



Crystel Gold

pure¹¹-Nr.: 09017, Hersteller: Tristel



Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1109017
- Achtung: Dieses Produkt wurde vom Hersteller eingestellt. Wir beraten Sie zu Alternativen!
- 70% IPA / 30% Wasser für Injektionszwecke (WFI)
- Eignet sich ideal zur Desinfektion von produktberührenden Oberflächen, Schutzhandschuhen, alle Oberflächen in pharmazeutischen Betrieben und Unternehmen für Körperpflegeprodukte geeignet
- Enthalten gebrauchsfertige 70% v/v IPA mit Wasser für Injektionszwecke
- EN ISO 11137, VDmax25
- Gammabestrahlt, aseptisch abgefüllt und zweifach verpackt
- Bitte beachten: Desinfektionsmittel vorsichtig verwenden. Vor Gebrauch stets Etikett und Produktinformationen lesen.

Empfohlene Reinraumklassen

ISO 3 4 5 6 7 8 9

GMP A/B C D

Produktvarianten

pure¹¹-Nr.: 09017

Herst.-Nr.: CRY101 / VE: 6 Stück

Quelle: <https://www.pure11.de/crystel-gold>



GOLD

70% IPA mit Wasser für Injektionszwecke (WFI)

EMPFOHLENE ANWENDUNG

Gold eignet sich ideal zur Desinfektion von produktberührenden Oberflächen und zum Besprühen der Hände, eingeschlossen Schutzhandschuhe.

Diese gebrauchsfertige Lösung ist für alle Oberflächen in pharmazeutischen Betrieben und Unternehmen für Körperpflegeprodukte geeignet.

GEBRAUCHSANWEISUNG

Diese sterilen Verpackungen enthalten gebrauchsfertige 70% v/v IPA mit Wasser für Injektionszwecke. Nur zum beruflichen Gebrauch, detaillierte Gebrauchshinweise finden Sie auf dem Produktetikett und dem Produktauswahlblatt.

STANDARDS UND RICHTLINIEN

Das Produkt ist registriert oder entspricht den folgenden Richtlinien:

- BS EN ISO 9001 :2008
- Biozid-Richtlinie 98/8/EG
- 1907/2006/EG REACH (Registrierung, Bewertung, Zulassung und Beschränkung chemischer Stoffe)

PRODUKTANALYSE

Die folgenden Tests wurden am Produkt durchgeführt:



- Mindesthaltbarkeitstest
- TOC - Gesamter organischer Kohlenstoff
- Auswaschbarkeit
- COD - Chemischer Sauerstoffbedarf
- Stickstoff-/Phosphorgehalt

MIKROBIOLOGISCHE TESTDATEN

- EN1276
- EN1650
- Validierung der Sterilität
- Validierung von Endotoxin

ZERTIFIZIERUNG

- Analysezertifikat mit jeder Charge
- Überprüfung zur Sterilität
- Endotoxin Überprüfung
- Bescheinigung zur Bestrahlung

PACKUNGSGRÖSSEN	STERIL / UNSTERIL	VERDÜNNUNG	PRODUKTCODE	PACKUNGEN PRO PALETTE
6x 1L 	Steril	Gebrauchsfertig	CRY101	72
2x 5L 	Steril	Gebrauchsfertig	CRY102	72

Gold ist auch als unsteriles Wischtuch, getränkt mit 70% IPA und deionisiertem Wasser, erhältlich.

Bitte beachten Sie für nähere Informationen das technische Datenblatt von Gold Wipe.

PACKUNGSGRÖSSEN	STERIL / UNSTERIL	VERDÜNNUNG	PRODUKTCODE	PACKUNGEN PRO PALETTE
12x  200 x 200mm ² Wischtuchspender	Unsteril	Gebrauchsfertig	CRY208	35



SAFETY DATA SHEET

GOLD (STERILE)

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Compilation date: 12/05/2011

Revision date: 30/04/2015

Revision No: 4

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

1.1. Product identifier

Product name: GOLD (STERILE)

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

Use of substance / mixture: Disinfectant solution. For professional use only. Uses advised against: Uses other than the intended use of the product

1.3. Details of the supplier of the safety data sheet

Company name: Tristel Solutions Limited

Lynx Business Park

Fordham Road

Newmarket

Cambridgeshire

CB8 7NY

United Kingdom

Tel: +44 (0) 1638 721 500

Fax: +44 (0) 1638 721 911

Email: healthandsafety@tristel.com

1.4. Emergency telephone number

Emergency tel: +44 (0) 1638 721 500

(office hours only)

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CLP: STOT SE 3: H336; Eye Irrit. 2: H319; Flam. Liq. 1: H224

Classification under CHIP: F: R11; Xi: R36; -: R67

Most important adverse effects: Extremely flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness.

