

Empfohlene Reinraumklassen

ISO 5 | 6 | 7 | 8 | 9

GMP A/B | C | D

InSpec QT (WFI) Premium (bag in bottle) #QTWFI30-1LS

pure[11]-Nr.: 1131284, Marke:

Eigenschaften

- Steril
- Marke: InSpec
- Desinfektion
- Wirkstoff: Quats
- Gebrauchsfertig
- Volumen in ml: 900 mL
- Behälterform: Sprühflasche
- Biozid
- Bag-in-Bottle System
- Filtriert auf 0,2µm
- Geprüft nach EN 13697 - bakterizid und/oder fungizid
- Geprüft nach EN 1650 - fungiziden oder levuroziden
- pH-Wert der gebrauchsfertigen Lösung: 12
- WFI (Water for Injection): 96 %
- Zustand: Flüssig

we care

pure[11] GmbH |
Bavariafilmplatz 7 | D-82031 Grünwald
T +49 89 5589434 0
F +49 89 5589434 77
www.pure11.de
info@pure11.de

Material

-

Verpackung

- 6STK

Produktvarianten

pure¹¹-Nr.: 1131284, InSpec QT (WFI) Premium (bag in bottle) #QTWFI30-1LS

Steril; Gebinde: 6 Flaschen á 900 ml / VE: 6STK

Safety Data Sheet

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

InSpec QT

Revision Date: 2023-10-10 Revision No. 7.0/EN

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

1.1 Product Identifier

Trade Name: InSpec QT
InSpec QT Burstable Wipes
InSpec QT Burstable Mops

Product Number: -

UFI: 4E00-V04G-D00T-CCMX

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

Identified Uses: Ready-to-use disinfectant with cleaning properties (for professional use only).

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: Not classified.

Health hazards: Skin irritation, Category 2 (H315).
Eye Irritation, Category 2 (H319).

Environmental hazards: Not classified.

2.2 Label elements

Pictograms:



Signal Word: Warning.

Hazard Statements:

- H315: Causes skin irritation.
- H319: Causes serious eye irritation.

Precautionary Statements:

- P264: Wash skin thoroughly after handling.
- P280: Wear protective gloves / protective clothing / eye protection / face protection.
- P302 + P352: IF ON SKIN: Wash with plenty of water.
- P332 + P313: If skin irritation occurs: Get medical advice/attention.
- P337 + P313: If eye irritation persists: Get medical advice/ attention.
- P362 + P364: Take off contaminated clothing and wash it before reuse.

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)
Didecyldimethyl-ammonium chloride	230-525-2	7173-51-5	01-2119945987-15-XXXX	Acute Tox. 3 (H301) Skin Corr. 1B (H314) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	-	< 1
Potassium carbonate	209-529-3	584-08-7	01-2119532646-36-XXXX	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE 3 (H335)	-	<1
2-Aminoethanol	205-483-3	141-43-5	01-2119486455-28-XXXX	Acute Tox. 4 (H302) Acute Tox. 4 (H312) Acute Tox. 4 (H332) Skin Corr. 1B (H314)	-	< 1

Propan-2-ol	200-661-7	67-63-0	01-2119457558-25-XXXX	Flam. Liq. (H225) Eye Irrit. 2 (H319) STOT SE 3 (H336)	-	< 1

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: Get medical attention / advice if affected person feels unwell.

Skin contact: Remove / Take off immediately all contaminated clothing. Rinse skin with plenty of soap and water / shower. Get medical attention / advice if affected person feels unwell.

Eye contact: Immediately rinse cautiously with water, also under the eyelids, for at least 15 minutes. Remove contact lenses if present and easy to do. Continue rinsing. If irritation persists get medical attention / advice.

Ingestion: Do NOT induce vomiting. Rinse mouth with water and drink plenty of water afterwards. Never give anything by mouth to an unconscious person. Get medical attention / advice if affected person feels unwell.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation: No information available.

Skin contact: No information available.

Eye contact: No information available.

Ingestion: No information available.

General Information: No information available.

