Empfohlene Reinraumklassen

ISO 5 | 6 | 7 | 8 | 9

GMP A/B | C | D

InSpec IPA 70/30 (WFI) premium (bag in the bottle) #IPAWFI1-1LS

pure[11]-Nr.: 1130841, Marke:

Eigenschaften

- Steril
- Marke: InSpec
- Desinfektion
- Wirkstoff: Isopropylalkohol (IPA)
- Gebrauchsfertig
- Volumen in ml: 1.000 mL
- Behälterform: Sprühflasche
- Rückstände: gering
- Biozid
- Schnell-Desinfektion (Wirksam in </= 5 Minuten)
- VOC-Anteil: 3,37 in KG VOC/VE
- Bag-in-Bottle System
- Filtriert auf 0,2µm
- Geprüft nach EN 13697 - bakterizid und/oder fungizid
- Geprüft nach EN 14476 - viruzid
- Geprüft nach EN 1650 - fungiziden oder levuroziden
- Isopropylalkohol (IPA): 70 %
- Viruzid (Einwirkzeit in min.): 0,5 min
- WFI (Water for Injection): 30 %

we care

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www.pure11.de
info@pure11.de

- Zustand: Flüssig

Material

-

Verpackung

- 6STK

Produktvarianten

pure¹¹-Nr.: 1130841, InSpec IPA 70/30 (WFI) premium (bag in the bottle) #IPAWFI1-1LS

Steril; Gebinde: 6 Flaschen á 1.000 ml / VE: 6STK

InSpec™
Solutions Delivered By Experience

Technisches Datenblatt

IPA

Steriler Isopropylalkohol v/v mit Wasser von WFI-Güte

Alkoholhaltiges, schnell wirkendes, schnell trocknendes Desinfektionsmittel mit geringe Rückstandsbildung

GEBRAUCHSANWEISUNG:

InSpec IPA ist zum Sprühen, Wischen von Hand und mit Mopp ausgelegt. Sprühstrahl mit etwa 15-20 cm Abstand aufbringen. 5-l-Versionen, zum Wischen mit Mopp in geeigneten Behälter gießen. Auf Fläche aufbringen, für vollständige Flächendeckung sorgen. Bei Schraubkappenflaschen bitte den gesamten Inhalt nach dem Öffnen aufbrauchen.

TECHNISCHE DATEN:

Aussehen: Transparente Flüssigkeit, partikelfrei. Spezifische Anziehungskraft (20 °C): 0,872 bis 0,883 Alkoholanteil: 70 % +/- 2 % v/v.

LAGERUNG:

Aufrecht in geschlossenem Originalbehälter, vor Sonnenlicht und extremen Temperaturen geschützt lagern. Umfassende Hinweise zu Handhabung und Entsorgung dieses Produkts finden Sie im Material-Sicherheitsdatenblatt (MSDB).

SICHERE HANDHABUNG:

Immer Handschuhe und Schutzbrille bzw. Gesichtsschutz tragen. Vor Gebrauch stets Kennzeichnung und MSDB lesen.

MATERIALKOMPATIBILITÄT:

Das Aufbringen von Lösungen beeinträchtigt bei vorschriftsmäßiger Anwendung keine in Reinräumen normalerweise vorkommenden Materialien. Siehe Kompatibilitätsangaben in der Technik-Datei.

VORTEILE:

- Nur wenig Rückstände hinterlassend
- Schnell wirkend
- Bakterizide und fungizide Wirkung
- Nach dem Öffnen validierte dreimonatige Haltbarkeitsdauer
- Inhalt geschützt durch Bag-in-Bottle-Verpackung bei Premium-Reihe.
- Inhalt geschützt durch gefilterte Abgabe aus Sprühflasche bei Standard-Reihe
- Formate mit 1 l und 5 l werden mit Wasser von WFI-Güte hergestellt
- Mehrfachbeutel für Reinraumtransfer
- Ideale Desinfektionsmittel für Flächen und keimfreien Transfer
- Hergestellt gemäß guter Herstellungspraxis (Good Manufacturing Practice, GMP)

TECHNISCHE BENUTZERINFORMATIONEN:

InSpec IPA ist ein steriles, gebrauchsfertiges Desinfektionsmittel. Es handelt sich um eine 70%ige v/v alkoholische Lösung mit Wasser von WFI-Güte.

