

Empfohlene Reinraumklassen

ISO 5 | 6 | 7 | 8 | 9

GMP A/B | C | D

InSpec OX (PW), Premium (bag in the bottle) #OXPW40-1LS

pure[11]-Nr.: 1131304, Marke:

Eigenschaften

- Steril
- Marke: InSpec
- Desinfektion
- Wirkstoff: Wasserstoffperoxid
- Gebrauchsfertig
- Volumen in ml: 1.000 mL
- Behälterform: Sprühflasche
- Bag-in-Bottle System
- Haltbarkeit nach Anbruch in Tagen (bei optimaler Lagerung): 90
- 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

pure[11]-Nr.: 1131304, InSpec OX (PW), Premium (bag in the bottle) #OXPW40-1LS

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

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

InSpec™
Solutions Delivered By Experience

Technisches Datenblatt

OX

Sterile Sporizidzubereitung mit Wasserstoffperoxid 6 % v/v und Peressigsäure 0,4 v/v

Schnell wirkend – Erreichen von zwei Minuten Abtötungsdauer mit EN-Sporizidstandard – 3-log-Reduktion in 2 Minuten



GEBRAUCHSANWEISUNG:
InSpec OX 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.

TECHNISCHE DATEN:
Aussehen: Farblose, transparente Flüssigkeit mit typischem, stark saurem Geruch. pH: 1,4

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:

- Eines der wirksamsten Sporizide auf dem Markt
- Alle Formate sind als Reizstoffe klassifiziert. Geringe Gefahr
- Stabilisierte Lösung – Haltbarkeitsdauer von 24 Monaten
- Nach dem Öffnen validierte dreimonatige Haltbarkeitsdauer
- Inhalt geschützt durch Bag-in-Bottle-Verpackung bei Premium-Reihe.
- Gebrauchsfertige Formate mit 1 l und 5 l erhältlich
- Mehrfachbeutel für Reinraumtransfer
- Idealer Rotationspartner für InSpec QT und AN
- Hergestellt gemäß guter Herstellungspraxis (Good Manufacturing Practice, GMP)

TECHNISCHE BENUTZERINFORMATIONEN:

InSpec OX ist als steriles gebrauchsfertige Sporizid erhältlich.

InSpec OX 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, dann keimfrei in eine zuvor gammabestrahlte Verpackung (25-45 kGy) gefüllt und getestet, um einen SAL-Wert (Sterilisierungsvertrauensgrad) von 10^{-6} zu erreichen.

InSpec OX wird mit Konformitätszertifikaten, Analysen, Bestrahlung und Sterilität ausgeliefert.

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

Bei Schraubkappenflaschen bitte den gesamten Inhalt nach dem Öffnen aufbrauchen.

Mikrobiologischer Abklatschtest zur Mindestwirksamkeit			
EN 1276 Bakterien	5 Minuten	EN 13697 Bakterien	5 Minuten
EN 1650 Pilze	15 Minuten	EN 13697 Pilze	15 Minuten
EN 13704	2 Minuten (Bacillus Subtilis)		

InSpec™ OX-Produkt			
Produkt	**Packungsgröße**	**Behältergröße**	**Produktcode**
InSpec™ OX 1 l Sprühflasche	1 l Sprühflasche	6 x 1 l	OXPW40-1LS
InSpec™ OX 5 l Schraubkappe	5 l Schraubkappe	2 x 5 l	OXPW40-5LS
InSpec™ OX Aufplatzbeutel	15 Feuchttücher/Beutel	20 Beutel	OXPW40BP15S

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**

InSpec® OX

Technical Datasheet

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



Features

- **One of the most effective sporicides available on the market**
- **Classified as low hazard**
- **Validated 6 months 'in-use' sterility for Trigger Spray Sterile formats**
- **All trigger spray formats presented as protected systems**
- **All formats are presented as Ready to Use (RTU)**
- **Multiple bags for cleanroom transfer**
- **Ideal rotational partner for InSpec QT, InSpec QT+ and InSpec AN**
- **Manufactured in accordance with GMP**
- **Active substance compliant with Article 95 of the Biocidal Products Regulation (BPR)**

Formulation

InSpec OX is an aseptically prepared 6% Hydrogen Peroxide / 0.4% Peracetic Acid solution diluted with purified water.

Instructions for Use

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 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
EN 13704 Spores	2 Minutes

Safe Handling and Storage Information

Always wear gloves and goggles or face protection. Always read the label and 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).

