

## STERILE ALCOHOL WIPES

IPA 70% WFI PRE-IMPREGNATED – READY TO USE / EASY TO USE.

ITEM NO. 192701

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

READY TO USE WIPES ARE A SIMPLE MEANS OF DISINFECTING A VARIETY OF SURFACES AND CLEANROOM ITEMS. THEY HAVE THE ADDED BENEFIT OF BEING ABLE TO PHYSICALLY REMOVE PARTICLES AND SPORES IN ADDITION TO PROVIDING GOOD DISINFECTION AGAINST VEGETATIVE MICROBES.

COST IN USE, TAKING INTO ACCOUNT OPERATOR TIME, GIVES FINANCIAL BENEFITS WHEN COMPARED TO DRY WIPES AND SPRAYS.

- READY TO USE-SAVES TIME.
- RE-SEALABLE TO PREVENT DRYING OUT.
- 69G PER M<sup>2</sup> LOW PARTICULATE POLYESTER/CELLULOSE WIPE.
- COST EFFECTIVE IN USE.
- BROAD SPECTRUM ACTIVITY.
- WFI QUALITY WATER – HIGH PURITY WATER.
- FULLY TRACEABILITY WITH SUPPORTING ANALYSIS.
- GAMMA IRRADIATED FOR STERILITY.
- 2-YEAR SHELF LIFE.
- 10 WIPES PER PACK, 10 PACKS PER CASE.
- ALSO AVAILABLE IN STERILE TRIGGER SPRAY BOTTLES.



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. 2-10/22



Agma Ltd Gemini Works Haltwhistle Northumberland England NE49 9HA Telephone 01434 320598 Fax 01434 321650  
 email:enquiries@agma.co.uk – website: www.agma.co.uk

## Product Specification

Date: Feb 23  
 Issue: 07  
 Review date: Feb 25

<b>Product Name</b>	IPA 70% / Isopropyl Alcohol 70% / Isopropanol 70%
<b>Packaging Type</b>	Liquid / Aerosol / Impregnant
<b>Proportion</b>	70:30 (v/v)
<b>Alcohol Grade</b>	99.7% min, typically 99.9%. Complies with BS1595, ASTM D770, British Pharmacopoeia, US Pharmacopoeia & European Pharmacopoeia
<b>Water Grade</b>	WFI Quality Water
<b>Filtration</b>	0.2 micron Filtered
<b>Appearance</b>	Clear and Colourless Liquid
<b>Odour</b>	Isopropanol
<b>SG@20°C</b>	0.872 – 0.883
<b>pH (Non Sterile Liquid Only)</b>	6.0 – 9.0
<b>Refractive Index / Percentage Activity @20°C</b>	1.370 – 1.380
<b>Irradiation Dosage (Sterile Products)</b>	20-45 kGy (for 5L) 25-45 kGy (for 900ml/ Aerosols/ Wipes)

Prepared by Name:	Halima Nasir	Date:	09 February 2023
Position:	QA 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 Alcohol Wipes – (10 x 10 Wipes)	<b>Certificate No. 6559</b>
<b>Product Code</b>	192701	
<b>Batch No.</b>	13351	
<b>Date of Manufacture</b>	17 February 2023	
<b>Date of Irradiation</b>	28 February 2023	
<b>Date of Expiry</b>	28 February 2025	
<b>TEST</b>	<b>SPECIFICATION</b>	
<b>Appearance</b>	Clear Impregnant & Wet White Wipes With No Particulates	Pass
<b>Odour</b>	Isopropanol	Pass
<b>SG @ 20°C (Impregnant)</b>	0.872 – 0.883	Pass(0.874)
<b>pH(Non-Sterile Impregnant Only)</b>	6.0 – 9.0	Pass(8.3)
<b>Refractive Index (Impregnant)</b>	1.370 – 1.380	Pass(1.374)
<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		

<b>Irradiation Certificate No.</b>	2173-35310A	<b>Confirm irradiation dose complies with 25 – 45kGy:</b>	Complies	<b>Checked by:</b>	M. Adamson
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<b>Authorised Signatures</b>			<b>DATE</b>	06/Mar/2023
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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

# STERIS: Gamma Certificate Of Processing

Prepared for: AGMA LTD (8247)

Gamma Process Run ID 2173-35310A

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<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
Alcohol Wipes DV5801	13351	300	Case
Validation Reference Number: 5801			

