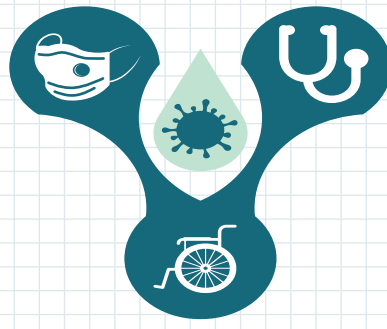


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## About Lysoform

**LYSOFORM** – Famous world-wide since 1900 as one of the major brand names for disinfectants.

**LYSOFORM** – A trademark for disinfectants and a neologism which has been in the dictionary for decades as a synonym for disinfection.

**LYSOFORM** – This means hygiene, cleanliness and health in general.

**LYSOFORM** – behind this name stands a firm of dedicated people full of ideas about the diverse aspects of hygiene. In order that you may become better acquainted with the people and ideas which have shaped Lysoform.



The story of a company introduces the firm to you with a look back at a long tradition and a look forward into a successful future.

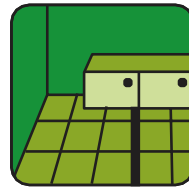


**LYSOFORM** – First aldehyde – containing disinfectant Formaldehyde  
(Dr. Hanns Rosemann 1890)

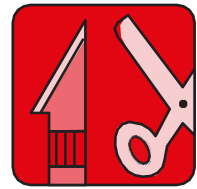
**LYSOFORM** – First alcohol – containing washing disinfectant.

**LYSOFORM** – First disinfectant with PH below 7 containing aldehydes.





SURFACE  
DISINFECTANT



INSTRUMENTS  
DISINFECTANT

# Lysoformin® ۳۰۰۰

Disinfecting and cleaning concentrate for instruments, and surfaces, especially suitable for flexible endoscopes



CE ۰۴۸۲

Instructions for use - Please read carefully!

# Lysoformin® 3000

## Concentrate

Disinfecting and cleaning concentrate for instruments, equipment and surfaces; particularly appropriate for flexible endoscopes

For professional use

### Composition:

100 g solution contains:  
 7,0 g Glyoxal, 9,0 g Glutaral, 9,6 g Didecyldimethylammonium chloride

### Range of application:

- Disinfection and cleaning of instruments, endoscopes, as well as equipment and surfaces as well as medical devices) in one Step only in case of all bacterial (Tb incl.) and viral infections
- Use according to the preparation instructions of the manufacturer of the medical device
- Control of nosocomial infections

### Mode of application / dosage:

Lysoformin® 3000 is a liquid concentrate with which any use-dilution required can be made by simply adding water (at max. room temperature). Always fill container with tap water first, then add disinfectant. Prepare dilution shortly before use (as recommended in the directives for Hospital Hygiene and Infection Prevention of the Robert-Koch-Institute, Berlin). The solutions ready for use are efficient for at least 14 days provided they are free of organic residue (disinfection of pre-cleaned instruments).

Disinfection of the medical instruments (incl.TB) by immersion / soaking		
Strong contamination including M. terrae	2,00 %	30 mn
	1,00 %	1 h
Virucidal against enveloped viruses* including HBV/HCV/HIV	0,20 %	10 mn
	2,00 %	30 mn
Virucidal*	0,50 %	30 mn
	0,20 %	10 mn
	0,20 %	1 mn
	1,00 %	0 mn
	0,50 %	10 mn
Disinfection by scrub / wiping disinfection and cleaning of surfaces		
Prophylactic treatment of nosocomial infections and routine disinfection	0,20 %	4 h
	0,50 %	1 h
	1,00 %	10 mn

\*according to recommendation of Robert Koch Institute Berlin in Federal Health Gazette 2004/1

**Important:** Place objects to be disinfected in the solution in such a way that all surfaces are in contact with the product. Close container tightly with lid. **Rinse instruments with water after disinfection / cleaning. Use germ-free water to rinse endoscopes.**

## Lysoform – Hygiene with System

concentration	0,20 %	2,00 %	2,50 %	1,00 %	2,00 %
<b>Dosing system</b> (for 1 l of water)					
Dosing-bag (1 bag = 20 ml)	1 bag	2 bags	3 bags	6 bags	12 bags
Dosing pump (1 stroke = 20 ml)	1 stroke	2 strokes	3 strokes	6 strokes	12 strokes
<b>Lysoform dosing devices</b>	Adjust concentration once only to obtain the concentration wished for				

To calculate the amount of water to be added, subtract the amount of disinfectant needed to obtain the concentration wished for from the amount of solution ready for use which has to be prepared

#### **Warnings / Storage:**

- Keep disinfectants in a cool but frost free, well ventilated and dry place and out of reach of children
- Wear suitable protective clothing, adequate protective gloves and eye protection when handling the product.
- Do not use beyond expiry date.
- Shelf life of the solution ready for use free from organic residue\* : 4 weeks when the product is stored under appropriate conditions (in a cool and dry place) in clean and tightly closed containers.

#### **Properties:**

- Control of bacteria (Tb incl.), fungus, viruses
- Good compatibility with **instruments** including **flexible endoscopes**, equipment and surfaces
- Fresh non-clinging scent
- Contains no formaldehyde, no phenols, no phosphates, no oxidizing compounds
- Cleans without adding detergents
- Resists hard water, biodegradable

#### **Special precautions:**

##### **a) Incompatibilities:**

Adding detergents as well as rests of care products present on the instruments can impair or neutralize the disinfecting properties of **Lysoformin** 3000® or its compatibility with the material of the instruments.

##### **b) Counter-measures in case of improper use:**

Should **Lysoformin** 3000® come into contact with the mucous membranes (eyes, throat, stomach, bowels etc.) get medical attention immediately. Dilute product without delay: if it has been swallowed, drink plenty of water; after contact with the eyes, rinse thoroughly with plenty of water.

##### **c) Use Lysoformin 3000® safely:**

Always read the label and product information before use.

Certified and mentioned in the relevant lists.

#### **Standard Packaging:**

- 200 x 20 ml dosing bags
- 12 x 1000 ml bottles
- 2 x 2 l-canisters
- 1 x 20 l-canister

#### **Art.-Nr.**

9397

#### **Accessories:**

Dosing pump for 2 l can (1 stroke  $\cong$  20 ml)

“The period of time during which the proven efficacy of the ready-for-use disinfectant solution remains unaffected, after preparation at the concentration according to the recommendations of the manufacturer and if it has been stored during the period of time mentioned according to the recommendations of the manufacturer and left to stand unused.”

**If you have special questions, call us. We call back immediately.**

**Lysoform Dr. Hans Rosemann GmbH**  
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## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### Lysoformin 3000

Revision date: 01.03.2018

Product code: LYS648

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

### 1.1. Product identifier

Lysoformin 3000

#### Further trade names

Wipe disinfection of surfaces, objects and medical devices Disinfection by immersion of medical devices or other objects. For professional use.

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

#### 1.3. Details of the supplier of the safety data sheet

Company name: Lysoform Dr. Hans Rosemann GmbH  
Street: Kaiser-Wilhelm-Straße 133  
Place: D-12247 Berlin  
Telephone: +49 (0)30 77992-0  
Contact person: Wissenschaftlich-Technische Abteilung Berlin  
e-mail: kontakt@lysoform.de  
Internet: [REDACTED]

Telefax: +49 (0)30 77992-219  
Telephone: +49 (0)30 / 77992-216

**1.4. Emergency telephone number:** +49 (0)89 19240 (Giftnotruf München Toxikologische Abteilung)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Regulation (EC) No. 1272/2008

Hazard categories:

Flammable liquid: Flam. Liq. 3

Acute toxicity: Acute Tox. 4

Skin corrosion/irritation: Skin Corr. 1

Respiratory or skin sensitisation: Resp. Sens. 1

Respiratory or skin sensitisation: Skin Sens. 1

Germ cell mutagenicity: Muta. 2

Hazardous to the aquatic environment: Aquatic Acute 1

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Flammable liquid and vapour.

Harmful if swallowed.

Causes severe skin burns and eye damage.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

Suspected of causing genetic defects.

Very toxic to aquatic life.

Harmful to aquatic life with long lasting effects.

### 2.2. Label elements

#### Regulation (EC) No. 1272/2008

##### Hazard components for labelling

didecyldimethylammonium chloride

1,5-pentanedial, glutaral

Ethandial

Isotridecanol, ethoxylated

**Signal word:** Danger

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**Pictograms:****Hazard statements**

H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.
H341	Suspected of causing genetic defects.
H410	Very toxic to aquatic life with long lasting effects.

