm
Thermometer Ref.:	451	Sentence:
Timer Ref.:	154	PASS
Gilson Pipette Ref.:	411 + 24S	
Time at 50°C:	15 mins	
Analysed By:	NDW	
Date of Analysis:	22 JUN 2021	
Analysis Checked By: <i>AL</i> Date: 22 June 2021		

Comments: N/A = Not Applicable  
 Ⓞ Should read 770/036/G NDW 22 JUN 2021

Results Approved For Release:	<i>Jing</i>	Date:	22 Jun 2021
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	<b>Client Name:</b>	AGMA Ltd		<b>Sample ID:</b>	Jun1521	
	<b>Sampled By:</b>	DS	<b>Sample Date:</b>	15 Jun 21	<b>HGL Code:</b>	734/126/C
	<b>Water Type:</b>	WFI	<b>Worksheet Number:</b>	273169 (278169)	<b>Issued By:</b>	CB

Total Organic Carbon (TOC) (EP) (Method AS-AM001)			
<b>TOC Meter No.:</b>	47	<b>Result</b>	
<b>Sucrose Standard Ref.:</b>	7101023/E	<b>TOC</b>	.635...ppb
<b>File Ref.:</b>	1606211NST41702	<b>Limit Response</b>	.499...ppb
<b>Recorded By:</b>	NDW	<b>Specification</b>	≤ Limit Response*
<b>Date Recorded:</b>	18 Jun 2021	<b>Sentence:</b>	PASS
<b>Analysis Checked By:</b>		AKL	<b>Date:</b> 18 June 2021

**Comments:** \* For EP compliance if the limit response is >500ppb the maximum allowed sample TOC is 500ppb

<b>Results Approved For Release:</b>	Jing	<b>Date:</b>	12 Jun 2021
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<b>Worksheet Number:</b>	WS024	<b>Version Number:</b>	015
<b>Written By:</b>	80 [Signature]	<b>Authorised By:</b>	NDW [Signature]
<b>Date Issued:</b>	21 Jun 21		

## ANALYTICAL DATA

<b>Product:</b>		Sterile Alcohol 70% v/v, 70% DE in WFI Quality Water, 5L Container			
<b>Batch No.:</b>	11868	<b>Manufacture Date:</b>	June 2021	<b>Expiry Date:</b>	June 2023

<b>Date(s) Tested:</b>	22 Jul 21, 02 Aug 21	<b>Results Received:</b>	06 Aug 21
<b>Analysed by:</b>	External Subcontractor Laboratory	<b>Report Reference(s):</b>	76580
<i>Analyses performed in accordance with current Ph. Eur, USP and JP.</i>			

PARAMETER	SPECIFICATION	SPECIFY RESULT / PASS OR FAIL
<b>Bacterial Endotoxin Test (BET)</b>	< 0.25 EU/mL	< 0.25 EU/MI/ PASS
<b>Sterility Test</b>	No Growth in Test Media	No Growth in Test Media/ PASS

<b>Prepared by, name:</b>	H Nasir	<b>Title:</b>	QA Technician
<b>Signature:</b>		<b>Date:</b>	27 Sept 22
<b>Countersigned by, name:</b>	J Pahamtang	<b>Title:</b>	QC Chemist
<b>Signature:</b>		<b>Date:</b>	27 Sept 22

## Certificate of Analysis

**Report Number:** 76580  
**Sample Name:** Sterile Alcohol 70% v/v, 70% DE in WFI  
 Quality Water, 5L Container  
**Client Batch:** 11868 Exp. June 2023  
**Sample Number:** 168812

**Client Address:**  
 Agma Ltd.  
 Apollo Works  
 Haltwhistle  
 Northumberland  
 Newcastle Upon Tyne  
 UK  
 NE49 9HA