InSpec IPA wird gemäß guter Herstellungspraxis (Good Manufacturing Practice, GMP) in einem Reinraum der Klasse ISO 6 hergestellt. Das Produkt wird in einer Umgebung der Klasse ISO 5 befüllt und verschlossen.

Die Lösung wird durch einen Filter mit 0,2 Mikron gefiltert und nach einem validierten Verfahren gammabestrahlt (bei 25-45k Gy), um einen SAL-Wert (Sterilisierungsvertrauensgrad) von 10^{-6} zu erreichen.

InSpec IPA wird mit Konformitätszertifikaten, Analysen, Bestrahlungssterilisation und Endotoxin ausgeliefert.

Alle IPA-Formate haben eine stabilisierte Haltbarkeitsdauer von 24 Monaten.

Mikrobiologischer Abklatschtest zur Mindestwirksamkeit			
EN 1276 Bakterien	5 Minuten	EN 13697 Bakterien	5 Minuten
EN 1650 Pilze	15 Minuten	EN 13697 Pilze	15 Minuten

InSpec™ IPA-Produkt			
Produkt	**Packungsgröße**	**Behältergröße**	**Produktcode**
InSpec™ IPA 1 l Premium	1 l Sprühflasche	6 x 1 l	IPAWFI1-1LS
InSpec™ IPA 5 l Schraubkappe	5 l Schraubkappe	2 x 5 l	IPAWFI1-5LS
InSpec™ IPA 500 ml Premium	500 ml Sprühflasche	8 x 500 ml	IPAWFI-500MLS

Redditch Medical
Innovative thinking

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Safety Data Sheet

According to Regulation (EC) No 1907/2006, amended by Regulation (EU) 2020/878

InSpec IPA

Revision Date: 2023-06-22 Revision No. 7.1

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

1.1 Product Identifier

Trade Names: InSpec IPA
InSpec IPA Wipes
InSpec IPA Mops

Product Number: -

UFI: 1200-U0CW-500U-Q09P

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

Identified Uses: Alcohol Disinfectant for professional use only.
AISE-P314 – Surface disinfectant (manual process).
AISE-P315 – Surface disinfectant (spray and rinse manual process).

Uses advises against: Uses other than those identified are not recommended.

1.3 Details of the supplier of the safety data sheet

Redditch Medical (a division of Entaco Ltd), Unit 90 Heming Rd, Washford, Redditch, B98 0EA, United Kingdom.

Contact Details

Redditch Medical (a division of Entaco Ltd),
Discovery 2, 2 William Armstrong Way,
NETPark, Sedgefield,
Co Durham, TS21 3FD, UK.
Telephone number: +44 (0) 1527 830940
Email: products@redditchmedical.com

EU Representative: Enviresearch Portugal Limitada
Address: Edifício Amoreiras Square,
Rua Carlos Alberto da Mota Pinto,
17, 3º A, 1070 - 313 LISBOA
Portugal

1.4 Emergency telephone number

For medical or environmental emergency only:
Call + 44 (0) 1527 830940 (office hours, UK)
+ 44 (0) 7377 544472 (out-of-office hours, UK)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The product has been classified and labelled in accordance with Regulation (EC) No 1272/2008.

Physical hazards: Flam. Liq. 2 (H225)

Health hazards: Eye Irrit. 2 (H319)
STOT SE 3 (H336)

Environmental hazards: Not classified.

2.2 Label elements

Signal Word: **Danger**

Contains propan-2-ol (isopropyl alcohol)

Hazard Statements:

- H225 – Highly flammable liquid and vapour.
- H319 – Causes serious eye irritation.
- H336 – May cause drowsiness or dizziness.

Precautionary Statements:

- P210 – Keep away from heat / sparks / open flames / hot surfaces. – No smoking.
- P261 – Avoid breathing fume / mist / vapour / spray.
- P280 – Wear eye protection/face protection.
- P312 - Call a POISON CENTRE/ doctor if you feel unwell
- P337+P313 – If eye irritation persists: Get medical advice/attention

2.3 Other hazards

No other hazards known. The product does not contain components which are known to meet the criteria for PBT or vPvB in accordance with Regulation (EC) No 1907/2006, Annex XIII.