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Processing Run Start Date: 28-Feb-2023 11:01 PM

Processing Run End Date: 01-Mar-2023 6:57 AM

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<b>Specified Dose Range (kGy):</b>	<b>25.0 - 45.0</b>	<b>Calculated Min Dose (kGy):</b>	<b>27.9</b>
<b>Reference Dose Range (kGy):</b>	<b>29.6 - 41.3</b>	<b>Calculated Max Dose (kGy):</b>	<b>37.4</b>

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PO Number: 11322

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

**Gamma Process Run Approval authorized by STERIS**

Date/Time E-Signed: 01-Mar-2023 9:47 AM

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



**Microbiological Efficacy Data Summary**

**Reference / Version: TI002 /04**

**Issue Date: 21 Apr 2021**

**70% IPA in WFI**

PROTOCOL	CHALLENGE ORGANISM	CONTACT TIME (minutes)	LOG REDUCTION PASS CRITERIA	PRODUCTS	RESULT
EN 1276	<i>S. aureus</i> ATCC 6538	5	>5.0	70% IPA Fluid, 70% IPA Wipes	PASS
	<i>Ps. aeruginosa</i> ATCC 15442				
	<i>E. coli</i> ATCC 10536				
	<i>Ent. hirae</i> ATCC 10541				
EN 1650	<i>C. albicans</i> ATCC 10231	15	>4.0	70% IPA Fluid, 70% IPA Wipes	PASS
	<i>A. brasiliensis</i> ATCC 16404				
EN 13697	<i>S. aureus</i> ATCC 6538	5	>4.0	70% IPA Fluid, 70% IPA Wipes	PASS
	<i>Ps. aeruginosa</i> ATCC 15442				
	<i>E. coli</i> ATCC 10536				
	<i>Ent. hirae</i> ATCC 10541				
	<i>C. albicans</i> ATCC 10231	15	>3.0		
	<i>A. brasiliensis</i> ATCC 16404				
EN 16615	<i>S. aureus</i> ATCC 6538	5	>5.0	70% IPA Wipes	PASS
	<i>Ps. aeruginosa</i> ATCC 15442				
	<i>Ent. hirae</i> ATCC 10541				
	<i>C. albicans</i> ATCC 10231	5	>4.0		
EN 14476:2013 +A2:2019	<i>Vaccinia virus</i> ATCC VR-1508	5	>4.0	70% IPA Fluid	* PASS

Analysed in accordance with CEN 216, the requirements of the Biocidal Products Regulations (BPR, Regulation (EU) 528/2012) and to evaluate virucidal activity

**Results confirm that 70% IPA in WFI has proven efficacy against bacteria, yeasts, moulds and enveloped viruses**

\* This product is effective against all enveloped viruses as defined in EN 14476:2013+A2:2019 Annex A including:

- Coronaviruses
- Poxviridae
- Filoviridae
- Orthmyxoviridae
- Flaviviridae
- Paramyxoviridae
- Herpesviridae

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Compilation Date: 04/10/2022  
Revision Date: 04/10/2024  
Revision No: 12

## MATERIAL SAFETY DATA SHEET

For

**IPA 70% Products**

**This Safety Data Sheet Covers Products**

<b>Product Name</b>	<b>Item Numbers</b>
Isopropanol 70% v/v in WFI Quality Water	All ranges
Sterile Alcohol 70% v/v- 70% IPA in WFI	All ranges
Isopropanol 70% Wipes	All ranges
IPA 70% in WFI – 2 x 5L	0038
IPA 70% in WFI – 1L x 5L	1215/ 1214
Sterile Alcohol T/Spray – 900ml	105666
Sterile IPA 70% Adjustable Triggerhead – 900 ml	105675
Sterile Alcohol T/Spray IPA – 6 x 900ml per case (Bagged)	105676
IPA 70% Triggers – 20 x 500ml	1138
Sterile Alcohol Wipes – 10 x 10 Wipes per case	192701
IPA-YPIN – 10 x 50 Wipes Per Case	1213
Sterile IPA-YPIN – 10 x 50 Wipes Per Case	31824

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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: ISOPROPANOL 70% v/v in WFI Quality Water
- Product Part Number: Numerous

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

- Use of the substance/mixture: Cleaning agent, Disinfectant

#### 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: STOT SE 3, Flam. Liq. 2, Eye Irrit. 2

#### 2.2 Label elements



- Signal Word: Danger

#### Hazard statements

- H225 - Highly flammable liquid and vapour.
- H336 - May cause drowsiness or dizziness.
- H319 - Causes serious eye irritation.
- EUH066 - Repeated exposure may cause skin dryness or cracking.