**External Link:** O:\Test Material Receipt\RFA's\168812.pdf

Test	Method	Specification	Result
<b>Sterility of Validated sample</b>			
Test Start Date	Ph.Eur.2.6.1/USP<71>	-	22 Jul 2021
Test End Date	Ph.Eur.2.6.1/USP<71>	-	05 Aug 2021
Quantity Tested	Ph.Eur.2.6.1/USP<71>	Result ≤ 2	2 Units
Volume tested	Ph.Eur.2.6.1/USP<71>	Result ≤ 2,000.0	2000 ml
Sterility	Ph.Eur.2.6.1/USP<71>	Equal to Complies	Complies
<b>Bacterial Endotoxin</b>			
Test Start Date	Ph.Eur.2.6.14/USP<85>	-	02 Aug 2021
Test End Date	Ph.Eur.2.6.14/USP<85>	-	02 Aug 2021
BET	Ph.Eur.2.6.14/USP<85>	<0.25 EU/ml	<0.250 EU/ml

Refer to NC 1949, initial test failure due to contamination.

**Authorised signatory:** Natalie Turnbull BSc. Hons.  
 Analyst III

**Date:** 06 Aug 2021

This report has been produced with a valid electronic signature and as such represent the legally binding equivalent of a hand written signature

It is our practice to inform clients that the results in this report apply only to the sample submitted for testing since we have no control over sampling nor the conditions which the whole is stored.

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Page 1 of 1

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Registered in Scotland No SC635641 • Registered office 163 Bath Street, • Glasgow, • Scotland, G2 4SQ

*L. P. Riden*

16/08/2021

**Microbiological Efficacy Data Summary**Reference / Version: **TI003 /01**Issue Date: **28 Jan 14****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  
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email: enquiries@agma.co.uk - website: www.agma.co.uk

Revision Date: 17/11//2022  
Revision No: 12

## MATERIAL SAFETY DATA SHEET

For

**Denatured Ethanol 70%/ TSDA7 70% Range Products**

**This Safety Data Sheet Covers Products**

<b>Product Name</b>	<b>Item Numbers</b>
Denatured Ethanol 70% in WFI	All ranges
TSDA7 70% in WFI	All ranges
Sterile Alcohol 70% v/v- 70% Denatured Ethanol in WFI	All ranges
Sterile Denatured Wipes	All ranges
DE 70% WFI- 5L	1116
Sterile DE 70% WFI- 5L	0036 / 0060
Sterile Alcohol T/Spray DE- 900ml	105665 / 0058
Sterile Alcohol T/Spray TSDA7- 900ml	105670
TSDA7 70% v/v in WFI- 860 kg	180204
DE 70% in WFI- 1L	0028
4YPIN- 10 X 50 per case	31823
Sterile Denatured Alcohol Wipes – 10 x 10 per case	5568
4YPIN Sterile Alcohol- 20 x 15 wipes per case	0075

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## SAFETY DATA SHEET

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### 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
- Product Part Number:

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

- Use of the substance/mixture: Cleaning agent

#### 1.3 Details of the supplier of the safety data sheet

- Name of Supplier: Agma Ltd
- Address of Supplier: Gemini Works  
Haltwhistle  
Northumberland  
NE49 9HA  
UK
- Telephone: Tel: +44(0) 1434 320598
- Responsible Person: Malcolm Franklin
- Email: Sds@agma.co.uk

#### 1.4 Emergency telephone number

- Emergency Telephone: Tel: +44(0) 1434 320598  
Monday - Thursday : 8:30 - 17:00 (GMT)  
Friday: 8:30 - 14:30(GMT)  
(office hours only)  
Out-of-hours Contact: Alan Barnes  
Tel:+44 (0)7936 966108

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

- CLP: Flam. Liq. 2, Eye Irrit. 2

#### 2.2 Label elements



- Signal Word: Danger

#### Hazard statements

- H225 - Highly flammable liquid and vapour.
- H319 - Causes serious eye irritation.
- EUH066 - Repeated exposure may cause skin dryness or cracking.

#### Precautionary statements



**SECTION 2: Hazards identification (....)**

P403+P235 - Store in a well-ventilated place. Keep cool.

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

P332+P313 - If skin irritation occurs: Get medical advice/attention.