Formulation Batch Release Specifications

Specification	Release Parameters
SG	0.995 - 1.037
Active Concentration	6% Hydrogen peroxide & 0.4% Peracetic acid v/v
pH	1.3 - 2.0
Colour	Colourless
Clarity	Clear
Odour	Acetic

Manufacturing Process

InSpec OX 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 are aseptically filled into pre-gamma irradiated packaging (validated dose range of 25 - 45 kGy) to give a sterility assurance level (SAL) of 10^{-6}.

Sterile formats of InSpec OX are tested for sterility for batch release. The trigger spray formats have a validated 6-months "in-use" sterility. This is delivered through a protected system 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.

Certificates

InSpec OX is provided with a Certificate of Analysis (COA) confirming batch release specifications and providing batch manufacturing information. The COAs for Sterile InSpec OX products contain information regarding the irradiation of the batch and the sterility test results.

Redditch Medical
Innovative thinking

InSpec® OX



Formats Available

The following formats of InSpec OX are available:

Product	Code	Cap	Case Size	Container Material	Bags and Material
Sterile Formats					
InSpec OX 1L Trigger	OXPW40-1LS	Trigger	6 x 1L Bottles	PP and co-extruded resin	Double-Bagged LDPE
InSpec OX 1L Dose	OXPWDOSE-1LS	Screw Cap	6 x 1L Bottles	HDPE	Double-Bagged LDPE
InSpec OX 5L Screw Cap	OXPW40-5LS	Screw Cap	2 x 5L Bottles	HDPE	Double-Bagged LDPE
Non-Sterile Formats					
InSpec OX 1L Trigger Non-Sterile	NSOXPW-1L	Trigger	6 x 1L Bottles	PP and co-extruded resin	Single-Bagged LDPE
InSpec OX 5L Screw Cap Non-Sterile	NSOXPW-5L	Screw Cap	2 x 5L Bottles	HDPE	Single-Bagged LDPE

Transport Information

Product	Code	Case Dimensions	Commodity Code	Cases per Pallet Euro/UK	Dangerous Goods*
Sterile Formats					
InSpec OX 1L Trigger	OXPW40-1LS	27cm x 19cm x 33cm 6.4Kg	29159070	64/60	UN 3082 Limited Quantity
InSpec OX 1L Dose	OXPWDOSE-1LS	27cm x 19cm x 33cm 6.4Kg	29159070	64/60	UN 3082 Limited Quantity
InSpec OX 5L Screw Cap	OXPW40-5LS	29cm x 20.5cm x 31cm 10.8Kg	29159070	52/51	UN 3082 Limited Quantity
Non-Sterile Formats					
InSpec OX 1L Trigger Non-Sterile	NSOXPW-1L	27cm x 19cm x 33cm 6.4Kg	29159070	64/60	UN 3082 Limited Quantity
InSpec OX 5L Screw Cap Non-Sterile	NSOXPW-5L	29cm x 20.5cm x 31cm 10.8Kg	29159070	52/51	UN 3082 Limited Quantity

*Limited quantity applies to inner packaging of 5L or less for products classed as UN 3082

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

Safety Data Sheet

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

InSpec OX

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

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

1.1 Product Identifier

Trade Name: InSpec OX
InSpec OX Burstable Wipes
InSpec OX Burstable Mops

Product Number: -

UFI: F800-U0RP-S00T-1PFT

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

Identified Uses: Disinfectant (sporicide), 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 Irrit. 2 (H315)
Eye Dam. 1 (H318)

Environmental hazards: Aquatic Chronic 2 (H411)

2.2 Label elements



Signal Word: **Danger**

Contains: **Peracetic acid**
Hydrogen peroxide
Acetic acid

Hazard Statements:

- H318 – Causes serious eye damage.
- H315 – Causes skin irritation.
- H411 – Toxic to aquatic life with long lasting effects.

Precautionary Statements:

- P273 – Avoid release to the environment.
- P280 – Wear protective gloves / protective clothing / eye protection / face protection.
- P303 + P361 + P353 – IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.
- P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P310 – Immediately call a POISON CENTER or doctor / physician.
- P391 – Collect spillage.