**Precautionary statements**

P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves, protective clothing and eye protection.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P310	In case of accident: Call a doctor immediately.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.

**Special labelling of certain mixtures**

EUH071	Corrosive to the respiratory tract.
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**2.3. Other hazards**

The substance in the mixture does not meet the PBT/vPvB criteria according to REACH, annex XIII.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures**

**Safety Data Sheet**

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**Hazardous components**

CAS No	Chemical name	Quantity		
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
7173-51-5	didecyldimethylammonium chloride			5 - < 10 %
	230-525-2	612-131-00-6		
	Acute Tox. 3, Skin Corr. 1B, Aquatic Acute 1 (M-Factor = 10), Aquatic Chronic 2; H301 H314 H400 H411			
111-30-8	1,5-pentanedial, glutaral			5 - < 10 %
	203-856-5	605-022-00-X	01-2119455549-26	
	Acute Tox. 2, Acute Tox. 3, Skin Corr. 1B, Resp. Sens. 1, Skin Sens. 1A, STOT SE 3, Aquatic Acute 1, Aquatic Chronic 2; H330 H301 H314 H334 H317 H335 H400 H411 EUH071			
107-22-2	Ethandial			5 - < 10 %
	203-474-9	605-016-00-7	01-2119455549-26	
	Muta. 2, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H341 H332 H315 H319 H317			
69011-36-5	Isotridecanol, ethoxylated			5 - < 10 %
	931-138-8			
	Acute Tox. 4, Eye Dam. 1; H302 H318			
67-63-0	propan-2-ol; isopropanol			1 - < 5 %
	200-661-7	603-117-00-0	01-2119457558-25	
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336			

Full text of H and EUH statements: see section 16.

**Labelling for contents according to Regulation (EC) No 648/2004**

disinfectants, 5 % - &lt; 15 % non-ionic surfactants, perfumes (Amyl cinnamal, Benzyl salicylate, Butylphenyl methylpropional, Citronellol, Hexyl cinnamal).

**SECTION 4: First aid measures****4.1. Description of first aid measures****General information**

Call a physician immediately. If medical advice is needed, have product container or label at hand.

**After inhalation**

Remove person to fresh air and keep comfortable for breathing.

**After contact with skin**

Take off immediately all contaminated clothing and wash it before reuse. Wash with plenty of water.

**After contact with eyes**

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

**After ingestion**

Rinse mouth immediately and drink plenty of water. Call emergency telephone number.

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

irritation of the mucous membranes, Headache, indisposition

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

Treatment of the patient is the same as for a chemical burn.

**SECTION 5: Firefighting measures****5.1. Extinguishing media**



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#### **Suitable extinguishing media**

Water spray jet, Carbon dioxide, Extinguishing powder, alcohol resistant foam

#### **5.2. Special hazards arising from the substance or mixture**

In case of fire dangerous vapors / gases can be released Carbon monoxide Carbon dioxide

#### **5.3. Advice for firefighters**

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

#### **Additional information**

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

### **SECTION 6: Accidental release measures**

#### **6.1. Personal precautions, protective equipment and emergency procedures**

Provide adequate ventilation. Use personal protection equipment.

#### **6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

#### **6.3. Methods and material for containment and cleaning up**

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

#### **6.4. Reference to other sections**

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

### **SECTION 7: Handling and storage**

#### **7.1. Precautions for safe handling**

##### **Advice on safe handling**

Provide adequate ventilation. Keep container tightly closed. To prepare a dilution, always first fill in the water and then add the product.

##### **Advice on protection against fire and explosion**

No special fire protection measures are necessary.

##### **Further information on handling**

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs. Remove contaminated, saturated clothing immediately. Avoid contact with eyes.

#### **7.2. Conditions for safe storage, including any incompatibilities**

##### **Requirements for storage rooms and vessels**

Keep only in the original container in a cool, well-ventilated place. Keep container dry. Avoid: Frost. Keep out of the reach of children.

##### **Advice on storage compatibility**

Do not store together with: Food and feedingstuffs

##### **Further information on storage conditions**

Protect from sunlight.

#### **7.3. Specific end use(s)**

none

### **SECTION 8: Exposure controls/personal protection**

#### **8.1. Control parameters**



# Safety Data Sheet

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### Exposure limits (EH40)

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
111-30-8	Glutaraldehyde	0.05	0.2		TWA (8 h)	WEL
		0.05	0.2		STEL (15 min)	WEL
67-63-0	Propan-2-ol	400	999		TWA (8 h)	WEL
		500	1250		STEL (15 min)	WEL

### DNEL/DMEL values

CAS No	Substance	Exposure route	Effect	Value
111-30-8	1,5-pentanedial, glutaral			
	Worker DNEL, acute	inhalation	local	0.25 mg/m <sup>3</sup>
67-63-0	propan-2-ol; isopropanol			
	Worker DNEL, long-term	inhalation	systemic	500 mg/m <sup>3</sup>
	Worker DNEL, long-term	dermal	systemic	888 mg/kg bw/day
	Consumer DNEL, long-term	inhalation	systemic	89 mg/m <sup>3</sup>
	Consumer DNEL, long-term	dermal	systemic	319 mg/kg bw/day
	Consumer DNEL, long-term	oral	systemic	26 mg/kg bw/day

### PNEC values

CAS No	Substance	Environmental compartment	Value
111-30-8	1,5-pentanedial, glutaral		
	Freshwater		0.0025 mg/l
	Marine water		0.00025 mg/l
	Freshwater sediment		5.27 mg/kg
	Marine sediment		0.009 mg/kg
	Micro-organisms in sewage treatment plants (STP)		0.8 mg/l
	Soil		0.18 mg/kg
107-22-2	Ethandial		
	Freshwater		0.319 mg/l
	Marine water		0.0319 mg/l
	Freshwater sediment		0.685 mg/kg
	Marine sediment		0.0685 mg/kg
	Micro-organisms in sewage treatment plants (STP)		4.1 mg/l
	Soil		4.06 mg/kg
67-63-0	propan-2-ol; isopropanol		
	Freshwater		140.9 mg/l
	Marine water		140.9 mg/l
	Freshwater sediment		552 mg/l
	Marine sediment		552 mg/l
	Micro-organisms in sewage treatment plants (STP)		2251 mg/l
	Soil		28 mg/l

### 8.2. Exposure controls



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**Protective and hygiene measures**

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat or drink.

**Eye/face protection**

When handling the concentrated product (for example, transferring) use tight fitting eye protection.

**Hand protection**

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. Chemical protective gloves must specifically chosen for each workplace depending on the concentration and amount of hazardous substances, temperature and contact time.

Recommendation:

NBR (Nitrile rubber), Butyl caoutchouc (butyl rubber)

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

To prevent skin irritation in the professional field - regardless of actual contact with disinfectants - it is recommended to use: • a fast absorbing skin care cream in between if necessary. • a greasy cream after washing at the end of work or before breaks.

**Skin protection**

Wear suitable protective clothing.

**Respiratory protection**

In case of inadequate ventilation wear respiratory protection. ABEK

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state:	liquid
Colour:	blue
Odour:	Perfumes, fragrances
pH-Value (at 20 °C):	ca. 7

**Changes in the physical state**

Melting point:	not determined
Initial boiling point and boiling range:	not determined
Flash point:	53 °C

**Flammability**

Solid:	not applicable
Gas:	not applicable

Lower explosion limits:	not determined
Upper explosion limits:	not determined

**Auto-ignition temperature**

Solid:	not applicable
Gas:	not applicable

Decomposition temperature:	not determined
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**Oxidizing properties**

Not oxidising.

Vapour pressure:	not determined
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Density (at 20 °C):	ca. 1.05 g/cm <sup>3</sup>
Water solubility:	easily soluble
<b>Solubility in other solvents</b>	
not determined	
Partition coefficient:	not determined
Vapour density:	not determined
Evaporation rate:	not determined

**9.2. Other information****SECTION 10: Stability and reactivity****10.1. Reactivity**

Flammable. No hazardous reaction when handled and stored according to provisions.

**10.2. Chemical stability**

The product is chemically stable under recommended conditions of storage, use and temperature.

**10.3. Possibility of hazardous reactions**

Flammable. No hazardous reaction when handled and stored according to provisions.

**10.4. Conditions to avoid**

Safe handling: see section 7

**10.5. Incompatible materials**

Oxidising agent, strong

**10.6. Hazardous decomposition products**

The product is chemically stable under recommended conditions of storage, use and temperature.

**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute toxicity**

Harmful if swallowed.