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing material: Dry powder, water spray, foam.

5.2 Special hazards arising from the substance or mixture

Heating or fire can release toxic gas.

5.3 Advice for firefighters

As in the event of any fire, wear self-contained breathing apparatus and suitable personal protective equipment. Use water spray to cool unopened containers.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use respirator when performing operations involving potential exposure to vapour of the product.

6.2 Environmental precautions

Do not allow to enter drainage system, surface or ground water.

6.3 Methods and material for containment and cleaning up

Contain spillage, and then collect with non-combustible absorbent material (e.g. sand, earth, diatomaceous earth, 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

Measure for protection of human health: Avoid contact with skin and eyes. Provide sufficient air exchange and / or exhaust in work rooms.

Measures to prevent fires and explosions: Take precautionary measures against static discharges.

Advice on general occupational hygiene: Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Wash hands before breaks and at the end of the work day. Wash face, hands and any exposed skin thoroughly after handling. Use with adequate ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local and national regulations. Keep container tightly closed and do not store in heat or direct sunlight. Store in a dry, cool and well-ventilated area. For conditions to avoid see sub-section 10.4 of this Safety Data Sheet.

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
2-Aminoethanol			
European Union	1 ppm ($2.5\ mg/m^3$)	3 ppm ($7.6\ mg/m^3$)*	IOELV / BOELV; commission Directive 2006/15/EC
United Kingdom	1 ppm ($2.5\ mg/m^3$)	3 ppm ($7.6\ mg/m^3$)	UK EH40 WEL; Workplace Exposure Limits
Austria	1 ppm ($2.5\ mg/m^3$)	3 ppm ($7.6\ mg/m^3$)	MAK / TRK; Austrian OEL Regulation
Belgium	1 ppm ($2.5\ mg/m^3$)	3 ppm ($7.6\ mg/m^3$)	VLEP / GWBB
Denmark	1 ppm ($2.5\ mg/m^3$)	2 ppm ($5\ mg/m^3$)	Arbejdstilsynet; Executive Order on Limit Values for Substances and Materials (Denmark)
Finland	1 ppm ($2.5\ mg/m^3$)	3 ppm ($7.6\ mg/m^3$)	HTO-arvot 2016, Ministry of Social Affairs and Health (Finland)
France	1 ppm ($2.5\ mg/m^3$)	3 ppm ($7.6\ mg/m^3$)	Restrictive statutory limit values; French Labour code / French Labour Ministry
Germany	0.2 ppm – AGS ($0.5\ mg/m^3$ - AGS)† / 0.2 ppm – DFG ($0.51\ mg/m^3$ – DFG)†	0.2 ppm – AGS ($0.5\ mg/m^3$ – AGS)†* / 0.2 ppm – DFG ($0.51\ mg/m^3$ – DFG)†*	DFG; Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area AGS; German Committee on Hazardous Substances
Hungary	$2.5\ mg/m^3$	$7.6\ mg/m^3$	Hungarian decree No. 25/2000 (IX.30)

Ireland	1 ppm (2.5 mg/m^3)	3 ppm (7.6 mg/m^3)*	Health and Safety Authority – Code of Practice for the Chemical Agents Regulation (Ireland)
Spain	1 ppm (2.5 mg/m^3)	3 ppm (7.6 mg/m^3)	Limit Values Spain, Royal Decree 374/2001
Propan-2-ol			
European Union	n/a	n/a	IOELV / BOELV; commission Directive 2006/15/EC
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)	VLE; 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	200mg/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

*15-minute average value / reference period
†Inhalable fraction and vapour

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 in well-ventilated areas / provide adequate general and local exhaust.
Personal Protective Equipment	
Eye/face protection:	Tightly fitting safety goggles to an approved standard. Face shield to an approved standard.
Respiratory protection:	In the case of vapour formation, use a respirator with an approved filter; respirator with a vapour filter (EN 141), respirator with ABEK filter.
Hand protection:	Wear chemical-resistant, impervious gloves to an approved standard: Suitable material: Nitrile rubber; break-through time: > 480 minutes. Take note of the information provided by the producer concerning permeability and break-through times, and of special workplace conditions (mechanical strain, duration of contact).
Other skin and body protection:	Choose body protection according to the amount and concentration of the substance at the work place; rubber or plastic apron, rubber or plastic boots.
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:	Do not allow to enter drainage system, surface or ground water.