2.2. Label elements

Label elements under CLP:

Hazard statements: H224: Extremely flammable liquid and vapour.

H319: Causes serious eye irritation.

H336: May cause drowsiness or dizziness.

Signal words: Danger

Hazard pictograms: GHS02: Flame

GHS07: Exclamation mark

[cont...]

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Precautionary statements: P210: Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P280: Wear protective gloves/protective clothing/eye protection.
P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3. Other hazards

PBT: This product is not identified as a PBT/vPvB substance.

Section 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients:

PROPAN-2-OL

EINECS	CAS	CHIP Classification	CLP Classification	Percent
200-661-7	67-63-0	-	Flam. Liq. 2: H225; Eye Irrit. 2: H319; STOT SE 3: H336	50-70%

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Remove all contaminated clothes and footwear immediately unless stuck to skin. Wash immediately with plenty of soap and water.

Eye contact: Bathe the eye with running water for 15 minutes. Consult a doctor.

Ingestion: Wash out mouth with water. Consult a doctor.

Inhalation: Remove casualty from exposure ensuring one's own safety whilst doing so. Consult a doctor.

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

Skin contact: There may be irritation and redness at the site of contact.

Eye contact: There may be irritation and redness. The eyes may water profusely.

Ingestion: There may be soreness and redness of the mouth and throat.

Inhalation: There may be irritation of the throat with a feeling of tightness in the chest. Exposure may cause coughing or wheezing.

Delayed / immediate effects: Immediate effects can be expected after short-term exposure.

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

Immediate / special treatment: Eye bathing equipment should be available on the premises.

[cont...]

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Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Alcohol resistant foam. Water spray. Carbon dioxide. Dry chemical powder. Use water spray to cool containers.

5.2. Special hazards arising from the substance or mixture

Exposure hazards: Highly flammable. In combustion emits toxic fumes. Forms explosive air-vapour mixture. Vapour may travel considerable distance to source of ignition and flash back.

5.3. Advice for fire-fighters

Advice for fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Refer to section 8 of SDS for personal protection details. If outside do not approach from downwind. If outside keep bystanders upwind and away from danger point. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Turn leaking containers leak-side up to prevent the escape of liquid. Eliminate all sources of ignition.

6.2. Environmental precautions

Environmental precautions: Do not discharge into drains or rivers. Contain the spillage using bunding.

6.3. Methods and material for containment and cleaning up

Clean-up procedures: Absorb into dry earth or sand. Transfer to a closable, labelled salvage container for disposal by an appropriate method. Do not use equipment in clean-up procedure which may produce sparks.

6.4. Reference to other sections

Reference to other sections: Refer to section 8 of SDS. Refer to section 13 of SDS.

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements: Avoid direct contact with the substance. Ensure there is sufficient ventilation of the area. Do not handle in a confined space. Avoid the formation or spread of mists in the air. Smoking is forbidden. Use non-sparking tools. Keep away from sources of ignition

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in cool, well ventilated area. Keep container tightly closed. Keep away from sources of ignition. Prevent the build up of electrostatic charge in the immediate area. Ensure lighting and electrical equipment are not a source of ignition.

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Suitable packaging: Must only be kept in original packaging.

7.3. Specific end use(s)

Specific end use(s): Disinfectant Solution. For professional use only.

Section 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits:

Respirable dust

State	8 hour TWA	15 min. STEL	8 hour TWA	15 min. STEL
EU	400ppm	500ppm	-	-

Hazardous ingredients:

PROPAN-2-OL

Workplace exposure limits:

Respirable dust

State	8 hour TWA	15 min. STEL	8 hour TWA	15 min. STEL
UK	999 mg/m ³	1250 mg/m ³	-	-

DNEL/PNEC Values

GOLD (STERILE)

Type	Exposure	Value	Population	Effect
DNEL	Dermal	888mg/kg/day	Workers	Systemic
DNEL	Inhalation	500mg/m ³	Workers	Systemic
DNEL	Dermal	319mg/kg/day	Consumers	Systemic
DNEL	Inhalation	89mg/kg/day	Consumers	Systemic
DNEL	Oral	26mg/kg/day	Consumers	Systemic
PNEC	Fresh water	140.9mg/l	-	-
PNEC	Marine water	140.9mg/l	-	-
PNEC	Marine sediments	552mg/kg	-	-
PNEC	Soil (agricultural)	28mg/kg	-	-

8.2. Exposure controls

Engineering measures: Ensure there is sufficient ventilation of the area. Ensure lighting and electrical equipment are not a source of ignition.