**ATEmix tested**

	Dose	Species	Source
LD50, oral	1218 mg/kg	Rat SPF-Wistar	
LD50, dermal	>8000 mg/kg	Rat	
LC50, inhalative (aerosol)	6 mg/l		

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
7173-51-5	didecyldimethylammonium chloride				
	oral	LD50 238 mg/kg	Rat		OECD 410
	dermal	LD50 3342 mg/kg	Rabbit		
111-30-8	1,5-pentanedial, glutaral				
	oral	LD50 77 mg/kg	Rat		OECD 401
	dermal	LD50 >2000 mg/kg	Rat		OECD 402
	inhalative vapour	LC50 mg/l			not determined
	inhalative (4 h) aerosol	LC50 0.28-0.39 mg/l	Rat		OECD 403
107-22-2	Ethandial				
	oral	LD50 2000 - 5000 mg/kg	Rat		
	dermal	LD50 > 2000 mg/kg	Rat		
	inhalative vapour	LC50 mg/l	Rat		not determined
	inhalative (4 h) aerosol	LC50 2.44 mg/l	Rat		
69011-36-5	Isotridecanol, ethoxylated				
	oral	ATE 500 mg/kg			
67-63-0	propan-2-ol; isopropanol				
	oral	LD50 5840 mg/kg	Rat		
	dermal	LD50 13900 mg/kg	Rabbit		
	inhalative (4 h) vapour	LC50 37.5 mg/l	Rat		OECD 403

**Irritation and corrosivity**

Causes severe skin burns and eye damage.

In case of skin contact

Concentration 100% Rat: strongly irritant.

In case of eye contact

Concentration 1% OECD 405 Rabbit Not an irritant.

Glutaral (in aqueous solution)

In case of skin contact Rabbit corrosive (OECD 404)

In case of eye contact Rabbit irreversible damage (Draize-Test)

Glyoxal 40%

In case of skin contact Irritant (OECD 404)

In case of eye contact Irritant (OECD 405)

Didecyldimethylammoniumchlorid

In case of skin contact: Rabbit 3 Min OECD 404 Irritant

**Sensitising effects**

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May cause allergy or asthma symptoms or breathing difficulties if inhaled. (1,5-pentanedial, glutaral)

May cause an allergic skin reaction. (1,5-pentanedial, glutaral; Ethandial)

Glutaral (in aqueous solution)

Positive data from patch testing. (OET) Guinea pig

Glyoxal 40%

OECD 406 Guinea pig sensitising

Didecyldimethylammoniumchlorid

Buehler Test US-EPA Guinea pig Guinea pig negative.

**Carcinogenic/mutagenic/toxic effects for reproduction**

Suspected of causing genetic defects. (Ethandial)

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

**STOT-single exposure**

Based on available data, the classification criteria are not met.

**STOT-repeated exposure**

Based on available data, the classification criteria are not met.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

**SECTION 12: Ecological information****12.1. Toxicity**

The product is not: Ecotoxic.



### Safety Data Sheet

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
7173-51-5	didecyldimethylammonium chloride					
	Acute fish toxicity	LC50 0.19 mg/l	96 h	Pimephales promelas (fathead minnow)		
	Acute algae toxicity	ErC50 0.026 mg/l	96 h	Pseudokirchneriella subcapitata		OECD 201
	Acute crustacea toxicity	EC50 0.062 mg/l	48 h	Daphnia magna (Big water flea)		OECD 211
	Fish toxicity	NOEC 0.032 mg/l	34 d	Danio rerio		OECD 210
	Crustacea toxicity	NOEC 0.016 mg/l	21 d	Daphnia magna (Big water flea)		OECD 211
	Acute bacteria toxicity	(11 mg/l)	3 h	Activated sludge		OECD 209
111-30-8	1,5-pentanedial, glutaral					
	Acute fish toxicity	LC50 0.8 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)		
	Acute algae toxicity	ErC50 0.6 mg/l	72 h	Desmodesmus subspicatus		OECD 201
	Acute crustacea toxicity	EC50 2.1 mg/l	48 h	Daphnia magna (Big water flea)		
	Fish toxicity	NOEC 1.6 mg/l	97 d	Oncorhynchus mykiss (Rainbow trout)		
	Crustacea toxicity	NOEC 5 mg/l	21 d	Daphnia magna (Big water flea)		OECD 211
107-22-2	Ethandial					
	Acute fish toxicity	LC50 460 - 680 mg/l	96 h	Leuciscus idus (golden orfe)		
	Acute algae toxicity	ErC50 >100 mg/l	72 h	Scenedesmus subspicatus		
	Acute crustacea toxicity	EC50 404 mg/l	48 h	Daphnia magna (Big water flea)		
	Fish toxicity	NOEC 112 mg/l	34 d	Pimephales promelas (fathead minnow)		
	Crustacea toxicity	NOEC 3.19 mg/l		Daphnia magna (Big water flea)		
69011-36-5	Isotridecanol, ethoxylated					
	Acute fish toxicity	LC50 1 - 10 mg/l	96 h	Cyprinus carpio (Common Carp)		
	Acute algae toxicity	ErC50 1 - 10 mg/l	72 h	Desmodesmus subspicatus		
	Acute crustacea toxicity	EC50 1 - 10 mg/l	48 h			
	Acute bacteria toxicity	(140 mg/l)		Activated sludge		
67-63-0	propan-2-ol; isopropanol					
	Acute fish toxicity	LC50 9640 mg/l	96 h	Pimephales promelas (fathead minnow)		
	Acute algae toxicity	ErC50 >100 mg/l	72 h	Selenastrum capricornutum		
	Acute crustacea toxicity	EC50 9714 mg/l	48 h	Daphnia magna (Big water flea)		
	Acute bacteria toxicity	(> 100 mg/l)				

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

**Lysoformin 3000**

Revision date: 01.03.2018

Product code: LYS648

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**12.2. Persistence and degradability**

DIN 38412-25, 17 d: 90%

Readily biodegradable.

CAS No	Chemical name	Method	Value	d	Source
		Evaluation			
7173-51-5	didecyldimethylammonium chloride				
	OECD 301B/ ISO 9439/ EEC 92/69/V, C.4-C		72%	28	
	Readily biodegradable (according to OECD criteria).				
	OECD 301A/ ISO 7827/ EEC 92/69/V, C.4-A		93.3	28	
	OECD 303/ EEC 92/69/V, C10		91%	70	
111-30-8	1,5-pentanedial, glutaral				
	OECD 301A/ ISO 7827/ EEC 92/69/V, C.4-A		90 - 100 %	28	
	Readily biodegradable (according to OECD criteria).				
107-22-2	Ethandial				
			90-100% (DOC)	19	
	Readily biodegradable (according to OECD criteria).				
69011-36-5	Isotridecanol, ethoxylated				
	OECD 301B/ ISO 9439/ EEC 92/69/V, C.4-C		>60%	28	
	Readily biodegradable (according to OECD criteria).				
67-63-0	propan-2-ol; isopropanol				
			53%	5	
	Readily biodegradable.				

**12.3. Bioaccumulative potential**

The product has not been tested.

**Partition coefficient n-octanol/water**

CAS No	Chemical name	Log Pow
111-30-8	1,5-pentanedial, glutaral	-0.36
67-63-0	propan-2-ol; isopropanol	0.05

**12.4. Mobility in soil**

The product has not been tested.

**12.5. Results of PBT and vPvB assessment**

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

**12.6. Other adverse effects**

No information available.

**Further information**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Advice on disposal**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

**Waste disposal number of waste from residues/unused products**

070604 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics; other organic solvents, washing liquids and mother liquors; hazardous waste

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according to Regulation (EC) No 1907/2006

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**Waste disposal number of contaminated packaging**


150102 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); plastic packaging

**Contaminated packaging**

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

**SECTION 14: Transport information****Land transport (ADR/RID)**


**14.1. UN number:** UN 2924  
**14.2. UN proper shipping name:** FLAMMABLE LIQUID, CORROSIVE, N.O.S. (glutaral; glutaraldehyde; 1,5-pentanedial, didecyldimethylammonium chloride)  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** III  
Hazard label: 3+8



Classification code: FC  
Special Provisions: 274  
Limited quantity: 5 L  
Excepted quantity: E1  
Transport category: 3  
Hazard No: 38  
Tunnel restriction code: D/E

**Marine transport (IMDG)**

**14.1. UN number:** UN 2924  
**14.2. UN proper shipping name:** FLAMMABLE LIQUID, CORROSIVE, N.O.S. (glutaral; glutaraldehyde; 1,5-pentanedial, didecyldimethylammonium chloride)  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** III  
Hazard label: 3+8



Special Provisions: 223, 274  
Limited quantity: 5 L  
Excepted quantity: E1  
EmS: F-E, S-C

**Air transport (ICAO-TI/IATA-DGR)**

**14.1. UN number:** UN 2924  
**14.2. UN proper shipping name:** FLAMMABLE LIQUID, CORROSIVE, N.O.S. (glutaral; glutaraldehyde; 1,5-pentanedial, didecyldimethylammonium chloride)  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** III  
Hazard label: 3+8

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

**Lysoformin 3000**

Revision date: 01.03.2018

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Special Provisions:	A3 A803
Limited quantity Passenger:	1 L
Passenger LQ:	Y342
Excepted quantity:	E1
IATA-packing instructions - Passenger:	354
IATA-max. quantity - Passenger:	5 L
IATA-packing instructions - Cargo:	365
IATA-max. quantity - Cargo:	60 L

**14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: yes

**14.6. Special precautions for user**

No information available.