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:	Light yellow.	-
Odour:	Characteristic.	-
pH:	12	@ 20 °C
Melting point /freezing point:	Not available.	-
Initial boiling point and boiling range:	Not available.	-
Flash point:	> 65 °C	-
Evaporation rate:	Not available.	-
Flammability (solid, gas):	Not applicable.	-
Upper/lower flammability or explosive limits:	Not available.	-
Vapour pressure:	23 hPa	@ 20 °C
Vapour density:	Not available.	-
Relative density:	Not available.	-
Density	1.06 g/cm^3	@ 20 °C
Solubility(ies)	Fully miscible with water.	-
Partition coefficient: n-octanol/water:	Not available.	-
Auto-ignition temperature:	Not auto-flammable.	-
Decomposition temperature:	Not available.	-
Viscosity (dynamic):	30 mPa.s	@20 °C
Explosive properties:	Not explosive.	-
Oxidising properties:	Not available.	-

9.2 Other information No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Exothermic reaction with strong acids. Stable under normal conditions.

According to section 2.4.2.5.1 of the IMDG Code InSpec QT RTU is not classed as a polymerising substance and is stable under normal conditions. Therefore, InSpec QT RTU can be transported at ambient temperatures.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

Acids.

10.6 Hazardous decomposition products

No decomposition if stored under normal conditions.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

The following information is available regarding the mixture / product:

Skin corrosion/irritation: Species: Human keratinocytes
Method: in vitro assay
Results: non-corrosive
Assessment: irritating to skin

Serious eye damage/eye irritation: Species: Human
Method: in vitro assay
Results: Eye irritation

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

Didecyldimethylammonium chloride		
Acute toxicity:	LD50 (Oral): 238 mg/kg	Method – OECD Test Guideline 401. Test species – rat. Exposure time – not available.
	LD50 (Dermal): 3342 mg/kg	Method – not available. Exposure time – not available.
Skin corrosion / irritation:	Irritating.	Method – OECD Test Guideline 404. Test species – rabbit. Exposure time – 3 minutes.
Serious eye damage / irritation:	No information available.	
Respiratory or skin sensitisation:	Not sensitising.	Method – US-EPA (Buehler Test). Test species – guinea pig.
Germ cell mutagenicity:	-	
Genotoxicity *in vitro*:	Negative.	Method – OECD Test Guideline 471 (Ames Test). Test item – *Salmonella typhimurium*.

	Negative.	Method – Chromosome aberration test in vitro. Test item – Chinese hamster ovary cells.
	Negative.	Methods – Gene mutation. Test item – Chinese hamster ovary cells.
Genotoxicity *in vivo*:	Negative.	Method – OECD Test Guideline 475 (Chromosome aberration test in vivo). Application route – oral Test species - rat
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).	

2-Aminoethanol			
Acute toxicity:	LD50 (Oral):	1510 mg/kg	Method – not available. Test species – rat. Exposure time – not available.
	LD50 (Dermal):	1025 mg/kg	Method – not available. Test species – rabbit. Exposure time – 24 hours.
Skin corrosion / irritation:	Corrosive		Method – not available. Test species – rabbit. Exposure time – 4 hours.
Serious eye damage / irritation:	Corrosive		Method – not available. Test species – rabbit. Exposure time – not available.
Respiratory or skin sensitisation:	No information available.		
Germ cell mutagenicity:	-		
Genotoxicity *in vitro*:	Negative		Method – Ames test. Test item – not available.
Genotoxicity *in vivo*:	Negative		Method – In Vivo Micronucleus Test. Test item – not available.
Genotoxicity *in vivo*:	No information available.		
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).		