SECTION 3: Composition / information on ingredients

3.1 Substances

The product is a mixture (see sub-section 3.2 of this Safety Data Sheet).

3.2 Mixtures

Ingredient(s)	EC number	CAS number	REACH number	Classification according Regulation (EU) No 1272/2008 (CLP)	Notes	Content (% w/w)
Propan-2-ol	200-661-7	67-63-0	01-2119457558-25-XXXX	Flam. Liq. 2 (H225) Eye Irrit. 2 (H319) STOT SE 3 (H336)	-	50-75

Additional information:
For full text of Hazard (H) statements see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation: Remove affected person to fresh air and keep at rest in position comfortable for breathing. Call a POISON CENTRE or doctor / physician if affected person feels unwell.

Skin contact: Wash hands and exposed skin before meals and after use. Repeated exposure may cause skin dryness or cracking.

Eye contact: If in eyes immediately rinse cautiously with lukewarm water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice / attention.

Ingestion: Rinse mouth out with water. Give plenty of water to drink. Get medical advice / attention if affected person feels unwell.

Self-protection of first-aider: Consider personal protective equipment as indicated in sub-section 8.2 of this Safety Data Sheet.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation: May cause drowsiness or dizziness.

Skin contact: No known effects or symptoms in normal use.

Eye contact: Causes severe irritation.

Ingestion: No known effects or symptoms in normal use.

General Information: No information available.

4.3 Indication of any immediate medical attention and special treatment needed

No information available on clinical testing and medical monitoring. Specific toxicological information on substances, if available, can be found in section 11 of this Safety Data Sheet.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing material: Carbon dioxide, dry powder, water spray jet. Fight larger fires with water spray jet or alcohol-resistant foam.

5.2 Special hazards arising from the substance or mixture

No special hazards known.

5.3 Advice for firefighters

As in the event of any fire, wear self-contained breathing apparatus and suitable personal protective equipment including gloves and eye / face protection.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Turn off all sources of ignition. Take precautionary measures against static discharge. Ventilate the area.

6.2 Environmental precautions

Do not allow to enter drainage system, surface or ground water. Dilute with plenty of water.

6.3 Methods and material for containment and cleaning up

Collect with non-combustible absorbent material (*e.g.* sand, diatomaceous earth, universal binders, sawdust, vermiculite) and place in a suitable container for disposal according to local / national regulations.

6.4 Reference to other sections

For personal protective equipment see sub-section 8.2 of this Safety Data Sheet. For disposal considerations on see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Measures to prevent fire and explosions: Keep away from heat, flames, hot surfaces, and sparks. Take precautionary measures against static discharge. Do not smoke.

Measures to protect the environment: For environmental exposure controls see sub-section 8.2 of this Safety Data Sheet.

Advice on general occupational hygiene: Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink, and animal feeding stuffs. Do not mix with other products unless advised by Redditch Medical. Wash hands before breaks and at the end of the work day. Wash face, hands, and any exposed skin thoroughly after handling. Take off immediately all contaminated clothing. Store used personal protective equipment separately. Use personal protective equipment as required. Use only with adequate ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local and national regulations. Keep only in original container. Keep container tightly closed and store in cool, well-ventilated place. Store locked up. For conditions to avoid see sub-section 10.4 of this Safety Data Sheet. For incompatible materials see sub-section 10.5.

7.3 Specific end use(s)

No additional information.

SECTION 8: Exposure controls / personal protection

8.1 Control parameters

Workplace exposure limits:

Air limit values, if available:

Ingredient(s) / Country	Long term exposure limit (8 hour TWA)	Short term exposure limits (STEL)	Reference / Legal Basis
Propan-2-ol			
United Kingdom	400 ppm (999 mg/m^3)	500 ppm (1250 mg/m^3)	UK EH40 WEL – Workplace Exposure Limits
Austria	200 ppm (500 mg/m^3)	500 ppm (1230 mg/m^3)	MAK / TRK; Austrian OEL Regulation
Belgium	200 ppm (500 mg/m^3)	400 ppm (1000 mg/m^3)	VLEP / GWBB
Denmark	200 ppm (490 mg/m^3)	400 ppm (980 mg/m^3)	Arbejdstilsynet; Executive Order on Limit Values for Substances and Materials (Denmark)
Finland	200 ppm (500 mg/m^3)	250 ppm (620 mg/m^3)*	HTO-arvot 2016, Ministry of Social Affairs and Health (Finland)
France	n/a	400 ppm (980 mg/m^3)	Restrictive statutory limit values; French Labour code / French Labour Ministry
Germany	200 ppm – AGS (500 mg/m^3 - AGS) / 200 ppm – DFG (500 mg/m^3 – DFG)	400 ppm – AGS (1000 mg/m^3 – AGS)* / 400 ppm – DFG (1000 mg/m^3 – DFG)	DFG; Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area AGS; German Committee on Hazardous Substances
Hungary	500 mg/m^3	2000 mg/m^3	Hungarian decree No. 25/2000