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

not applicable

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulatory information**

Employment restrictions:	Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).
Water contaminating class (D):	3 - highly water contaminating

**15.2. Chemical safety assessment**

Chemical safety assessments for substances in this mixture were not carried out.

**SECTION 16: Other information****Changes**

This data sheet contains changes from the previous version in section(s): 2.

**Abbreviations and acronyms**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service  
LC50: Lethal concentration, 50%  
LD50: Lethal dose, 50%

**Relevant H and EUH statements (number and full text)**

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H301	Toxic if swallowed.



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H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H341	Suspected of causing genetic defects.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.

**Further Information**

The data contained in this safety data sheet is based on our current knowledge and experience and describe the product with regard to safety requirements. The information should not be regarded in any way as a description of the product's properties (product specification). Agreed characteristics nor the suitability of the product for a specific purpose can not be derived from the information in the SDS. We will advise you as to whether and under what circumstances, the preparation is suitable for a defined purpose. Proprietary rights and existing laws and regulations must be respected by the receiver of our product.

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*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*



an alle Anwender
致所有用户
To all users

Ihre Zeichen

Ihre Nachricht vom

Unsere Zeichen



Datum

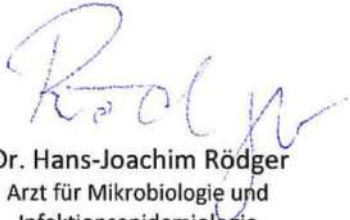
HJR/Hm

2 99 77 (30) 49+ -211

29.01.2020

Table with 3 columns: German title, Chinese title, English title. Each column contains a paragraph of text describing the efficacy of Lysoform disinfectants against the novel coronavirus.

<p>wir bei Coronavirus-Verdacht folgende Präparate zur Händedesinfektion, u. a. nach direktem Patientenkontakt, nach Kontakt mit erregerehaltigem Material oder nach Ablegen der Handschuhe:</p> <p>AHD 2000 gebrauchsfertig bei einer Einwirkzeit von 1 Minute</p> <p>oder</p> <p>Hospisept gebrauchsfertig bei einer Einwirkzeit von 0 Minuten</p> <p>Zur täglichen Scheuer- / Wisch-Desinfektion (z. B. Nachttisch, Türgriffe, Nassbereich) oder zur Desinfektion der Kontaktflächen unmittelbar nach dem Transport eines Erkrankten und vor erneuter Nutzung des Transportmittels u. ä. sollen folgende Präparate eingesetzt werden:</p> <p>Aerodesin 2000: gebrauchsfertig – 10 Minuten</p> <p>Fugaten-Spray: gebrauchsfertig – 10 Minuten</p> <p>Aldasan 2000: 10,0 – 10 Minuten, 20,0 – 10 Minuten</p> <p>Lysoformin 3000: 10,0 – 10 Minuten, 10,0 – 0 Minuten</p> <p>Clorina: 10,0 – 2 Minuten</p> <p>Trichlorol: 10,0 – 10 Minuten</p> <p>Es gibt bisher keinerlei Methoden zur Prüfung der Resistenz von Coronaviren gegenüber Desinfektionsmitteln.</p>	<p>所以我们建议如果怀疑新型冠状病毒产生的情况下，特别是直接接触被怀疑受感染的病人或接触过有可能受到病原体感染的材料，脱掉手套后用以下产品进行手消毒：</p> <p>AHD 2000 原液作用1分钟</p> <p>或者</p> <p>Hospisept 原液作用0分钟</p> <p>对于每天进行的搓擦/洗擦消毒步骤（例如床头柜，门把手，潮湿的地方）或者对于运输过病人的运输工具特别是病人接触过的表面在运输其他病人前用以下产品：</p> <p>Aerodesin 2000 艾罗兹英 2000 :原液 – 10分钟</p> <p>Fugaten-Spray: 原液 – 10分钟</p> <p>Aldasan 2000: 10,0 稀释液 – 10分钟, 20,0 稀释液 – 0分钟</p> <p>Lysoformin 3000: 10,0 稀释液 – 10 分钟 10,0 稀释液 – 0 分钟</p> <p>Clorina: 10,0 稀释液 – 2 分钟</p> <p>Trichlorol: 10,0 稀释液 – 10分钟</p> <p>目前尚无任何实验方法来验证新型冠状病毒是否对消毒剂产生耐药性。</p>	<p>apply the following products for hand disinfection e.g. after direct contact with a patient, after contact with pathogenic material or after taking off gloves:</p> <p>AHD 2000 ready-to-use at a contact time of 1 minute</p> <p>or</p> <p>Hospisept ready-to-use at a contact time of 0 minutes.</p> <p>For daily rub-/wipe disinfection (e.g. bedside table, door handles, wet area) or for disinfecting the contact surfaces immediately after having transported an ill patient before re-using the means of transportation etc., the following products should be used:</p> <p>Aerodesin 2000: ready-to-use – 10 minutes</p> <p>Fugaten-Spray: ready-to-use – 10 minutes</p> <p>Aldasan 2000: 10,0 – 10 minutes 20,0 – 10 minutes</p> <p>Lysoformin 3000: 10,0 – 10 minutes 10,0 – 0 minutes</p> <p>Clorina 10,0 – 2 minutes</p> <p>Trichlorol: 10,0 – 10 minutes</p> <p>At present there are no methods available for verifying the resistance of coronaviruses against disinfectants.</p>
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<p>Die Angaben zu den Konzentrationen und Einwirkzeiten beruhen auf Analogschlüssen bereits vorhandener Testergebnisse.</p> <p>Lysoform Dr. Hans Rosemann GmbH</p>  <p><b>Dr. Hans-Joachim Rödger</b> Arzt für Mikrobiologie und Infektionsepidemiologie</p>	<p>以上标注的使用浓度和作用时间基于有效的实验报告。</p> <p>德国莱素芳消毒剂有限公司</p> <p>Hans-Joachim Rödger博士 微生物学和感染流行病学 专科医生</p>	<p>Concentrations and contact times are based on analogous conclusions referring to already existing test results.</p> <p>Lysoform Dr. Hans Rosemann GmbH</p> <p>Dr. Hans-Joachim Rödger M.D. for Microbiology and Epidemiology of Infectious Diseases</p>
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# Lysoformin 3000®



Disinfectant	Uses	Properties	Dilution
<b>LYSOFORMIN 3000</b>  <u>100 gm solution contains :</u> <ul style="list-style-type: none"><li>➤ 7.5 g Glyoxal</li><li>➤ 9.5 g Glutaral</li><li>➤ 9.6 g Didecyldimethyl ammonium Chloride</li></ul>	<ul style="list-style-type: none"><li>➤ Disinfection of Surfaces ,</li><li>➤ Walls ,</li><li>➤ Floors</li></ul>	<ul style="list-style-type: none"><li>➤ High Level Disinfectant</li><li>➤ Control of bacteria (TB), viruses and fungi.</li><li>➤ Activation with tap water or hard water.</li><li>➤ No Aldehyde Fumes.</li><li>➤ Cleaning &amp; disinfection in one-step.</li><li>➤ The solution (free from organic residue) valid for 14 days after activation.</li><li>➤ Contain no Aldehydes, no phenols no oxidizing compounds</li></ul>	<b>20 ml diluted to 8 liter water</b>

التخفيف	الخصائص	الاستخدامات	المطهر
<b>20 ml diluted to 8 liter water</b>	<ul style="list-style-type: none"><li>➤ مطهر عالي الاداء.</li><li>➤ القضاء على معظم أنواع البكتريا (السل) والفيروسات والفطريات.</li><li>➤ يتم تنشيط المطهر باستخدام ماء الصنبور أو الماء العسر.</li><li>➤ لا تتصاعد أبخرة الألداهيد السامه بعد التنشيط .</li><li>➤ التعقيم والتنظيف في خطوه واحده.</li><li>➤ المحلول صالح للاستخدام لمدة 14 يوما بعد التنشيط.</li></ul>	<ul style="list-style-type: none"><li>➤ تعقيم وتطهير الاسطح، الارضيات و الحوائط</li></ul>	<b>LYSOFORMIN 3000</b>  <u>100 gm solution contains :</u> <ul style="list-style-type: none"><li>➤ 7.5 g Glyoxal</li><li>➤ 9.5 g Glutaral</li><li>➤ 9.6 g Didecyldimethyl ammonium Chloride</li></ul>

Lysoform Dr. Hans Rosemann GmbH

Head Office: Jeddah, KSA

mob.: 8749 287 54 966+

mashaly@sapphire.com.sa

[www.lysoform.de](http://www.lysoform.de)

## Lysoformin 3000®

- Dilution Rate

- 20 ml diluted to 8 liter water.