Respiratory protection: Self-contained breathing apparatus must be available in case of emergency.

Hand protection: Protective gloves.

Eye protection: Safety glasses. Ensure eye bath is to hand.

Skin protection: Protective clothing.

Section 9: Physical and chemical properties

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9.1. Information on basic physical and chemical properties

State: Liquid

Colour: Colourless

Odour: Alcohol

Evaporation rate: No data available.

Oxidising: No data available.

Solubility in water: Soluble

Viscosity: Non-viscous

Boiling point/range °C: No data available.

Flammability limits %: lower: No data available.

Flash point °C: <21

Autoflammability °C: No data available.

Relative density: 0.870-0.890

VOC g/l: No data available.

Melting point/range °C: No data available.

upper: No data available.

Part.coeff. n-octanol/water: No data available.

Vapour pressure: No data available.

pH: No data available.

9.2. Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2. Chemical stability

Chemical stability: Stable under normal conditions. Stable at room temperature.

10.3. Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.
Decomposition may occur on exposure to conditions or materials listed below.

10.4. Conditions to avoid

Conditions to avoid: Heat. Hot surfaces. Sources of ignition. Flames.

10.5. Incompatible materials

Materials to avoid: Strong oxidising agents. Strong acids.

10.6. Hazardous decomposition products

Haz. decomp. products: In combustion emits toxic fumes.

Section 11: Toxicological information

11.1. Information on toxicological effects

[cont...]

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Hazardous ingredients:

PROPAN-2-OL

IVN	RAT	LD50	1088	mg/kg
ORL	MUS	LD50	3600	mg/kg
ORL	RAT	LD50	5045	mg/kg
SCU	MUS	LDLO	6	gm/kg

Relevant effects for mixture:

Effect	Route	Basis
Irritation	OPT	Hazardous: calculated

Symptoms / routes of exposure

Skin contact: There may be irritation and redness at the site of contact.

Eye contact: There may be irritation and redness. The eyes may water profusely.

Ingestion: There may be soreness and redness of the mouth and throat.

Inhalation: There may be irritation of the throat with a feeling of tightness in the chest. Exposure may cause coughing or wheezing.

Delayed / immediate effects: Immediate effects can be expected after short-term exposure.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

12.2. Persistence and degradability

Persistence and degradability: Biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential: No bioaccumulation potential.

12.4. Mobility in soil

Mobility: Readily absorbed into soil.

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT/vPvB substance.

12.6. Other adverse effects

Other adverse effects: Negligible ecotoxicity.

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations: Transfer to a suitable container and arrange for collection by specialised disposal company.

[cont...]

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NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Section 14: Transport information

14.1. UN number

UN number: UN1219

14.2. UN proper shipping name

Shipping name: ISOPROPANOL (ISOPROPYL ALCOHOL)

14.3. Transport hazard class(es)

Transport class: 3

14.4. Packing group

Packing group: II

14.5. Environmental hazards

Environmentally hazardous: No

Marine pollutant: No

14.6. Special precautions for user

Special precautions: No special precautions.

Tunnel code: D/E

Transport category: 2

Section 15: Regulatory information

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

Specific regulations: This product has been classified in accordance with CLP and CHIP regulations and compiled in accordance with Annex II of REACH.

15.2. Chemical Safety Assessment

Chemical safety assessment: A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

Section 16: Other information

Other information

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

* indicates text in the SDS which has changed since the last revision.

Phrases used in s.2 and s.3: H224: Extremely flammable liquid and vapour.

H225: Highly flammable liquid and vapour.

H319: Causes serious eye irritation.

H336: May cause drowsiness or dizziness.

R11: Highly flammable.

[cont...]

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R36: Irritating to eyes.

R67: Vapours may cause drowsiness and dizziness.

Legend to abbreviations: PNEC = predicted no effect level

DNEL = derived no effect level

LD50 = median lethal dose

LC50 = median lethal concentration

EC50 = median effective concentration

IC50 = median inhibitory concentration

dw = dry weight

bw = body weight

cc = closed cup

oc = open cup

MUS = mouse

GPG = guinea pig

RBT = rabbit

HAM = hamster

HMN = human

MAM = mammal

PGN = pigeon

IVN = intravenous

SCU = subcutaneous

SKN = skin

DRM = dermal

OCC = ocular/corneal

PCP = physico-chemical properties

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.