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. Test species – rat. Exposure time – 6 hours.
Skin corrosion / irritation:	Not irritant.	Method – OECD Test Guideline 404. Test species – rabbit.
Serious eye damage / irritation:	Irritant.	Method – OECD Test Guideline 405. Test species – rabbit.
Respiratory or skin sensitisation:	Skin contact: Not sensitising.	Method – OECD Test Guideline 406 (Buehler test). Test species – guinea pig.
Germ cell mutagenicity:	-	
Genotoxicity *in vitro*:	Negative – no evidence for mutagenicity.	Method – OECD Test Guideline 471.
Genotoxicity *in vivo*:	No information available.	
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:

Didecyldimethylammonium chloride			
Aquatic acute (short-term) toxicity			
Aquatic acute (short-term) toxicity – fish:	LC50:	0.19 mg/l	Method – US-EPA. Test species – *Pimephales promelas* (Fathead minnow). Exposure time – 96 hours.
Aquatic acute (short-term) toxicity – crustacea:	EC50:	0.062 mg/l	Method – EPA-FIFRA (immobilisation). Test species – *Daphnia magna* (Water flea). Exposure time – 48 hours.
Aquatic acute (short-term) toxicity – algae:	ErC50:	0.026 mg/l	Method – OECD Test Guideline 201 (growth inhibition). Test species – *Pseudokirchnerirella subcapitata* (Green algae).

			Exposure time – 96 hours.
Aquatic acute (short-term) toxicity – marine species:	No information available.		
Toxicity to bacteria:	EC0:	11 mg/l	Method – OECD Test Guideline 209. Test species – Activated sludge. Exposure time – 3 hours.
M-Factor (acute):	10		
Aquatic chronic (long-term) toxicity			
Aquatic chronic (long-term) toxicity – fish:	**NOEC:**	0.032 mg/l	Method – OECD Test Guideline 210. Test species – *Danio rerio* (Zebra fish). Exposure time – 34 days.
Aquatic chronic (long-term) toxicity – crustacea:	**NOEC:**	0.010 mg/l	Method – OECD Test Guideline 211 (reproduction test). Test species – *Daphnia magna* (Water flea). Exposure time – 21 days.
Aquatic acute (short-term) toxicity – marine species:	No information available.		
Toxicity to bacteria:	No information available.		
M-Factor (chronic):	1		

2-Aminoethanol			
Aquatic acute (short-term) toxicity			
Aquatic acute (short-term) toxicity – fish:	LC50:	150 mg/l	Method – not available. Test species – *Oncorhynchus mykiss* (Rainbow trout). Exposure time – 96 hours.
Aquatic acute (short-term) toxicity – crustacea:	EC50:	120 mg/l	Method – OECD Test Guideline 202 (immobilization). Test species – *Daphnia magna* (Water flea). Exposure time – 24 hours.
Aquatic acute (short-term) toxicity – algae:	EC50:	15 mg/l	Method – not available. Test species – *Desmodesmus subspicatus* (Green algae). Exposure time – 72 hours.
Aquatic acute (short-term) toxicity – marine species:	No information available.		
Toxicity to bacteria:	EC50:	> 1000 mg/l	Method – OECD Test Guideline 209 (respiration inhibition). Test species – Activated sludge. Exposure time – 3 hours.
	EC10:	6300 mg/l	Method – DIN 38412 Part 8. Test species – *Pseudomonas putida*. Exposure time – 16 hours.
Aquatic chronic (long-term) toxicity			
Aquatic chronic (long-term) toxicity – fish:	No information available.		
Aquatic chronic (long-term) toxicity – crustacea:	No information available.		
Aquatic acute (short-term) toxicity – marine species:	No information available.		
Toxicity to bacteria:	No information available.		

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:

Didecyldimethylammonium chloride			
Biodegradability:	72%	Readily biodegradable.	Method – OECD Test Guideline 301 B. (Modified Sturm Test). Testing period – 28 days.
	93.3%	-	Method – Die-away test. Testing period – 28 days.
	91%	-	Method – OECD Test Guideline 303 A. (OECD Confirmatory Test). Testing period: 24 – 70 days.
	The surfactant(s) contained in this mixture complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.		