- Application on Surfaces :

- Clean the surface well
- Spray the solution on the surface and keep it 5 mins
- Wipe the surface in one way direction

- Application on Floors :

- Clean the floors first
- Spray the solution on floors and keep it to dry



Lysoform

Dr. Hans Rosemann GmbH

Berlin - Germany

KSA ≈ Tel.: 54 966+ 287 8749

## Lysoformin 3000®



### التخفيف :-

➤ 20 مل تخفف الى 8 لتر ماء

### تعقيم الاسطح :-

- تنظيف الاسطح جيدا
- يرش المحلول المعقم على الاسطح ويترك لمدة 5 دقائق
- تمسح الاسطح في اتجاه واحد

### تعقيم الارضيات :-

- تنظيف الارضيات جيدا
- يرش المحلول المعقم على الاسطح ويترك حتى يجف



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## Lysoformin 3000®



### ● प्रदूषण दर :-

- 20 मिलीलीटर 8 लीटर पानी के मलए पतला

### ● सतहों पर आवेदन :-

- सतह क **अच्छे** से साफ **करें**
- घ ल क सतह पर **स्प्रे करें** और इसे 5 मनिट **रखें**
- सतह क एक तरह से मदशा **में पोछें**

### ● फशश पर आवेदन :-

- फशश क **अच्छी** तरह से साफ **करें**
- घ ल क फशश पर **स्प्रे करें** और सूखने के मलए रख **दें**



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Dr. Hans Rosemann GmbH

Berlin - Germany

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# Lysoform Dr. Hans Rosemann GmbH

Lysoform Dr. Hans Rosemann GmbH · Kaiser-Wilhelm-Straße 133 · 12247 Berlin / Deutschland

Sapphire for Medical Services  
P.O. Box 122540  
Jeddah 21332  
Kingdom of Saudi Arabia

Ihre Zeichen	Ihre Nachricht vom	Unsere Zeichen HJR/Hm	 +49 (30) 77 99 2-211	Datum 20.12.2019
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We herewith confirm that Sapphire for Medical Services Co. Ltd. is still our agent in Saudi Arabia.

Lysoform Dr. Hans Rosemann GmbH

  
Dr. Hans-Joachim Rödger  
CEO

**Lysoform**  
Dr. Hans Rosemann GmbH  
Kaiser-Wilhelm-Str. 133  
12247 Berlin

UR-Nr. 9/2020

Die Frage des Notars nach einer Vorbefassung gem. § 3 Abs. 1 Nr. 7 Beurkundungsgesetz wurde von dem Erschienenen verneint.

Vorstehende vor mir anerkannte Unterschrift des

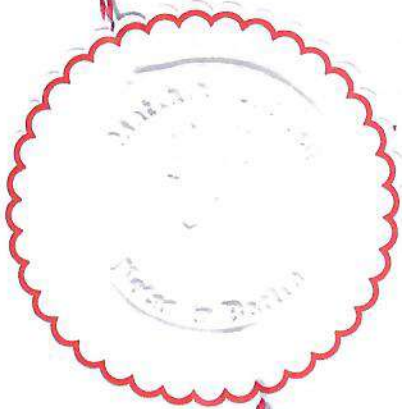
Herrn Dr. Hans-Joachim Rödger, geb. am 01.05.1948,  
wohnhaft Edelhofdamm 45 in 13465 Berlin,

beglaubige ich hiermit.

Der Erschienenene ist dem Notar von Person bekannt.

Berlin, den 16.01.2020

  
Notar



Die Echtheit vorstehender Unterschrift des Notars in Berlin

**Matthias Olbrich**

und die Echtheit des beigedrückten Dienstsiegels werden hiermit bestätigt. Zugleich wird bescheinigt, dass der Vorgenannte zur Vornahme der Amtshandlung gesetzlich befugt war.

Berlin, den 23. Januar 2020

Der Präsident des Landgerichts  
Im Auftrag



  
(Höning)

Vorsitzender Richter am Landgericht

9101 E/F 281/20

Gebühren 25,00 € bezahlt.

Berlin, den 23. Januar 2020



(Kujath)  
Justizamtsinspektorin





Die Unterschrift  
des Herrn Höning,  
Vorsitzender Richter am  
Landgericht Berlin,  
wird hiermit beglaubigt.  
50728 Köln, den 14.02.2020



**Nur zur Legalisation für das Land:  
Saudi-Arabien**

**Das Bundesverwaltungsamt  
im Auftrag des Auswärtigen Amtes  
der Bundesrepublik Deutschland**

Im Auftrag

  
Conrad  
Tarifbeschäftigte

Gebühr EUR 25,--



٩٤٥٠٠٤١  
الرسوم مدفوعة  
Gebühren bezahlt

إتفاق سفارة المملكة العربية السعودية  
القسم القنصلي في برلين على صحة  
التوقيع والتوقيع دون مسؤولية عن المتويات  
التاريخ: ٠٨ رجب ١٤٤١  
03. März. 2020 ٧٦٤٤  
من رئيس القسم القنصلي



Mohammed M. Al Kahtani  
محمد بن معيض القحطاني



Verbund für Angewandte Hygiene (VAH)  
Association for Applied Hygiene  
– Desinfektionsmittel-Kommission im VAH –  
Disinfectant Commission in VAH

**Zertifikat / Certificate**

über die Konformität der Wirksamkeitsprüfungen für / for conformity of efficacy tests for  
**Lysoformin® 3000**

mit den Anforderungen und Methoden zur VAH-Zertifizierung chemischer Desinfektionsverfahren –  
Stand 2.4.2015 - bzw. den Übergangsbestimmungen vom 2.4.2015  
with the requirements and methods of VAH-certification for chemical disinfection procedures –  
as per 2 April 2015 - and the transitional provisions of 2 April 2015, respectively.

ANTRAGSTELLER / APPLICANT:

**Lysoform Dr. Hans Rosemann GmbH  
Kaiser-Wilhelm-Str. 133  
12247 Berlin**

WIRKSTOFFE nach Art und Menge bezogen auf 100 g: / Quantity of active substances per 100 g:  
**9,60 g Didecylidimethylammoniumchloride      9,50 g Glutaral      7,50 g Glyoxal**

Hiermit wird bestätigt, dass das o.g. Produkt für die prophylaktische Desinfektion in den aufgeführten Anwendungsbereichen in folgenden Konzentrations-Zeit-Relationen als wirksam eingestuft wird:  
This is to confirm that the above product was found to be effective for prophylactic disinfection in the application domains listed below at the specified concentration/contact time ratios:

Instrumentendesinfektion zur Prophylaxe in Krankenhaus und Praxis (Bakterizide und Levurozide)			
Instrument disinfection for prophylaxis in hospital and primary healthcare (bactericidal activity and yeasitcidal activity)			
Organische Belastung Interfering substance		Einwirkzeit in min Contact time in min	
gering/clean conditions	5	15	30
hoch/dirty conditions	X		60

Das Zertifikat ist gültig vom 28.02.2020 bis zum 28.02.2023 (3 Jahre) /  
Certificate is valid from 28.02.2020 until 28.02.2023 (3 years)

Der Antragsteller hat sich mit den Bedingungen der zum Zeitpunkt der Antragstellung gültigen Geschäftsordnung der Desinfektionsmittelkommission im VAH einverstanden erklärt und rechtsverbindlich bestätigt, dass das von ihm in Handel gebrachte Präparat in seiner Zusammensetzung identisch mit den für die Erstellung der Gutachten eingereichten Mustern ist. /  
The applicant has agreed to the conditions laid down in the rules of the disinfectant commission in the VAH valid at the time of application and has legally binding confirmed that the distributed product is identical with the product used for the activity testing.