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)
Peracetic acid	201-186-8	79-21-0	01-2119531330-56-0004	Flam. Liq. 3 (H226) Org. Perox. D (H242) Acute Tox. 4 (H302) Acute Tox. 4 (H312) Acute Tox. 4 (H332) Skin Corr. 1A (H314) Eye Dam. 1 (H318) STOT SE 3 (H335) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) ***M-Factors:*** M-Factor (acute) = 1 M-Factor (aquatic) = 10	-	0.1-0.5
Hydrogen peroxide solution	7722-84-1	231-765-0	01-2119485845-22-0000; 01-2119485845-22-0012; 01-2119485845-22-0016	Ox. Liq. 1 (H271) Acute Tox. 4 (H302) Acute Tox. 4 (H332) Skin Corr. 1A (H314) ***Specific Concentration Limits:*** Skin Corr. 1A (H314: C ≥ 70%) Ox. Liq. 1 (H271: C ≥ 70%) STOT SE 3 (H335: C ≥ 35%) Eye Irrit. 2 (H319: 5% ≤ C < 8%) Skin Corr. 1B (H314: 50% ≤ C < 70%) Eye Dam. 1 (H318: 8% ≤ C < 50%) Skin Irrit. 2 (H315: 35% ≤ C < 50%) Ox. Liq.2 (H272: 50% ≤ C < 70%)		6-7
Acetic acid	64-19-7	200-580-7	01-2119475328-30-0023	Flam. Liq. 3 (H226) Skin. Corr. 1A (H314)		4-5

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

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice: Pay attention to self-protection. Removed affect person from hazardous area. Immediately remove soiled or soaked clothing and remove it to a safe distance. Keep affected person warm, in a stabilised position and covered. Do not leave unaffected person unattended. If the affected person is unconscious place them in the recovery position.

Inhalation: Potential for exposure by inhalation if aerosols or mists are generated. Move affected person into fresh air and keep comfortable for breathing. If breathing is laboured provide oxygen if available, and consult a doctor / physician.

Skin contact: Remove / Take off immediately all contaminated clothing. Rinse affected area immediately with plenty of water for at least 15 minutes. If irritation / symptoms persist get medical attention / advice.

Eye contact: With eye held open, rinse cautiously with water for at least 10 minutes. If irritation / symptoms persist get medical advice / attention.

Ingestion: Rinse mouth. Do NOT induce vomiting. Give large quantities of water to drink. Get medical advice / attention. When dealing with caustic substances, notify emergency doctor / physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

Strongly irritating to corrosive; harmful in contact with skin and if swallowed: Irritation of skin and mucous membranes. Causes burns.

Vapours may cause drowsiness and dizziness: May cause daze, headache, vertigo, somnolence (drowsiness), nausea.

Health injuries may be delayed.

4.3 Indication of any immediate medical attention and special treatment needed

• **Localised action:** characterized by quickly progressing deep tissue damage. Signs of irritation of the respiratory tract such as coughing, burning behind the sternum, tears, burning in the eyes or nose. There is a risk of pulmonary edema.
• **In the eye:** caustic / irritating and harmful liquids cause, depending on the intensity of exposure, various levels of irritation, destruction, and ablation of the epithelium of the conjunctiva and cornea, corneal clouding, edema and ulcerations. Danger - Possible loss of eyesight.
• **Skin contact:** Superficial irritations and damage up to ulcerations and scarring develop on the skin.
• After accidental absorption in the body, the pathology and clinical findings are dependent on the kinetics of the substance (*e.g.* quantity absorbed, absorption time, effectiveness of early first aid measures, and metabolism / excretion).
• Specific action of the substance is unknown.
• In case of substances with high water solubility, irritations up to formation of necrosis in the upper respiratory tract may result after inhalation of caustic/ irritating aerosols and mists.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing material: Carbon dioxide, dry powder, water, foam.

Unsuitable extinguishing media: Organic compounds.

5.2 Special hazards arising from the substance or mixture

Fire can result in decomposition, yielding oxygen.

Risk of overpressure and burst due to composition in confined spaces and pipes.

5.3 Advice for firefighters

In case of fire, remove the endangered containers and bring to a safe place, if this can be done safely. In the case of fire, cool the containers that are at risk with water or dilute with water (flooding). Water used to extinguish fire should not enter drainage systems, soil or stretches of water. Contaminated extinguishing water must be treated at a suitable disposal plant in accordance with waste management laws. Fire residues should be disposed of in accordance with the regulations. Keep out unprotected persons. As in any fire, wear self-contained breathing apparatus and suitable personal protective equipment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Keep unauthorised person away.