**2.3 Other hazards**

- EUH018 - In use may form flammable/explosive vapour-air mixture.
- 

**SECTION 3: Composition/information on ingredients****3.2 Mixtures****Ethanol; Ethyl Alcohol**

CAS Number: 64-17-5

EC Number: 200-578-6

Concentration: 50-70%

Specific Concentration Limits: Not available

M factor: Not available

Acute toxicity estimate: Not available

Categories: Eye Irrit. 2; Flam. Liq. 2

H Statements: H225, H319

**Propan-2-ol; Isopropyl Alcohol; Isopropanol**

CAS Number: 67-63-0

EC Number: 200-661-7

Concentration: 1-10%

Specific Concentration Limits: None assigned

M factor: Not available

Acute toxicity estimate: Not available

Categories: Eye Irrit. 2; STOT SE 3; Flam. Liq. 2

H Statements: H225, H336, H319

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**SECTION 4: First aid measures****4.1 Description of first aid measures****Contact with eyes**

If substance has got into eyes, immediately wash out with plenty of water for at least 15 minutes

P337+P313 - If eye irritation persists: Get medical advice/attention.

**Contact with skin**

P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

---

## SECTION 4: First aid measures (....)

### Ingestion

- P331 - Do NOT induce vomiting.
- Rinse mouth with water (only if the person is conscious)
- Give plenty of water to drink
- P315 - Get immediate medical advice/attention.

### Inhalation

- P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P314 - Get medical advice/attention if you feel unwell.

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

- May cause redness and irritation
- May cause irritation
- H335 - May cause respiratory irritation.
- May cause breathing difficulty

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

- No information available
- 

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- In case of fire use water spray or fog, alcohol resistant foam, dry chemical or carbon dioxide

### 5.2 Special hazards arising from the substance or mixture

- Highly Flammable
- May give off noxious and toxic fumes in a fire

### 5.3 Advice for firefighters

- P280 - Wear protective gloves/protective clothing/eye protection/face protection.
  - Wear self-contained breathing apparatus.
- 

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

- Eliminate all sources of ignition.
- Wear protective clothing as per section 8
- Turn leaking containers leak-side up to prevent the escape of liquid.

### 6.2 Environmental precautions

- P273 - Avoid release to the environment.
- Contain the spillage using bunding.

### 6.3 Methods and material for containment and cleaning up

- Absorb spillage in earth or sand
- Remove contaminated material to safe location for subsequent disposal
- Disposal should be in accordance with local, state or national legislation
- P242 - Use non-sparking tools.

### 6.4 Reference to other sections

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**SECTION 6: Accidental release measures (....)**

- Refer to section 8 of SDS for personal protection details.
- 

**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

- Ensure adequate ventilation
- P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
- Wear suitable protective clothing and gloves
- Shut off all ignition sources
- P242 - Use non-sparking tools.

**7.2 Conditions for safe storage, including any incompatibilities**

- Keep container tightly closed, in a cool, well ventilated place
- Keep only in the original container
- P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

**7.3 Specific end use(s)**

- No information available
- 

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters**

- Hazardous Material: Ethanol; Ethyl Alcohol
- TLV (TWA): 1000 ppm, 154 mg/m<sup>3</sup>
- Hazardous Material: Propan-2-ol; Isopropyl Alcohol; Isopropanol
- TLV (TWA): 400 ppm, 999 mg/m<sup>3</sup>
- TLV (STEL): 500 ppm 1250 mg/m<sup>3</sup>

**8.2 Exposure controls**

- P280 - Wear protective gloves/protective clothing/eye protection/face protection.
  - Ensure adequate ventilation
  - Eyewash bottles should be available
- 

**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

- Physical state: Liquid
  - Colour: Colourless
  - Odour: Alcohol odour
  - Melting point/Range: Not available
  - Boiling Point/Range: Not available
  - Flammability: Not available
  - Flashpoint: 20.5 C c.c. (closed cup)
-

## SECTION 9: Physical and chemical properties (....)

- pH: 6.0 - 9.0
- Solubility in water: Completely soluble in water
- Density: 0.880 - 0.888 g/cm<sup>3</sup> at 20 °C
- Viscosity: Non-viscous