Bonn, den **12.12.2019**  
Place/Date

Der Vorsitzende der Desinfektionsmittelkommission im VAH /  
The Chairman of the Disinfectant Commission in VAH

Az.: N19/232



Verbund für Angewandte Hygiene (VAH)  
Association for Applied Hygiene  
– Desinfektionsmittel-Kommission im VAH –  
Disinfectant Commission in VAH

## Zertifikat / Certificate

über die Konformität der Wirksamkeitsprüfungen für / for conformity of efficacy tests for

### Lysoformin® 3000

mit den Anforderungen und Methoden zur VAH-Zertifizierung chemischer Desinfektionsverfahren –  
Stand 2.4.2015 - bzw. den Übergangsbestimmungen vom 2.4.2015  
with the requirements and methods of VAH-certification for chemical disinfection procedures –  
as per 2 April 2015 - and the transitional provisions of 2 April 2015, respectively.

ANTRAGSTELLER / APPLICANT:

**Lysoform Dr. Hans Rosemann GmbH**  
**Kaiser-Wilhelm-Str. 133**  
**12247 Berlin**

WIRKSTOFFE nach Art und Menge bezogen auf 100 g: / Quantity of active substances per 100 g:

**9,6 g Didecyldimethylammoniumchlorid      9,5 g Pentanedial (Glutaral)**

**7,5 g 1,2-Ethandial (Glyoxal)**

Hiermit wird bestätigt, dass das o.g. Produkt für die prophylaktische Desinfektion in den aufgeführten Anwendungsbereichen in folgenden Konzentrations-Zeit-Relationen als wirksam eingestuft wird:

This is to confirm that the above product was found to be effective for prophylactic disinfection in the application domains listed below at the specified concentration/contact time ratios:

Flächendesinfektion zur Prophylaxe in Krankenhaus und Praxis (Bakterizide und Levurozide) Surface disinfection for prophylaxis in hospital and primary healthcare (bactericidal activity and yeasticidal activity)		Flächeneinsatztyp / Type of Surface disinfectant:			
Mechanical action	Organische Belastung Interfering substance	Einwirkzeit in min Contact time in min			
		Wischen ohne/ with/without	gering/clean conditions	hoch/dirty conditions	
X			X		

Das Zertifikat ist gültig vom 08.08.2018 bis zum 08.08.2021 (3 Jahre) /  
Certificate is valid from 08.08.2018 until 08.08.2021 (3 years)

Der Antragsteller hat sich mit den Bedingungen der zum Zeitpunkt der Antragstellung gültigen Geschäftsordnung der Desinfektionsmittelkommission im VAH einverstanden erklärt und rechtsverbindlich bestätigt, dass das von ihm in Handel gebrachte Präparat in seiner Zusammensetzung identisch mit den für die Erstellung der Gutachten eingesetzten Mustern ist. /  
The applicant has agreed to the conditions laid down in the rules of the disinfectant commission in the VAH valid at the time of application and has legally binding confirmed that the distributed product is identical with the product used for the activity testing.

Bonn, den **08.08.2018**  
Place/Date

Der Vorsitzende der / The Chairman of the  
Desinfektionsmittel-Kommission im VAH / Disinfectant Commission in VAH - Ident.No N18/192





# Certificate

## The Certification Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH  
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**Lysoform Dr. Hans Rosemann GmbH  
Kaiser-Wilhelm-Straße 133  
12247 Berlin  
Germany**

has introduced, applies and maintains a Quality Management System in the area of:

### **Design, manufacture, final inspection and distribution of**

- **Disinfectants**
- **Disinfecting detergents**
- **Detergents**
- **Dosing techniques for disinfectants, disinfecting detergents and detergents**
- **Application accessories for disinfectants, disinfecting detergents and detergents**

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

**EN ISO 13485:2016**

The license of certification is subject to surveillance by MEDCERT.

**This certificate is valid until: 30 April 2022**

Report No.: 1208FS22F

Process No.: QS - 1208

Certificate No.: 1208GB445190801

Hamburg, 01 August 2019

  
MEDCERT Certification Body  
(Dr. Andreas Schich)

# EC Certificate of Conformity

## The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH  
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company:

**Lysoform Dr. Hans Rosemann GmbH  
Kaiser-Wilhelm-Straße 133  
12247 Berlin  
Germany**

has introduced and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

## Annex II without section 4

This certification is subject to surveillance by MEDCERT.

**This certificate is valid until 30 April 2024**

Report No.: 1208FS22F  
Process No.: QS – 1208  
Certificate No.: 1208GB410190801  
Hamburg, 01 August 2019

  
MEDCERT Certification Body  
(Dr. Andreas Schichl)

The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 10 / 2019.05.22



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zig.de  
ZIG-BS-237.10.15



## Appendix of EC Certificate of Conformity

Process No.: QS – 1208

Certificate No.: 1208GB410190801

### List of products / product categories included in the scope of certificate

- **Disinfectants**

– End of list –

This appendix is integral part of the above-referenced certificate.  
The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 10 / 2019.05.22



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-237.10.15

Executive Department of Registration and Licensing

إذن تسويق جهاز / منتج طبي

الإدارة التنفيذية للتسجيل والتراخيص

### Medical Device Marketing Authorisation

Issuing Date (dd/mm/yyyy) : ٢٠١٨/٠٢/٢١ Authorization Number : MDMA١٨٠٢٠٢٠١ : رقم الاذن : ٠٥/٠٦/١٤٣٩ تاريخ الإصدار :  
Expiry Date (dd/mm/yyyy) : ٢٠٢١/٠٤/٣٠ Issuing Number : ١ : رقم الإصدار : ١٨/٠٩/١٤٤٢ تاريخ الانتهاء :

This authorisation is issued in accordance with the Medical devices interim regulation (MDIR) and in particular to the implementing rule MDS-IR<sup>١</sup> for Medical Device Marketing Authorisation (MDMA)

أصدر هذا الإذن بموجب لائحة رقابة الأجهزة والمنتجات الطبية والقواعد الإجرائية (MDS-IR<sup>١</sup>) الخاصة بإذن تسويق الأجهزة والمنتجات الطبية.

This authorization allows:

هذا الإذن يخول :

Manufacturer Identification Number M٠٦١٥٢
LYSOFORM DR. HANS ROSEMANN GMBH
Kaiser-Wilhelm - Str. ١٣٣ , Berlin D١٢٢٤٧- Germany

To market the medical devices listed in the attached annex\* in the Kingdom of Saudi Arabia.

بتسويق الأجهزة / المنتجات الطبية المحددة في القائمة المرفقة\* في المملكة العربية السعودية.

المدير التنفيذي للتسجيل و التراخيص

Executive Director of Registration & Licensing



\*The attached annex is an integral part of this authorisation

\* بعد المرفق جزءا مكملًا لهذا الاذن.

## قائمة مرفقه بإذن تسويق جهاز / منتج طبي

## Annex of Medical Device Marketing Authorisation

Issuing Date (dd/mm/yyyy) : ٢٠١٨/٠٢/٢١      Annex Number : MDMA١٨٠٢٠٢٠١      رقم المرفق : ٠٥/٠٦/١٤٣٩      تاريخ الإصدار : ٠٥/٠٦/١٤٣٩  
Expiry Date (dd/mm/yyyy) : ٢٠٢١/٠٤/٣٠      Number of Annex Pages : ١      عدد صفحات المرفق : ١٨/٠٩/١٤٤٢      تاريخ الانتهاء : ١٨/٠٩/١٤٤٢

This annex is an integral part of the Medical Devices Marketing Authorisation Number ( MDMA١٨٠٢٠٢٠١ ), issuing Number ( ١ ).

يعد هذا المرفق جزءاً مكملاً لإذن تسويق جهاز / منتج طبي رقم ( MDMA١٨٠٢٠٢٠١ ) ورقم إصدار ( ١ ).