6.2 Environmental precautions

Do not permit to enter into surface water, stretches of water undiluted. If the product contaminates rivers and lakes, or drains, inform the relevant authorities.

6.3 Methods and material for containment and cleaning up

• Observe national / local regulations on prevention of water pollution.
Isolate defective containers immediately if possible and safe to do. Shut of leak if possible and safe to do. Place defective containers in suitable waste receptacle made of plastic. Do not seal defective containers or waste receptacles air tight (danger of bursting due to product decomposition).
• 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. Rinse away any residues with plenty of water. Do not detach label

from the delivery containers prior to disposal. Dispose of contents / container to national / local authority regulations.
• Product taken out of its container should not be returned to the container; never return spilled product to its original container for re-use.

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 for protection of human health / safe handling: Handle in accordance with good industrial hygiene and safety practices. Avoid impurities and heat effect. Avoid residues of the product on the containers. Wear personal protection equipment (protective gloves, safety goggles, protective clothing). Avoid contact with skin and eyes. Wash hands thoroughly after handling. Do not breathe vapours / aerosol / mist / spray, and ensure good ventilation in area of work. Immediately change moistened and saturated work clothes. Provide for installation of emergency shower and eye bath.

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 thoroughly after handling product, 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. Use personal protective equipment as required. Use only with adequate ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Avoid sun rays / heat / heat effect. Keep away from incompatible substances (see section 10 of this Safety Data Sheet).

Maximum temperature during storage – 40^{o}C. Store locked up in in well-ventilated, dry, clean place.

Suitable materials for storage: stainless steel (1.4571), plastics (polyethylene, polypropylene, polytetrafluoroethylene, polyvinylchloride), glass, ceramics.

Unsuitable materials for storage: corrodes metal. Avoid iron, copper, brass, bronze, aluminium, zinc (corrodes metals).

Additional packaging considerations: Use adequate venting devices on packages, containers and tanks and check correct operation periodically. Risk of overpressure and burst due to decomposition in confined spaces and pipes. Always close container tightly after removal of product. Do not keep the container sealed. Avoid leakage. Transport and store in upright position only. Do not empty container by means of pressure.

Further information: For detailed information on design specifications for the construction of tank – and dosing installations ask the producer for advice. Protect from sunlight, warmth and heat. To ensure due transportation, make certain that stacks are of the correct height, containers are securely fastened so not to fall off, and labelled according the relevant regulations.

Advice on common storage: Do not store together with metallic salts, alkalis, reducing agents.

7.3 Specific end use(s)

For more details see attached Annexes for exposure scenarios.

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
Hydrogen peroxide			
United Kingdom	1 ppm (1.4 mg/m^3)	2 ppm (2.8 mg/m^3)	UK EH40 WEL; Workplace Exposure Limits†
Austria	1 ppm (1.4 mg/m^3)	n/a	MAK / TRK; Austrian OEL Regulation

Belgium	1 ppm (1.4 mg/m^3)	n/a	VLEP / GWBB
Denmark	1 ppm (1.4 mg/m^3)	2 ppm (2.8 mg/m^3)	Arbejdstilsynet; Executive Order on Limit Values for Substances and Materials (Denmark)
Finland	1 ppm (1.5 mg/m^3)	3 ppm (4.2 mg/m^3)*	HTO-arvot 2016, Ministry of Social Affairs and Health (Finland)
France	1 ppm (1.4 mg/m^3)	1 ppm (1.4 mg/m^3)	VLE; French Labour code / French Labour Ministry
Germany	0.5 ppm (0.71 mg/m^3)	0.5 ppm (0.71 mg/m^3)	DFG; Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area AGS; German Committee on Hazardous Substances
Ireland	1 ppm (1.5 mg/m^3)	2 ppm (3 mg/m^3)*	Hungarian decree No. 25/2000 (IX.30)
Spain	1 ppm (1.4 mg/m^3)	n/a	Health and Safety Authority – Code of Practice for the Chemical Agents Regulation (Ireland)
Acetic acid			
European Union	10 ppm (25 mg/m^3)	20 ppm (50 mg/m^3)	IOELV / BOELV; commission Directive 2017/164
United Kingdom	10 ppm (25 mg/m^3)	15 ppm (37 mg/m^3)	UK EH40 WEL; Workplace Exposure Limits†
Austria	10 ppm (25 mg/m^3)	15 ppm (37 mg/m^3)	MAK / TRK; Austrian OEL Regulation
Belgium	10 ppm (25 mg/m^3)	15 ppm (38 mg/m^3)	VLEP / GWBB
Denmark	10 ppm (25 mg/m^3)	20 ppm (50 mg/m^3)	Arbejdstilsynet; Executive Order on Limit Values for Substances and Materials (Denmark)
Finland	5 ppm (13 mg/m^3)	10 ppm (25 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	10 ppm – AGS (25 mg/m^3 - AGS) / 10 ppm – DFG (25 mg/m^3 – DFG)	20 ppm – AGS (50 mg/m^3 – AGS)* / 20 ppm – DFG (50 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	25 mg/m^3	25 mg/m^3	Hungarian decree No. 25/2000 (IX.30)
Ireland	10 ppm (25 mg/m^3)	15 ppm (37 mg/m^3)*	Health and Safety Authority – Code of Practice for the Chemical Agents Regulation (Ireland)
Spain	10 ppm	15 ppm	Limit Values Spain, Royal Decree