			(IX.30)
Ireland	200 ppm	400 ppm*	Health and Safety Authority – Code of Practice for the Chemical Agents Regulation (Ireland)
Spain	200 ppm (500 mg/m^3)	400 ppm (1000 mg/m^3)	Limit Values Spain, Royal Decree 374/2001
Switzerland	200 ppm (500 mg/m^3)	400 ppm (1000 mg/m^3)	National Institute for Occupational Safety and Health

*15-minute average value / reference period

DNEL and PNEC Values

Human Exposure

DNEL oral exposure – Consumer (mg/kg bw)

Ingredients	Short term – Local effects	Short term – Systemic effects	Long term – Local effects	Long term – Systemic effects
Propan-2-ol	No data available	No data available	No data available	26

DNEL dermal exposure – Worker (mg/kg bw)

Ingredients	Short term – Local effects	Short term – Systemic effects	Long term – Local effects	Long term – Systemic effects
Propan-2-ol	No data available	No data available	No data available	888

DNEL dermal exposure – Consumer (mg/kg bw)

Ingredients	Short term – Local effects	Short term – Systemic effects	Long term – Local effects	Long term – Systemic effects
Propan-2-ol	No data available	No data available	No data available	319

DNEL inhalation exposure – Worker (mg/m^3)

Ingredients	Short term – Local effects	Short term – Systemic effects	Long term – Local effects	Long term – Systemic effects
Propan-2-ol	No data available	No data available	No data available	500

DNEL inhalation exposure – Consumer (mg/m^3)

Ingredients	Short term – Local effects	Short term – Systemic effects	Long term – Local effects	Long term – Systemic effects
Propan-2-ol	No data available	No data available	No data available	89

Environmental Exposure

Environmental exposure - PNEC

Ingredients	Surface water, fresh (mg/l)	Surface water, marine (mg/l)	Intermittent (mg/l)	Sewage treatment plant (mg/l)
Propan-2-ol	140.9	140.9	140.9	2251

Environmental exposure – PNEC, continued

Ingredients	Sediment, freshwater (mg/kg)	Sediment, marine (mg/kg)	Soil (mg/kg)	Air (mg/m^3)
Propan-2-ol	552	552	28	No data available

Biological limits, if available:	Not available.
Recommended monitoring procedures, if available:	Not available.
Additional exposure limits under the conditions of use, if available:	Not available.

8.2 Exposure controls

The following information applies for the uses indicated in sub-section 1.2 of this Safety Data Sheet.
If available, please refer to the product information sheet for application and handling instructions.
Normal use conditions are assumed for this section.

Recommended safety measures for handling the *undiluted* product:

Engineering measures:	Use only outdoors or in well-ventilated areas. Application of technical/engineering controls to remove airborne residues is mandatory (e.g. room ventilation or LEV) before operatives are permitted to enter into treated areas after large surface disinfection. Where necessary, setting a waiting restriction of sufficient duration to allow time for the removal of airborne residues. For use during disinfection of large surfaces (e.g. floors) in cleanrooms/controlled environments, application of technical/engineering controls to remove airborne residue is mandatory (e.g. room ventilation or LEV). Avoid direct contact and / or splashes where possible. Train personnel.
Personal Protective Equipment	
Eye/face protection:	Eye protection/face protection is required.
Respiratory protection:	Respiratory protection is not normally required. However, inhalation of vapour, spray, gas or aerosols should be avoided.
Hand protection:	Wash hands thoroughly after handling. For prolonged contact, protection for the skin may be necessary.
Other skin and body protection:	For use during large surface disinfection by spraying or mopping where considerable contamination may occur, gloves and coveralls is recommended.
Hygiene measures:	Do not smoke in work area. Wash hands before work breaks, immediately after handling the product, and before eating, smoking and using the toilet. Avoid contact with skin, eyes, and clothing. Remove and wash contaminated clothing and gloves, including the inside, before re-use. When using, do not eat, drink, or smoke.
Environmental Exposure Controls	
General advice:	Should not reach sewage water or drainage ditch undiluted or unneutralised

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Information in this section refers to the mixture.