2-Aminoethanol			
Biodegradability:	>80%	Readily biodegradable.	Method – OECD Test Guideline 301 B. Testing period – 19 days.

Propan-2-ol			
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:

Didecyldimethylammonium chloride		
Behaviour in environmental compartments:	Mobility in soil.	Method – US-EPA

2-Aminoethanol		
Behaviour in environmental compartments:	No information available.	Method – not available.

Propan-2-ol		
Behaviour in environmental compartments:	Potential for mobility in soil; soluble in water	Method – not available.

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 additional information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of contents / container in accordance with local / national regulations. Contact waste disposal services.

SECTION 14: Transport information

General advice: Not classified as dangerous goods for transport.

	ADR/RID:	**IMDG:**	**ICAO/IATA:**	**ADN:**
14.1 UN number:	Non-dangerous goods for transport.			
14.2 UN proper shipping name:	n/a			

14.3	**Transport hazard class(es):**	n/a
14.4	**Packing group:**	n/a
14.5	**Environmental hazards**	
	Environmentally hazardous:	No
	Marine pollutant:	No
14.6	**Special precautions for user:**	n/a
14.7	**Maritime transport in bulk according to IMO instruments:**	n/a

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

Water contamination class (Germany): WGK 2: water endangering.

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 suitability of this product for any particular use is not suggested. 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: 7.0/EN **Revision Date:** 2023-10-10

Revision Note:

The following updates have been made in this revision of the Safety Data Sheet: Sections 1.1 and 1.3, Sections 2.1 and 2.2, Section 11.1.

Key literature references and sources for data:

Safety Data Sheet (Ver. 6.0), the ECHA classification and labelling Inventory, the Health and Safety Executive's (UK) EH40/2005 Workplace exposure limits, GESTIS Substance Databased (Occupational Exposure Limits).

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

- H225 – Highly Flammable liquid and vapour.
- H301 – Toxic if swallowed.
- H302 – Harmful if swallowed.
- H312 – Harmful in contact with skin.
- H314 – Causes severe skin burns and eye damage.
- H318 – Causes serious eye damage.
- H332 – Harmful if inhaled.
- H336 – May cause drowsiness or dizziness.
- H400 – Very toxic to aquatic life.
- H411 – Toxic to aquatic life with long-lasting effects.
- H412 – Harmful to aquatic life with long-lasting effects.

Abbreviations and acronyms:

- 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® QT

Technical Datasheet

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



Features

- An exceptional non-oxidising biocide
- Bactericidal and fungicidal
- Validated 6 months 'in-use' sterility for trigger spray sterile formats
- Trigger spray formats presented as protected systems
- Ready-to-use (RTU) formats manufactured with Water for Injection
- Multiple bags for cleanroom transfer
- Ideal rotational partner for InSpec AN, HA and OX
- RTU and Concentrated formats available
- Manufactured in accordance with GMP
- Active substance compliant with Article 95 of the Biocidal Products Regulation (BPR)

Formulation

InSpec QT is a Quaternary Ammonium Compound (QAC) disinfectant. Ready-to-use formats blended with Water for Injection (WFI).

Active substance concentration, RTU formats: 0.2-0.3% w/w DDAC.

Active substance concentration, concentrated formats: 6-7% w/w DDAC.

Instructions for Use

InSpec QT is designed for spraying, wiping and mopping applications.

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 Cap versions: Pour into an appropriate container for mopping. 100ml concentrate added to 2.4L of water is required for mopping. Apply to surface to ensure complete coverage for the required contact times.

Material Compatibility

Application of solutions, 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 1650 Fungi	15 Minutes
EN 13697 Fungi	15 Minutes

Safe Handling and Storage Information

Always wear gloves and goggles or face protection. 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 Safety Data Sheet (SDS).

Manufacturing Process

InSpec QT 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.