	(25 mg/m^3)	(37 mg/m^3)	374/2001

*15-minute average value / reference period

†According to the GESTIS database for International Limit Values: the UK Advisory Committee on Toxic Substances has expressed concern that, for the OELs shown in parentheses, health may not be adequately protected because of doubts that the limit was not soundly-based. These OELs were included in the published UK 2002 list and its 2003 supplement, but were omitted from editions published from 2005 onwards.

DNEL and PNEC values

Human Exposure

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

Acute – Local effects	Acute – Systemic effects	Long-term effects – local effects	Long-term effects – Systemic effects
0.6	0.6	0.6	0.6

DNEL dermal exposure – Workers (mg/kg)

Acute – Local effects	Acute – Systemic effects	Long-term effects – local effects	Long-term effects – Systemic effects
12000	No data available.	No data available.	No data available.

DNEL inhalation – General Population (mg/m^3)

Acute – Local effects	Acute – Systemic effects	Long-term effects – local effects	Long-term effects – Systemic effects
0.3	0.6	0.6	0.6

DNEL dermal exposure – General Population (mg/kg)

Acute – Local effects	Acute – Systemic effects	Long-term effects – local effects	Long-term effects – Systemic effects
12000	No data available.	No data available.	No data available.

Environmental Exposure

PNEC environmental exposure

Freshwater (mg/l)	STP (mg/l)	Fresh water sediment (mg/l)	Soil (µg/kg dry weight)
0.000224	0.051	0.00018	320

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: Ensure suitable suction / aeration at the work place and with operational machinery. Provide

for installation of emergency shower and eye bath.

Suitable measure processes are: Hydrogen peroxide: OSHA method ID 006; OSHA method VI-6.
Acetic acid: NIOSH method 1603; OSHA method ID 186.

Personal Protective Equipment

Eye/face protection: Safety glasses with side-shields conforming to EN166, or when handling in larger quantities: basket-shaped glasses.

Respiratory protection: Do not inhale vapour / aerosols / mist.
In case of larger quantities, if open handling is unavoidable: if workplace exposure limit is exceeded apply respiratory protective equipment – wear self-contained respiratory apparatus:
Respirator with A2B2E 2K1P2 combination filter (Draeger).
Respirator with OV/AG combination filter (3M).
Respirator with ABEKK2P3 combination filter (3M).
If necessary ensure local ventilation. Not time limit for wearing respiratory protective equipment.

Hand protection: Disposable gloves
When handling for brief periods or small amounts:
Glove material: Natural rubber, Natural latex (NR)
Material thickness: 0.22 mm
Break-through time > 480 minutes; Method: DIN EN 374.
When handling for longer periods or large amounts:
Glove material: Polychloroprene (PCP), *e.g.* Camapren 720, Kächele-Cama Latex
Material thickness: 0.65 mm
Break-through time: > 480 minutes; Method: DIN EN 374.

Other skin and body protection: Laboratory protective clothing or when handling in larger quantities: chemical protective suit, disposable protective suit.

Hygiene measures: Avoid contact with skin and eyes. Ensure there is good room ventilation.
Do not eat, drink, smoke, or sniff while at work. Wash your hands and / or face before breaks and before termination of work. Avoid contaminating clothing with product. Immediately change moistened and saturated work clothes. Immediately rinse contaminated or saturated clothing with water. Wash contaminated clothing before reuse. Apply adequate skin protection agents before handling the product. Assure skin cleaning and skin care after work. Preventative skin protection is recommended.