		Method / remark
Physical State:	Liquid.	-
Colour:	Clear, colourless.	-
Odour:	Product specific.	-
pH:	*ca.* 7	Neat.
Melting point /freezing point:	Not available.	-
Initial boiling point and boiling range:	> 70 °C	-
Flash point:	*ca.* 19 °C	Closed cup.
Evaporation rate:	Not available.	-

Flammability (solid, gas):	Not available.	-
Upper/lower flammability or explosive limits:	Not available.	-
Vapour pressure:	Not available.	-
Vapour density:	Not available.	-
Relative density:	Not available.	-
Density:	0.88 g/cm^3	@ 20 ^{o}C.
Solubility(ies)	Fully miscible with water.	-
Partition coefficient: n-octanol/water:	Not available.	-
Auto-ignition temperature:	Not available.	-
Decomposition temperature:	Not available.	-
Viscosity:	Not available.	-
Explosive properties:	Not explosive.	Vapours may form explosive mixtures with air.
Oxidising properties:	Not oxidising.	-

The following substance data is provided for ingredients in the mixture / product:

Propan-2-ol		**Method / remark**
Initial boiling point and boiling range:	82 ^{o}C	@ 1013 hPa
Upper/lower flammability or explosive limits:	Lower limit: 2 % volume. Upper limit: 13% volume.	-
Vapour pressure	4200 Pa	@ 20 ^{o}C
Solubility(ies)	Soluble in water.	-

9.2 Other information No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity

No reactivity hazards known under normal storage and use conditions.

10.2 Chemical stability

Stable under normal storage and use conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known under normal storage and use conditions.

10.4 Conditions to avoid

Take precautionary measures against static discharge. Keep in a cool place. Keep container in a well-ventilated place.

10.5 Incompatible materials

None known under normal use conditions.

10.6 Hazardous decomposition products

None known under normal storage and use conditions.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

No data is available on the mixture / product.

The following substance data is provided for ingredients in the mixture / product:

Propan-2-ol

Acute toxicity:	LD50 (Oral):	3570 mg/kg	Method – not available. Test species – rat. Exposure time – not available.
	LD50 (Dermal):	> 2000 mg/kg	Method – not available. Test species – rabbit. Exposure time – not available.
	LD50 (Inhalation):	> 25 mg/l (vapour)	Method – OECD Test Guideline 403 (EU B.2). Test species – rat. Exposure time – 6 hours.
Skin corrosion / irritation:	Not irritant.		Method – OECD Test Guideline 404 (EU B.4). Test species – rabbit.
Serious eye damage / irritation:	Irritant.		Method – OECD Test Guideline 405 (EU B.5). Test species – rabbit.
Respiratory or skin sensitisation:	Skin contact:	Not sensitising.	Method – OECD Test Guideline 406 (EU B.6) (Buehler test). Test species – guinea pig.
Germ cell mutagenicity:	Negative – no evidence for mutagenicity.		Method – OECD Test Guideline 471 (EU B.12 / 13).
Carcinogenicity:	No information available.		
Reproductive toxicity:	No information available.		
STOT-single exposure:	No information available.		
STOT-repeated exposure:	No information available.		
Aspiration hazard:	The classifications of substances in the mixture / product are detailed in Section 3 of this Safety Data Sheet. No substances in the mixture / product are classified as an aspiration hazard (H304).		

11.2 Information on Other Hazards

11.2.1 Information on Endocrine Disrupting Properties

Mixture/product not classified for endocrine disruption, in accordance with Regulations ((EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605)

11.2.2 Information on Other Hazards

No further information

SECTION 12: Ecological information

12.1 Toxicity

No information is available on the product / mixture.