### 9.2 Other information

- No information available
- 

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

- This article is considered stable under normal conditions

### 10.2 Chemical stability

- This article is considered stable under normal conditions

### 10.3 Possibility of hazardous reactions

- No hazardous reactions known if used for its intended purpose

### 10.4 Conditions to avoid

- Keep away from heat and sources of ignition

### 10.5 Incompatible materials

- Strong acids.
- Strong oxidising agent

### 10.6 Hazardous decomposition products

- May give off noxious and toxic fumes in a fire
- 

## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### Acute toxicity

Hazardous Material: Ethanol; Ethyl Alcohol

LD<sub>50</sub> (oral, rat): >2000 mg/kg

LD<sub>50</sub> (dermal, rabbit): >2000 mg/kg

LC<sub>50</sub> (inhalation, rat): >20 mg/l/4h

Hazardous Material: Propan-2-ol; Isopropyl Alcohol; Isopropanol

LD<sub>50</sub> (oral, rat): >2000 mg/kg

LD<sub>50</sub> (dermal, rabbit): >2000 mg/kg

LC<sub>50</sub> (inhalation, rat): >25 mg/l/6h

#### Skin corrosion/irritation

See Section 4.1.2

#### Serious eye damage/irritation

See Section 4.1.1

#### Respiratory or skin sensitisation

**SECTION 11: Toxicological information (....)**

See Section 4.1

**Germ cell mutagenicity**

No information available

**Carcinogenicity**

No information available

**Reproductive toxicity**

No information available

**STOT (specific target organ toxicity) - single exposure**

No information available

**STOT (specific target organ toxicity) - repeated exposure**

No information available

**Aspiration hazard**

See Section 4.1.4

**11.2 Information on other hazards**

- No information available

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**SECTION 12: Ecological information****12.1 Toxicity**

- Hazardous Material: Ethanol; Ethyl Alcohol
- LC<sub>50</sub> (golden orfe (Leuciscus idus)): >100 mg/l (48 hr)
- EC<sub>50</sub> (Daphnia magna): >100 mg/l (24 hr)
- EC50 (algae) >100 mg/l (72 hr)
- Hazardous Material: Propan-2-ol; Isopropyl Alcohol; Isopropanol
- LC<sub>50</sub> (golden orfe (Leuciscus idus)): >100 mg/l (48 hr)
- EC<sub>50</sub> (Daphnia magna): >100 mg/l (48 hr)
- EC50 (algae) >100 mg/l (72 hr)

**12.2 Persistence and degradability**

- No information available

**12.3 Bioaccumulative potential**

- No information available

**12.4 Mobility in soil**

- No information available

**12.5 Results of PBT and vPvB assessment**

- No information available

**12.6 Endocrine disrupting properties****12.7 Other adverse effects**

- No information available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

- Disposal should be in accordance with local, state or national legislation
- 

## SECTION 14: Transport information



### 14.1 UN number or ID number

- UN No.: 1170

### 14.2 UN proper shipping name

- Proper Shipping Name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

### 14.3 Transport hazard class(es)

- Hazard Class: 3
- ADR Hazard Class: 3
- ADR Classification Code: F1
- IMDG Hazard Class: 3

### 14.4 Packing group

- Packing Group: II

### 14.5 Environmental hazards

- Presents no hazard to the environment

### 14.6 Special precautions for user

- Limited Quantity 1L
- IMDG EmS: F-E, S-D
- Tunnel Code: D/E

### 14.7 Maritime transport in bulk according to IMO instruments

- No information available
- 

## SECTION 15: Regulatory information

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

- This Safety Data Sheet is provided in compliance with the EC Regulation 1907/2006-2015/830
- and CLP (Regulation 1272/2008)

### 15.2 Chemical safety assessment

- A chemical safety assessment (CSA) for this product has not yet been completed
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## SECTION 16: Other information

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## SECTION 16: Other information (....)

Text not given with phrase codes where they are used elsewhere in this safety data sheet:-  
**H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or 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.

--- end of safety datasheet ---

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