Other protective measures: Handle in accordance with good industrial hygiene and safety practice. If there is the possibility of skin/eye contact, the indicated hand/eye/ body protection should be used. The work-place related airborne concentrations must be kept below of the indicated exposure limits. If workplace exposure limits are exceeded and/or larger amounts are released (leakage, spilling, dust) the indicated respiratory protection should be used. The personal protective equipment used must meet the requirements of directive 89/686/EEC and amendments (CE certification). It should be defined in the work place in the form of a risk analysis according to directive 89/686/EEC and amendments.

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:	Colourless, clear.	-
Odour:	Slightly of acetic acid.	-
pH:	*ca.* 1.4	@ 20 °C
Melting point /freezing point:	*ca.* -15 °C	-
Initial boiling point and boiling range:	Not available.	-
Flash point:	Not combustible.	-
Evaporation rate:	Not available.	-
Flammability (solid, gas):	Not applicable.	-
Upper/lower flammability or explosive limits:	Not available.	-
Vapour pressure:	Not available.	-
Vapour density:	Not available.	-
Relative density:	Not available.	-
Density	*ca.* 1.03 g/cm^3	@ 20 °C
Solubility(ies)	Fully miscible with water.	-
Partition coefficient: n-octanol/water:	Not available.	-
Auto-ignition temperature:	Not self-heating.	-
Decomposition temperature:	Not available.	-
Viscosity (dynamic):	Not available.	-
Explosive properties:	Not available.	-
Oxidising properties:	Not available.	-

9.2 Other information	No additional information.	
Metal corrosion:	< 6.25 mm/a	Method – NACE standard, TM 0169-95 AlZnMgCu 1.5; W. No. 3,4365
	< 6.25 mm/a	Method – NACE standard, TM 0169-95 Carbon steel ST 37-2, S235JR, Mat. No 1.0037
Speed of hydrolysis (test substance – peracetic acid):	Half-life: 48 hours	@ 25°C, pH 4 Method – 92/69/EEC, C.7
	Half-life: 48 hours	@ 25°C, pH 7 Method – 92/69/EEC, C.7
	Half-life: 3.6 hours	@ 25°C, pH 9 Method – 92/69/EEC, C.7

SECTION 10: Stability and reactivity

10.1 Reactivity

Risk of self-accelerating, exothermic decomposition with the development of oxygen, at, Effect of thermal energy / heat.

10.2 Chemical stability

Stable at room temperature. Product is supplied in stabilised form.

10.3 Possibility of hazardous reactions

Possibility of hazardous reactions. Risk of overpressure and burst due to decomposition in confined spaces and pipes.
Risk of decomposition in contact with incompatible substances, impurities, metals, alkalis, reducing agents.
SAPT: > = 60 °C, therefore, the product can be shipped at ambient temperature.

10.4 Conditions to avoid

Sun rays, heat, heat effect.

10.5 Incompatible materials

Impurities, decomposition catalysts, metals, nonferrous heavy metal, aluminium, zinc, metals, metallic salts, alkalis, reducing agents.

10.6 Hazardous decomposition products

Products formed under conditions of thermal decomposition: steam, oxygen, acetic acid.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

The following information is available regarding the mixture / product:

InSpec OX	
Acute toxicity:	No information available.
Skin corrosion / irritation:	Skin irritation.
Serious eye damage / irritation:	Irreversible effects on the eye.
Respiratory or skin sensitisation:	No information available.
Germ cell mutagenicity:	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:	No information available.

No toxicological tests are available on the mixture / product. The following substance data is provided for ingredients in the mixture / product:

Peracetic acid			
Acute toxicity:	No information available.		
Skin corrosion / irritation:	Corrosive.		Method – OECD Test Guideline 404. Test species – rabbit. Test substance – 5% peracetic acid. Exposure time – 4 hours.
Serious eye damage / irritation:	Irritating.		Method – US-EPA. Test species – rabbit. Test substance – 17% peracetic acid. Exposure time – not available.
Respiratory or skin sensitisation:	Not sensitising.		Method – OECD Test Guideline 406. Test species – guinea pig. Test item – 10% peracetic acid.
Repeat dose toxicity:	NOAEL (Oral):	1.17 mg/kg	Method – OECD Test Guideline 408. Test species – rat (male / female). Test item – 100% peracetic acid. Testing period – 13 weeks / 92-93 days.
Germ cell mutagenicity:	-		
Genotoxicity *in vitro*:	Negative.		Method – OECD Test Guideline 471 (Ames Test). Metabolic activation – with or without. Test organism – *Salmonella typhimurium*. Test item – 5% peracetic acid.
	Negative.		Method – OECD Test Guideline 476 (HGPTR Test). Metabolic activation – with or without. Test material – Chinese hamster V79-cells. Test item – 11% peracetic acid.
	Negative.		Method – OECD Test Guideline 473 (Chromosomal