The following substance data is provided for ingredients in the mixture / product:

Propan-2-ol			
Aquatic acute (short-term) toxicity			
Aquatic acute (short-term) toxicity – fish:	LC50:	> 100 mg/l	Method – not available. Test species – *Pimephales promelas*. Exposure time – 48 hours.
Aquatic acute (short-term) toxicity – crustacea:	EC50:	> 100 mg/l	Method – not available. Test species – *Daphnia magna Straus*.

		Exposure time – 48 hours.
Aquatic acute (short-term) toxicity – algae:	EC50: > 100 mg/l	Method – not available. Test species – *Scenedesmus quadricauda*. Exposure time – 72 hours.
Aquatic acute (short-term) toxicity – marine species:	No information available.	
Toxicity to bacteria:	EC50: > 1000 mg/l	Method – not available. Test species – Activated sludge. Exposure time – not available.
Aquatic chronic (long-term) toxicity		
Aquatic chronic (long-term) toxicity – fish:	No information available.	
Aquatic chronic (long-term) toxicity – crustacea:	No information available.	

12.2 Persistence and degradability

No information is available on the product / mixture.

The following substance data is provided for ingredients in the mixture / product:

Propan-2-ol			
Ready biodegradability – aerobic conditions:	DT50:	95% in 21 days – readily biodegradable.	Method – OECD Test Guideline 301 E.

12.3 Bioaccumulative potential

No information is available on the product / mixture.

The following substance data is provided for ingredients in the mixture / product:

Propan-2-ol			
Partition coefficient:	n-octanol / water (Log kow):	0.05 – no bio-accumulation expected.	OECD Test Guideline 107.
Bioconcentration Factor (BCF):	No information available.		

12.4 Mobility in soil

No information is available on the product / mixture.

The following substance data is provided for ingredients in the mixture / product:

Propan-2-ol	
Adsorption / Desorption to soil or sediment:	Potential for mobility in soil; soluble in water.

12.5 Results of PBT and vPvB assessment

The mixture contains no components that are known to be Persistent, Bioaccumulative and Toxic (PBT), or very Persistent and very Bioaccumulative (vPvB).

12.6 Endocrine Disrupting Properties – Environment

Mixture/product not classified for endocrine disruption, in accordance with Regulations ((EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605)

12.7 Other adverse effects

No other adverse effects known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste from residues / unused product:	Dispose of contents according to national / location regulations. The concentrated contents or contaminated packaging should be disposed of by a certified handler or according to the site permit. Release of waste to sewers is discouraged. The cleaned packaging material is suitable for energy recovery or recycling in line with local legislation.
European waste catalogue:	16 03 05* - organic wastes containing dangerous substances.
Empty packaging recommendation:	Dispose of container according to national / local regulations.
Suitable cleaning agents:	Water, if necessary, with cleaning agent.

SECTION 14: Transport Information

		ADR/RID:	IMDG:	ICAO/IATA:	ADN:
14.1	**UN number:**	1219	1219	1219	1219
14.2	**UN proper shipping name:**	ISOPROPANOL (ISOPROPYL ALCOHOL) (solution)	ISOPROPANOL (ISOPROPYL ALCOHOL) (solution)	ISOPROPANOL (ISOPROPYL ALCOHOL) (solution)	ISOPROPANOL (ISOPROPYL ALCOHOL) (solution)
14.3	**Transport hazard class(es):**	3	3	3	3
	Label(s):	3	3	3	3
	Classification code:	F1	-	-	-
	Tunnel restriction code:	D/E	-	-	-
	Hazard identification number:	33	-	-	-
	EmS:	-	F-E, S-D	-	-
14.4	**Packing group:**	II	II	II	II
14.5	**Environmental hazards**				
	Environmentally hazardous:	No			
	Marine pollutant:	No			
14.6	**Special precautions for user:**	None known			
14.7	**Maritime transport in bulk according to IMO instruments:**	Not applicable – the product is not transported in bulk containers.			

SECTION 15: Regulatory information

This Safety Data Sheet is compiled in accordance with the requirements of Regulation (EC) No 1907/2006 (REACH), amended by Regulation (EU) 2020/878.

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

-

15.2 Chemical safety assessment

Not available for this product / mixture.

SECTION 16: Other information

The information is given in good faith and is based upon current available data. The user must determine if the product is correct for any particular application; the information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text. This document is not a warranty or specification. This document does not constitute a guarantee for any specific product features and does not establish a legally binding contract.

