



STERILE ALCOHOL 900ML TRIGGER SPRAY IPA 70% WFI BAG IN BOTTLE TRIGGER SPRAY. ITEM NO. 105666

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

BAG IN BOTTLE TRIGGER SPRAYS ARE 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 WIPES.

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

- EFFICACY INDEPENDENTLY VALIDATED.
- WFI QUALITY WATER HIGH PURITY WATER.
- ERGONOMIC TRIGGER WITH EFFECTIVE RETURN MECHANISM.
- RELIABLE BOTTLE WITH HEADROOM FOR EXPANSION.
- BAG IN BOTTLE TO MAINTAIN STERILITY IN USE.
- 13 WEEK IN-USE VALIDATION.
- MANUFACTURED IN ISO CLASS 5 CLEANROOM.
- FULLY TRACEABILITY WITH SUPPORTING ANALYSIS.
- GAMMA IRRADIATED FOR STERILITY.
- 2-YEAR SHELF LIFE.
- DOUBLE BAGGED.
- AVAILABLE IN STERILE WET WIPE FORMATS.

DIRECTION FOR USE:

AGMA IPA 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. 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

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

Prepared by Name:	T Elliott		
		Date:	14 June 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

Product	Sterile Alcohol T/Sprays (IPA 70% v/v in WFI Quality Water) – 6 x 900ml	Certificate No.
Product Code	105666	
Batch No.		
Date of Manufacture		
Date of Irradiation		
Date of Expiry		
TEST	SPECIFICATION	PASS/FAIL (RESULTS)
Appearance	Clear Colourless Liquid	Pass
Odour	Isopropanol	Pass
SG @ 20°C	0.872 – 0.883	Pass ()
pH (Non-Sterile Liquid Only)	6.0 - 9.0	Pass ()
Refractive Index	1.370 – 1.380	Pass ()
DECLARATION OF CONFORMITY It is hereby certified that the supplies detailed hereon have been inspected and are in compliance in all respects to the specification relevant thereto		

Irradiation Certificate No. Confirm irradi complies with 2	ation dose 5 – 45kGy: Checked by:
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Authorised Signatures DATE	
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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

<u>Product Code</u> IPA 70% Trigger Sprays DV5698	Lot Number	Quantity	<u>UOM</u> Case
Validation Reference Number:	5698		Case
Processing Run Start Date:			
Processing Run End Date:			
Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	
Reference Dose Range (kGy):		Calculated Max Dose (kGy):	

PO Number:

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed:

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



70% IPA in WFI

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

CoronavirusesPoxviridae

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- FiloviridaeOrthmyxoviridae
- Flaviviridae
 Paramyxovir
- Flaviviridae Herpesviridae Paramyxoviridae

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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

Product Name	Item Numbers
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	105666/0072
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

SAFETY DATA SHEET

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

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

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

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/m³
- TLV (STEL): 500 ppm 1250 mg/m³

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/cm³ 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 LD₅₀ (oral, rat): >2000 mg/kg LD₅₀ (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

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
- LC₅₀ (golden orfe (Leuciscus idus)): >100 mg/l (48 hr)
- EC₅₀ (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:
- ADR Hazard Class: 3
- ADR Classification Code: F1
- IMDG Hazard Class:

14.4 Packing group

- Packing Group: II

14.5 Environmental hazards

- On available data, substance is not harmful to the environment

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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 ---