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

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.  
P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.  
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  
P312 - Call a POISON CENTRE or doctor if you feel unwell.  
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P403+P235 - Store in a well-ventilated place. Keep cool.  
P501 - Dispose of contents/container to an authorised waste collection point

**2.3 Other hazards**

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**SECTION 3: Composition/information on ingredients****3.2 Mixtures****propan-2-ol; isopropyl alcohol; isopropanol**

CAS Number:	67-63-0
EC Number:	200-661-7
Concentration:	60-75%
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**

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.

**Contact with skin**

P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

**Ingestion**

Give plenty of water to drink  
Do not induce vomiting  
P313 - Get medical advice/attention.



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

### 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 severe irritation
- May cause redness and irritation
- May cause nausea/vomiting
- H335 - May cause respiratory irritation.
- May cause dizziness, confusion, headache or stupor

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

- P314 - Get medical advice/attention if you feel unwell.
- 

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- P370+P378 - In case of fire: Use light water spray, alcohol resistant foam, carbon dioxide to extinguish.
- Do not use water jets

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

- Flammable

### 5.3 Advice for firefighters

- Wear Positive-Pressure Breathing Apparatus
  - P280 - Wear protective gloves/protective clothing/eye protection/face protection.
- 

## SECTION 6: Accidental release measures

**Spillage causes slippery surface**

**Vapours may ignite**

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

- Wear protective clothing as per section 8
- Shut off all ignition sources
- Shut off source of leak if safe to do so

### 6.2 Environmental precautions

- Do not allow to enter public sewers and watercourses

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

- P242 - Use non-sparking tools.
- Absorb spillage in inert material and shovel up
- Dispose of contents to a hazardous or special waste collection point

### 6.4 Reference to other sections

- See Section 13
-

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- Avoid contact with skin and eyes
- Ensure adequate ventilation
- P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
- P280 - Wear protective gloves/protective clothing/eye protection/face protection.

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

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

### 7.3 Specific end use(s)

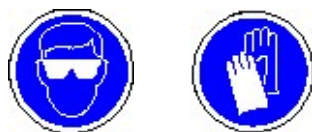
- See Section 1.2
- 

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

- 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: Flammable
- Flashpoint: 20.5 C c.c. (closed cup)
- pH: 6.0-9.0
- Solubility in water: Completely soluble in water
- Density: 0.872-0.883 g/cm<sup>3</sup> at 20 °C
- Viscosity: Non-viscous

### 9.2 Other information

- None
-

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

- No hazardous reactions known if used for its intended purpose

### 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

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

### 10.5 Incompatible materials

- Strong oxidising agent
- Avoid contact with acid

### 10.6 Hazardous decomposition products

- No hazardous decomposition products known
- 

## SECTION 11: Toxicological information

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

#### Acute toxicity

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

#### Skin corrosion/irritation

See Section 4.1.2

#### Serious eye damage/irritation

See Section 4.1.1

#### Respiratory or skin sensitisation

See Section 4.1

#### Germ cell mutagenicity

No evidence of mutagenic effects

#### Carcinogenicity

No information available

#### Reproductive toxicity

No information available

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

No information available

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

### 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
- 

## SECTION 12: Ecological information

### 12.1 Toxicity

- 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

- Biodegradable

### 12.3 Bioaccumulative potential

- Bioaccumulation is insignificant

### 12.4 Mobility in soil

- miscible with water

### 12.5 Results of PBT and vPvB assessment

- Not a PBT according to REACH Annex XIII

### 12.6 Endocrine disrupting properties

### 12.7 Other adverse effects

- No information available
- 

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

- Dispose of this material and its container at hazardous or special waste collection point
  - Disposal should be in accordance with local, state or national legislation
- 

## SECTION 14: Transport information



### 14.1 UN number or ID number

- UN No.: 1219

### 14.2 UN proper shipping name

## SECTION 14: Transport information (....)

- Proper Shipping Name: ISOPROPANOL (ISOPROPYL 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

- On available data, substance is not harmful 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
- 

## 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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