Version: 7.1 **Revision Date:** 2023-06-22

Revision Note: -

The following updates have been made in this revision of the Safety Data Sheet: Section 1, updated.

Key literature references and sources for data

Safety Data Sheet (Ver 7.0), the ECHA classification and labelling Inventory, the Health and Safety Executive's (UK) EH40/2005 Workplace exposure limits, GESTIS Substance Database (Occupational Exposure Limits).

Full text of the H and EUH phrases mentioned in section 3:

- H225 – Highly flammable liquid and vapour.
- H319 – Causes serious eye irritation.
- H336 – May cause drowsiness or dizziness.

Abbreviations and acronyms:

- AISE – The international association for soaps, detergents and maintenance products.
- DNEL – Derived no effect level.
- PBT – Persistent, Bioaccumulative and Toxic.
- REACH number – REACH registration number, without supplier specific part.
- vPvB – very Persistent and very Bioaccumulative.
- STOT – specific target organ toxicity.
- TWA – Time weighted average.
- STEL – Short term exposure limit.
- ADR / RID – European Agreement concerning the International Carriage of Dangerous Goods by Road / Regulation concerning the International Carriage of Dangerous Goods by Rail.
- IMDG – International Maritime Dangerous Goods Code.
- ICAO / IATA – International Civil Aviation Organization / International Air Transport Association.
- ADN – European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
- MARPOL – International Convention for the Prevention of Pollution from Ships.

End of Safety Data Sheet

InSpec® IPA

Technical Datasheet

Comprehensive Technical Resource Sheet for the Full Range of InSpec IPA Liquid Formats

Features

- **Low residue and rapid action**
- **Bactericidal and Fungicidal**
- **Validated 6 months 'in-use' sterility for 1L Trigger Spray Sterile formats**
- **All trigger spray formats presented as protected systems**
- **Manufactured with Water for Injection**
- **Multiple bags for cleanroom transfer**
- **Ideal surface and aseptic transfer disinfectants**
- **Manufactured in accordance with GMP**
- **Product approved under the Biocidal Products Regulation (BPR)**

Formulation

InSpec IPA is a blend of BPR grade isopropyl alcohol with Water for Injection (WFI).

Active substance concentration: 70 % v/v isopropyl alcohol.

The formulation is consistent across the range with the same blend for all sterile and non-sterile formats.

Instructions for Use

InSpec IPA is a ready-to-use product, do not dilute.

Spray Bottles: Hold approximately 15cm to 20cm from area to be treated. Apply to surface to ensure complete coverage for the required contact times.

Screw Top Bottles: Pour into an appropriate container for mopping. Apply to floor to ensure complete coverage for the required contact times.

Material Compatibility

Application of InSpec IPA products, when used as directed, will not affect materials normally encountered in the cleanroom. See compatibility information in the Technical File.

Microbiological Minimum Efficacy Contact Times

Standard	Contact Time
EN 1276 Bacteria	5 minutes
EN 13697 Bacteria	5 minutes
EN 13697 Fungi	15 minutes
EN 1650 Fungi	15 minutes

Safe Handling and Storage Information

Always read the label and Safety Data Sheet (SDS) before use.

Store upright in original closed containers away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is available in the SDS.

Formulation Batch Release Specifications

The formulation is tested for the following specifications for batch release:

Specification	Release Parameters
SG	0.872 - 0.883
Concentration	68 - 72 % v/v
Colour	Colourless
Clarity	Clear
Odour	Alcoholic

Manufacturing Process

InSpec IPA is manufactured in accordance with GMP in an ISO 5 cleanroom. The solution is filtered through a 0.2-micron filter at point of fill.

Sterility

The sterile formats of InSpec IPA are gamma irradiated to a validated process (20-50kGy for 5L products, 25-45kGy for all other sizes) to give a sterility assurance level SAL of 10^{-6}.

Sterile InSpec IPA products are tested for sterility and endotoxin for batch release.

The trigger spray formats have a validated 6 -months "in-use" sterility. This is delivered through a protected system of using "bag-in- bottle" technology and a membrane-filter trigger or by using a collapsible bag and a non-venting trigger.

For screw cap formats, use the entire contents in one session/4-hours to ensure sterility.

Double and triple-bagged formats are available for the cleanroom transfer process.