Issued to:	Manufacturer Identification Number M٠٦١٥٢		أصدرت لـ:
	LYSOFORM DR. HANS ROSEMANN GMBH		
	Kaiser-Wilhelm - Str. ١٣٣ , Berlin D١٢٢٤٧- Germany		
	الاسم التجاري	وصف الجهاز/المنتج الطبي	رقم قيد الجهاز / المنتج الطبي في السجل الوطني
	Brand / Trade Name	Product Description	Medical Device National Listing Number
١.	Almyrol	Disinfection solution for medical devices	MM٠٦١٥٢SFDA٠٠٠٣
٢.	Lysoformin ٣٠٠٠	Disinfection solution for surfaces and medical devices	MM٠٦١٥٢SFDA٠٠٠٤



### Medical Device Establishment License

Saudi Food and Drug Authority certifies that:

تشهد الهيئة العامة للغذاء والدواء بأن:

Sapphire for Medical Services

Establishment National Registry Number: MDNR٠٩٠٩٠١٠١

Is licensed by the Saudi Food and Drug Authority to operate in the field of Medical devices pursuant to the Medical Device Interim Regulation for the activities defined in the license.

The establishment must obtain a separate market authorization certificate for each of its' product

مُرخصة لديها للعمل في مجال الأجهزة والمنتجات الطبية بموجب لائحة رقابة الاجهزة والمنتجات الطبية لممارسة الأنشطة المحددة في هذه الرخصة هذه الرخصة لا تعني المنشأة عن ضرورة الحصول على إذن للتسويق لكل منتج من منتجاتها

License Number :	٠٦١٩٠٢٢٣	٠٦١٩٠٢٢٣	رقم الرخصة :
Issuing Date :	٢٠١٩/٠٦/٣٠	٢٧/١٠/١٤٤٠	تاريخ الإصدار :
Expiry Date :	٢٠٢٠/٠٦/١٨	٢٦/١٠/١٤٤١	تاريخ الانتهاء :
Establishment Category :	D	د	درجة تصنيف المنشأة :
Establishment Activity :	Distribution & Importation	توزيع و إستيراد	نشاط المنشأة :
			المدير التنفيذي للتسجيل و التراخيص

Executive Director of Registration & Licensing

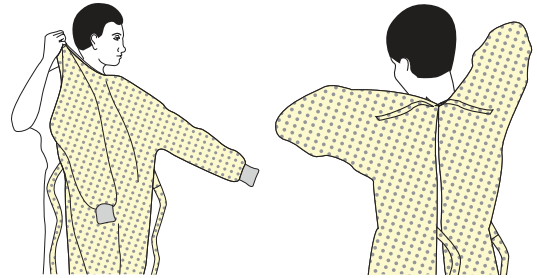


## SEQUENCE FOR PUTTING ON PERSONAL PROTECTIVE EQUIPMENT (PPE)

The type of PPE used will vary based on the level of precautions required, such as standard and contact, droplet or airborne infection isolation precautions. The procedure for putting on and removing PPE should be tailored to the specific type of PPE.

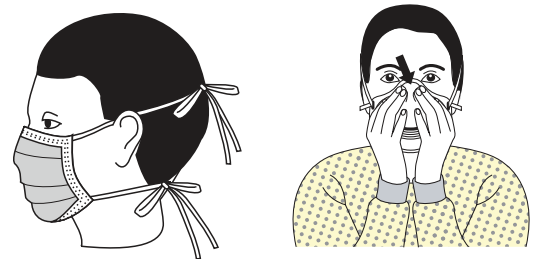
### 1. GOWN

- Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back
- Fasten in back of neck and waist



### 2. MASK OR RESPIRATOR

- Secure ties or elastic bands at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin
- Fit-check respirator



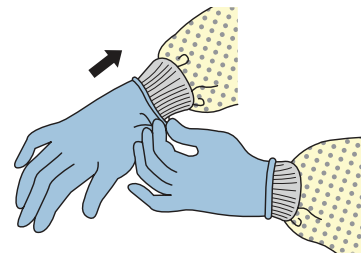
### 3. GOGGLES OR FACE SHIELD

- Place over face and eyes and adjust to fit



### 4. GLOVES

- Extend to cover wrist of isolation gown



## USE SAFE WORK PRACTICES TO PROTECT YOURSELF AND LIMIT THE SPREAD OF CONTAMINATION

- Keep hands away from face
- Limit surfaces touched
- Change gloves when torn or heavily contaminated
- Perform hand hygiene



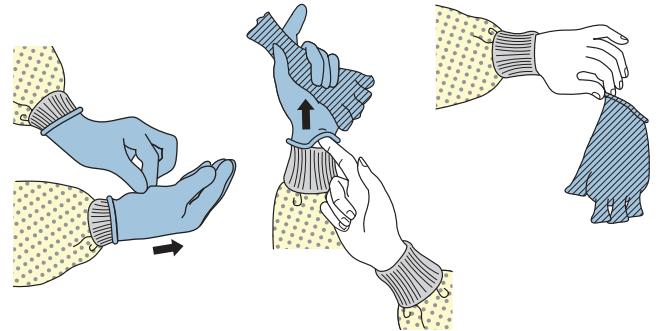
# HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE)

## EXAMPLE 1

There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Here is one example. Remove all PPE before exiting the patient room except a respirator, if worn. Remove the respirator after leaving the patient room and closing the door. Remove PPE in the following sequence:

### 1. GLOVES

- Outside of gloves are contaminated!
- If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
- Discard gloves in a waste container



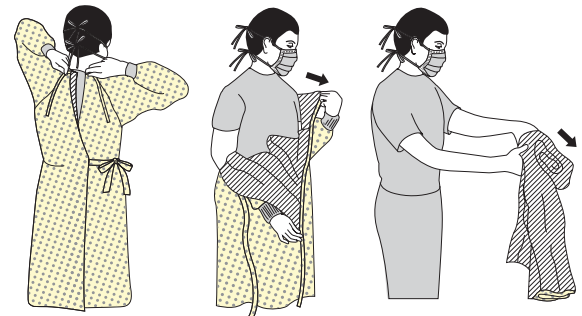
### 2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggles or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band or ear pieces
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container



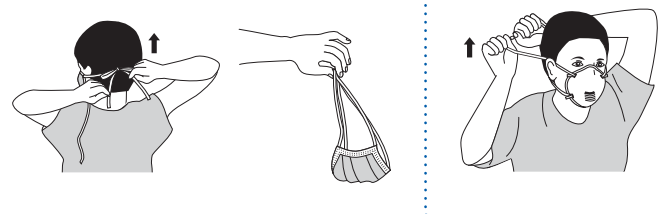
### 3. GOWN

- Gown front and sleeves are contaminated!
- If your hands get contaminated during gown removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Unfasten gown ties, taking care that sleeves don't contact your body when reaching for ties
- Pull gown away from neck and shoulders, touching inside of gown only
- Turn gown inside out
- Fold or roll into a bundle and discard in a waste container

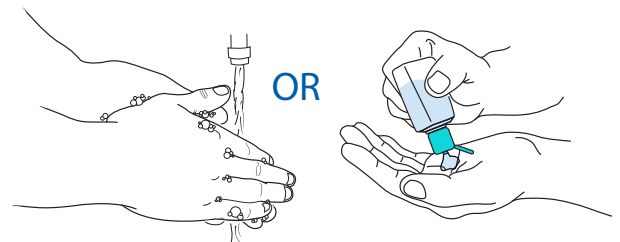


### 4. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — **DO NOT TOUCH!**
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container



### 5. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE





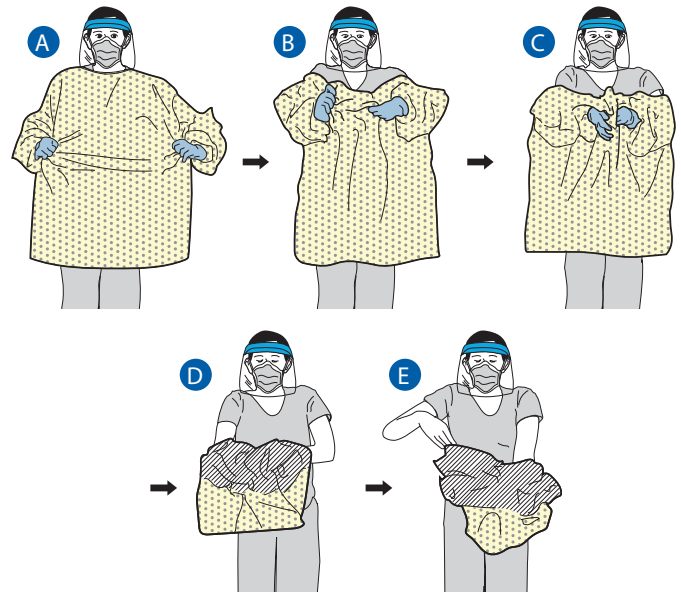
# HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE)