		Aberration). Metabolic activation – with or without. Test material – Chinese hamster V79-cells. Test item – 11% peracetic acid.
	Negative.	Method – OECD Test Guideline 482 (Unscheduled DNA synthesis (UDS) test). Metabolic activation – without. Test material – Human diploid fibroblasts. Test item – 42% peracetic acid.
Genotoxicity *in vivo*:	Negative.	Method – OECD Test Guideline 474 (Micronucleus Test). Application route – oral (30 hours). Test species – mouse. Test item – 5% peracetic acid.
	Negative	Method – Mutagenicity (micronucleus test). Application route – oral. Test species – mouse. Test item – 5% peracetic acid.
	Negative	Method – OECD Test Guideline 486 (Unscheduled DNA Synthesis (UDS) Test). Application route – oral. Test species – rat. Test item – 5% peracetic acid.
Carcinogenicity:	No information available; not considered mutagenic.	
Reproductive toxicity:	NOAEL: 12.5 mg/kg	Method – OECD Test Guideline 414 (Prenatal Development Toxicity Study). Test species – rat. Application route – oral. Test item – 100% peracetic acid.
	NOAEL (F1): 30.4 mg/kg	
STOT-single exposure:	No information available.	
STOT-repeated exposure:	No evidence for hazardous properties.	
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).	

Hydrogen peroxide		
Acute toxicity:	No information available.	
Skin corrosion / irritation:	Corrosive.	Method – not available. Test species – rabbit. Exposure time – 4 hours. Test item – 35% hydrogen peroxide.
Serious eye damage / irritation:	No information available.	
Respiratory or skin sensitisation:	No information available.	
Repeat dose toxicity:	No information available.	
Germ cell mutagenicity:	No information available.	
Genotoxicity *in vitro*:	No information available.	
Genotoxicity *in vivo*:	No information 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).

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:

Peracetic acid			
Aquatic acute (short-term) toxicity			
Aquatic acute (short-term) toxicity – fish:	LC50:	0.53 mg/l	Method – OECD Test Guideline 203. Test species – *Oncorhynchus mykiss* (Rainbow trout). Exposure time – 96 hours. Test substance – 100% peracetic acid.
Aquatic acute (short-term) toxicity – crustacea:	EC50:	0.18 mg/l	Method – ISO 6341 (literature). Test species – *Daphnia magna* (Water flea). Exposure time – 24 hours. Test substance – 100% peracetic acid.
Aquatic acute (short-term) toxicity – algae:	EC50:	0.16 mg/l	Method – US EPA (growth rate). Test species – *Pseudokirchneriella subcapitata* (algae). Exposure time – 72 hours. Test substance – 100% peracetic acid.
	NOEC:	0.061 mg/l	Method – US EPA (growth rate). Test species – *Pseudokirchneriella subcapitata* (algae). Exposure time – 72 hours. Test substance – 100% peracetic acid.
Aquatic acute (short-term) toxicity – marine species:	No information available.		
Toxicity to bacteria:	EC50:	38.6 mg/l	Method – OECD Test Guideline 209 (static test). Test species – Activated sludge. Exposure time – 3 hours. Test substance – 100% peracetic acid.
	EC50:	5.1 mg/l	Method – OECD Test Guideline 209 (static test).

		Test species – Activated sludge. Exposure time – 3 hours. Test substance – 100% peracetic acid.
Aquatic chronic (long-term) toxicity		
Aquatic chronic (long-term) toxicity – fish:	NOEC: 0.00094 mg/l	Method – OECD Test Guideline 210 (flow-through test). Test species – *Danio rerio* (Zebra fish). Exposure time – 33 days.
Aquatic chronic (long-term) toxicity – crustacea:	NOEC: 0.05 mg/l	Method – OECD Test Guideline 211 (semi-static 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.	