Formulation Batch Release Specifications

Specification	Release Parameters
RTU Formats	
SG	0.990 - 1.010
DDAC Concentration	0.2 - 0.3% w/w
pH	11.5 - 12.5
Colour	Yellow Tint
Clarity	Clear
Odour	Typical
Concentrate Formats	
SG	1.055 - 1.180
DDAC Concentration	6 - 7% w/w
pH	≥12.5
Colour	Light Yellow
Clarity	Clear
Odour	Typical

Sterility

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

Sterile InSpec QT products are tested for sterility for batch release.

The trigger spray formats have a validated 6-months 'in-use' sterility. The contents are protected using "bag-in-bottle" technology and a membrane-filter trigger.

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

Products are double-bagged for the cleanroom transfer process.

Redditch Medical
Innovative thinking

InSpec® QT



Certificates

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

The COAs for Sterile InSpec QT products contain information regarding the irradiation of the batch and sterility test results.

Formats Available

The following formats of InSpec QT are available:

Product	Code	Cap	Case Size	Container Material	Bags and Material
Sterile Formats					
InSpec QT 900MLS	QTWFI30-900MLS	Trigger	6 x 1L Bottles	PP and co-extruded resin	Double-Bagged LDPE
InSpec QT 900MLS Dose	QTWFIDOSE-900MLS	Screw Cap	6 x 1L Bottles	HDPE	Double-Bagged LDPE
InSpec QT 5L	QTWFI30-5LS	Screw Cap	2 x 5L Bottles	HDPE	Double-Bagged LDPE
InSpec QT Concentrate 100ml	QTCNC30-100	Screw Cap	50 x 100ml Bottles	HDPE	Double-Bagged LDPE
Non-Sterile Formats					
InSpec QT 900ML Non-Sterile	NSQTWFI-900ML	Trigger	6 x 1L Bottles	PP and co-extruded resin	Single-Bagged LDPE
InSpec QT 5L Non-Sterile	NSQTWFI-5L	Screw Cap	2 x 5L Bottles	HDPE	Single-Bagged LDPE
InSpec QT Concentrate 100ml Non-Sterile	NSQTCONC-100ML	Screw Cap	50 x 100ml Bottles	HDPE	Single-Bagged LDPE

Transport Information

Product	Code	Case Dimensions	Commodity Code	Cases per Pallet Euro/UK	Dangerous Goods*
Sterile Formats					
InSpec QT 900MLS	QTWFI30-900MLS	27cm x 19cm x 33cm 6.4Kg	38089410	64/60	Not classified as hazardous for transport
InSpec QT 900MLS Dose	QTWFIDOSE-900MLS	27cm x 19cm x 33cm 6.4Kg	38089410	64/60	Not classified as hazardous for transport
InSpec QT 5L	QTWFI30-5LS	29cm x 20.5cm x 31cm 10.8Kg	38089410	52/51	Not classified as hazardous for transport
InSpec QT Concentrate 100ml	QTCNC30-100	24cm x 24cm x 24cm 5.9Kg	38089410	60/80	UN 1903 Limited Quantity
Non-Sterile Formats					
InSpec QT 900ML Non-Sterile	NSQTWFI-900ML	27cm x 19cm x 33cm 6.4Kg	38089410	64/60	Not classified as hazardous for transport
InSpec QT 5L Non-Sterile	NSQTWFI-5L	29cm x 20.5cm x 31cm 10.8Kg	38089410	52/51	Not classified as hazardous for transport
InSpec QT Concentrate 100ml Non-Sterile	NSQTCONC-100ML	24cm x 24cm x 24cm 5.9Kg	38089410	60/80	UN 1903 Limited Quantity

*Limited quantity applies to inner packaging of 1L or less for UN 1903

Redditch Medical
Innovative thinking

Discovery 2 • NETPark • 2 William Armstrong Way • Sedgefield County Durham • TS21 3FD • UK
UK Tel: 0845 073 9529 • International Tel: +44(0) 1527 830 942
Web: www.redditchmedical.com • Email: sales@redditchmedical.com