Endotoxin

All sterile formats of InSpec IPA are tested for endotoxin, with a release specification of < 0.25 EU/ml.

Certificates

Each batch of InSpec IPA is provided with a Certificate of Analysis (COA) confirming batch release specifications and providing batch manufacturing information.

The COAs for Sterile InSpec IPA products contain information regarding the irradiation of the batch and the concentration, sterility and endotoxin test results.

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InSpec® IPA

Formats Available

The following formats of InSpec IPA are available:

Product	Code	Cap	Case Size	Container Material	Bags and Material
Sterile Formats					
InSpec IPA 1L	IPAWFI1-1LS	Trigger	6 x 1L Bottles	PP and co-extruded resin	Double-bagged LDPE
InSpec IPA 1L Dose	IPAWFIDOSE-1LS	Screw Cap	6 x 1L Bottles	HDPE	Double-bagged LDPE
InSpec IPA 1L Triple Bagged	IPAWFI3-1LS	Trigger	6 x 1L Bottles	PP and co-extruded resin	Triple-Bagged LDPE
InSpec IPA 5L	IPAWFI1-5LS	Screw Cap	2 x 5L Bottles	HDPE	Double-bagged LDPE
InSpec IPA 500ml	IPAWFI-500MLS	Trigger	8 x 500ml Bottles	HDPE	Double-bagged LDPE
InSpec IPA 500ml Flip Top Cap	IPAWFI-500FLP	Flip-Top Cap	8 x 500ml Bottles	HDPE	Double-bagged LDPE
InSpec IPA 5L Bag	IPAWFIBAG-5LS	Trigger	2 x 5L Bags	PE, PET Nylon	Double-bagged LDPE
Non-Sterile Formats					
InSpec IPA 1L Non-Sterile	NSIPAWFI-1L	Trigger	6 x 1L Bottles	PP and co-extruded resin	Single-bagged LDPE
InSpec IPA 5L Non-Sterile	NSIPAWFI-5L	Screw Cap	2 x 5L Bottles	HDPE	Single-bagged LDPE
InSpec IPA 500ml Flip-Top Cap Non-Sterile	NSIPAWFI-1LFLP	Flip-Top Cap	8 x 500ml Bottles	HDPE	Single-bagged LDPE

Transport Information

Product	Code	Case Dimensions	Commodity Code	Cases per pallet Euro/UK	Dangerous Goods
Sterile Formats					
InSpec IPA 1L	IPAWFI1-1LS	27cm x 19cm x 33cm 6.4Kg	29051200	64/60	UN 1219 Limited Quantity
InSpec IPA 1L Dose	IPAWFIDOSE-1LS	27cm x 19cm x 33cm 6.4Kg	29051200	64/60	UN 1219 Limited Quantity
InSpec IPA 1L Triple Bagged	IPAWFI3-1LS	27cm x 19cm x 33cm 6.4Kg	29051200	64/60	UN 1219 Limited Quantity
InSpec IPA 5L	IPAWFI1-5LS	29cm x 20.5cm x 31cm 9.5Kg	29051200	52/51	UN 1219
InSpec IPA 500ml	IPAWFI-500MLS	23.5cm x 23.5cm x 24.5cm 4.3Kg	29051200	60/80	UN 1219 Limited Quantity
InSpec IPA 500ml Flip Top Cap	IPAWFI-500FLP	23.5cm x 23.5cm x 24.5cm 4.8Kg	29051200	60/80	UN 1219 Limited Quantity
InSpec IPA 5L Bag	IPAWFIBAG-5LS	35.5cm x 32.5cm x 35cm 9.5Kg	29051200	18/18	UN 1219
Non-Sterile Formats					
InSpec IPA 1L Non-Sterile	NSIPAWFI-1L	27cm x 19cm x 33cm 6.4Kg	29051200	64/60	UN 1219 Limited Quantity
InSpec IPA 5L Non-Sterile	NSIPAWFI-5L	29cm x 20.5cm x 31cm 9.5Kg	29051200	52/51	UN 1219
InSpec IPA 500ml Flip-Top Cap Non-Sterile	NSIPAWFI-1LFLP	23.5cm x 23.5cm x 24.5cm 4.3Kg	29051200	60/80	UN 1219 Limited Quantity

*Limited quantity applies to inner packaging of 1L or less for products classed as UN 1219

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