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:

Peracetic acid			
Biodegradability:	98%	Readily biodegradable.	Method – OECD Test Guideline 301 E (aerobic conditions; at non-bacteriotoxic concentrations). Inoculum – Activated sludge. Testing period – 28 days. Test item – 40% peracetic acid.
	93.3%	Totally biodegradable.	Method – OECD Test Guideline 209 (aerobic conditions). Inoculum – Activated sludge. Testing period – 3 minutes. Test item – 40% peracetic acid.
Further information:	The product does not contain any organically bonded halogens. Under ambient conditions quick hydrolysis, reduction, or decomposition occurs; the following substances are formed: oxygen and water, acetic acid. Acetic acid is readily biodegradable.		

Hydrogen peroxide	
Biodegradability:	Photochemical degradation of hydrogen peroxide takes place.

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

12.3 Bioaccumulative potential

Bioaccumulation potential of the product / mixture is low.

12.4 Mobility in soil

No information is available on the product / mixture.

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

The mixture / product does not contain any heavy metals and compounds from EC Directive 76/454 (*e.g.* arsenic, lead, cadmium, mercury, organic compounds, halogenated organic compound.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: This product must be disposed of as an organic chemical in accordance with the regulations issued by the appropriate localauthorities. Offer surplus and non-recyclable solutions to a licensed disposal company.
If necessary, small amounts: May be disposed of as sewage water in accordance with local legal regulations by previously diluting with plenty of water (drainage systems, sewage treatment plant). If necessary contact the relevant authorities.

Uncleaned packaging: Rinse empty containers with water prior to disposal. Offer rinsed packaging material to local recycling facilities. Do not reuse empty containers and dispose of in accordance with the regulations issued by the appropriate localauthorities.

Waste Key Number: The waste key number must be determined as per the European Waste Types List (decision on EU Waste Types List 2000/532/EC) in cooperation with the disposal firm / producing firm / official authority.

SECTION 14: Transport information

		ADR/RID:	**IMDG:**	**ICAO/IATA:**	**ADN:**
14.1	**UN number:**	3082	3082	3082	3082
14.2	**UN proper shipping name:**	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains Peracetic acid, stabilized).	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains Peracetic acid, stabilized).	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains Peracetic acid, stabilized).	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains Peracetic acid, stabilized).
14.3	**Transport hazard class(es):**	9 (miscellaneous dangerous goods)	9 (miscellaneous dangerous goods)	9 (miscellaneous dangerous goods)	9 (miscellaneous dangerous goods)
14.4	**Packing group:**	III	III	III	III
	EmS	-	F-A, S-F	-	-
14.5	**Environmental hazards**				
	Environmentally hazardous:	Yes	Yes	Yes	Yes
	Marine pollutant:	Yes			
14.6	**Special precautions for user:**				
14.7	**Maritime transport in bulk according to IMO instruments:**	For transport approval see regulatory information.			

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 contaminating class (Germany):	GK 1 – slightly water endangering. Classification according to VwVwS, supplement 4.	
Regulations on labour safety:	It must be determined whether preventive substance-specific occupational medical examinations in accordance with national law in each case must be offered / carried out at regular intervals.	
Employment restriction:	Please note Directive 93/85/EEC (Pregnant Workers Directive) and amendments. Please note Directive 94/33/EC (Protection of Young Workers at the Workplace Directive) and amendments. Observe national regulations.	
Other regulations:	Please observe Appendix XVII of the EU Regulation 1907/2006 (Restrictions on the manufacture, placing on the market, and use of certain dangerous substances, preparations and articles) as well as their amendments.	
Registration:	**Europe (EINECS / ELINCS):**	All ingredients listed / registered.
	USA (TSCA):	All ingredients listed / registered.
	Philippines (PICCS):	All ingredients listed / registered.
	New Zealand:	All ingredients listed / registered.
	Korea:	All ingredients listed / registered.
	China:	All ingredients listed / registered.
	Australia:	All ingredients listed / registered.

15.2 Chemical safety assessment

A chemical safety assessment has been carried out for this product.

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

Revision Note:

This version of the Safety Data Sheet replaces all previous versions. 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 Databased (Occupational Exposure Limits).

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

- H226 – Flammable liquid and vapour.
- H242 – Heating may cause fire.
- H302 – Harmful if swallowed.
- H312 – Harmful in contact with skin.
- H315 – Causes skin irritation.
- H318 – Causes serious eye damage.
- H335 – May cause respiratory irritation.
- H400 – Very toxic to aquatic life.
- H411 – Toxic 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.
• NOAEL – no observed adverse effect level.
• NOEC – no observed effect concentration.
• 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