## EXAMPLE 2

Here is another way to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Remove all PPE before exiting the patient room except a respirator, if worn. Remove the respirator after leaving the patient room and closing the door. Remove PPE in the following sequence:

### 1. GOWN AND GLOVES

- Gown front and sleeves and the outside of gloves are contaminated!
- If your hands get contaminated during gown or glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp the gown in the front and pull away from your body so that the ties break, touching outside of gown only with gloved hands
- While removing the gown, fold or roll the gown inside-out into a bundle
- As you are removing the gown, peel off your gloves at the same time, only touching the inside of the gloves and gown with your bare hands. Place the gown and gloves into a waste container



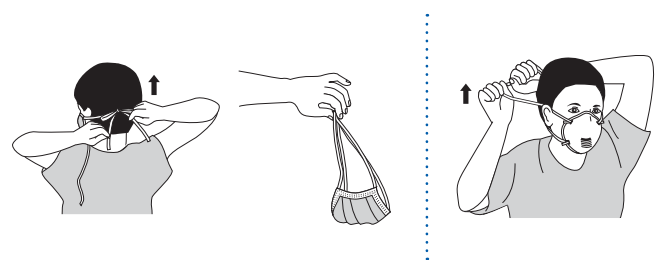
### 2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggles or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band and without touching the front of the goggles or face shield
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container

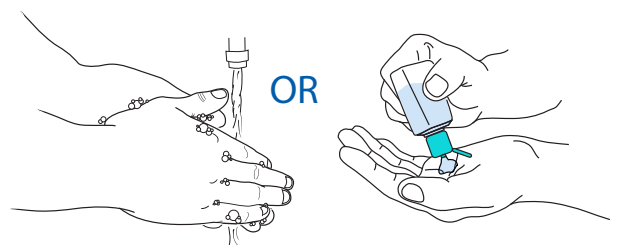


### 3. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container



### 4. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE



الرقم: ١٦٤٧١/٧/٧  
التاريخ: ١٤٤١/٧/١١  
التلفقات: Encl: .....



الإدارة العامة للصيانة  
Maintenance Department  
قطاع المطارات

المكرم/ مدير مشروع الطيران المدني  
شركة الجودة للمقاولات المحدودة بالتزامن مع مجموعة المجال العربي (المجموعة الثانية - عقد ١)  
السلام عليكم ورحمة الله وبركاته

الموضوع: طلب الموافقة على مواد مطهرة ومعقمة ضد البكتيريا والفيروسات لجميع مرافق وأسطح  
مطارات المجموعة الثانية

إشارة الى خطابكم رقم G2PM/2020/93 بتاريخ ١٤٤١/٦/٨ هـ بشأن الموافقة  
على المواد المطهرة والمعقمة لجميع مرافق واسطح مطارات المجموعة الثانية.

عليه نفيديكم بأنه لا مانع لدينا من استخدام المواد المطهرة والمعقمة للوقاية من  
العدوى الفيروسية والبكتيرية وتعقيم جميع الأرضيات والأسطح ومنصات إنهاء إجراءات  
السفر والجوازات ونقاط التفتيش وأي مكان آخر يستخدمه مرتادي المطار.

وتقبلوا تحياتنا «»

نائب مساعد الرئيس للمطارات  
مدير عام الإدارة العامة للصيانة المكلف  
د/ عيد بن موسى المطيري

ص. مدير تقييم الصيانة وأداء المقاولين

ص. مدير إدارة المرافق.

ص. مشرف تقييم الصيانة بالمجموعة.

ص. مشرف قسم النظافة المكلف.

ص. مكتب المدير العام (للمراجعة).

م. ج. (MKQ) (AS) (TOK) (PHD)

س. م. (SABER ALQARNI) ١٤٤١/٧/١٢



**GACA INCOMING LETTER - ACTION SHEET**

<input checked="" type="checkbox"/> O&M Coordinator	<input type="checkbox"/> L / S Engineer
<input type="checkbox"/> Mechanical Engineer	<input checked="" type="checkbox"/> Log Coordinator
<input type="checkbox"/> Electrical Engineer	<input type="checkbox"/> BOQ Coordinator
<input type="checkbox"/> Civil Engineer	<input type="checkbox"/> Accountant
<input type="checkbox"/> Electronics Engineer	<input type="checkbox"/> Architect
<input type="checkbox"/> Telephonically <input type="checkbox"/> In person <input type="checkbox"/> In Discuss <input type="checkbox"/> Confidential <input type="checkbox"/> Reply <input type="checkbox"/> Top Urgent <input type="checkbox"/> For Information <input type="checkbox"/> For Action <input type="checkbox"/> Memo <input type="checkbox"/> Other <input type="checkbox"/> Follow Up <input type="checkbox"/> To Study	
<input checked="" type="checkbox"/> Air Traffic Manager	<input checked="" type="checkbox"/> Hail Site Manager
<input checked="" type="checkbox"/> Air Ops Site Manager	JEDDAH - 2
<input checked="" type="checkbox"/> Tower Site Manager	<i>[Signature]</i>
Action by :	Due Date : / /
Remarks :	
لا يوجد عمل في الموقع <i>[Signature]</i>	
Signature :	Due Date : / /

*[Handwritten signature and notes]*



الرقم : G2PM/2020/93

التاريخ : 2020/02/02م

الموافق : 1441/06/08هـ

المرفقات : (إسطوانة كومبيوتر) + (ملف مطبوع).

المحترمين

الموقر

السادة/ الهيئة العامة للطيران المدني

إدارة صيانة المطارات

سعادة/ الدكتور عيد بن موسى المطيري

نائب مساعد الرئيس للمطارات

مدير عام الصيانة المكلف

السلام عليكم ورحمة الله وبركاته،،،،

الموضوع / طلب الموافقة على مواد مطهرة ومعقمة ضد البكتيريا والفيروسات لجميع مرافق وأسطح  
مطارات المجموعة الثانية.

المراجع :-

- 1- الوثائق الثبوتية لشركة سافير للخدمات الطبية.
- 2- جميع التفاصيل المتعلقة بالمنتجات الكيماوية.
- 3- وثائق الموافقة التجارية.
- 4- شهادات موافقة وإعتماد الحكومة الألمانية.

بالإشارة للموضوع أعلاه، ولحرصنا في الحفاظ على مستوى نظافة وتعقيم مرافق مطارات المجموعة الثانية ووقايتها من العدوى الفيروسية والبكتيرية، نود أن نوصي ونقترح على هيئتك الموقرة استخدام مواد شركة سافير للخدمات الطبية الكيماوية المبينة أدناه وذلك لوقاية مطارات المجموعة الثانية من خطر العدوى الفيروسية والبكتيرية (لا سمح الله).

رقم المنتج	وصف المنتج	موقع الأسطح والمرافق
1	Lysoformin spezial – Gel Component	جميع الأرضيات
2	Trichlorol – Powder Component	جميع أنواع الأسطح مثل الزجاج، الأثاث الخشبي، أفمشة التنجيد.

وبناءً عليه نرفق لسعادتكم طلب على إسطوانة كومبيوتر وملف مطبوع ووسائل الإتصال بشركة

سافير للخدمات الطبية للتكرم بالموافقة على الطلب.

هذا لإطلاع عنايه سعادتكم علماً وللموافقة على الطلب.

شاكرين لكم حسن تعاونكم ،

وتفضلوا بقبول خالص الاحترام.

مدير مشروع الطيران المدني

المجموعة الثانية

محبوب بن فرحان القطاني





Ref. : G2PM/2020/٩٣  
Date. : 02/02/2020 G  
Corres.: 08/06/1441 H  
Attach.: 02 (01 CD + 01 Box file)

General Authority of Civil Aviation  
Maintenance Dept. For Airports,  
Saudi Arabia

Attn. : **Dr. Eid Moosa Al-Motairi**

Vice Assistant President of Airports  
Director Maintenance Department, GACA

Sub. : **REQUEST FOR NEW APPROVAL OF ANTI BACTERIAL&VIRUS  
DISINFECTION CHEMICAL TO ALL SURFACES IN GROUP-II AIRPORTS.**

Ref# : 01) Prequalification documents of company  
02) All details related to products  
03) Approved commercial documents  
04) Germany Govt. Approved Certificates

Dear Sir,

With reference to the subject and precaution to protect from virus and bacterial infection, we are recommending GACA these below products from M/s. Sapphire to protect our Group Airports from Virus/Bacterial Infection.

Product #	Product Description	Surface location
01	Lysoformin® spezial – Gel component	All Kind of Floors
02	Trichlorol® - Powder component	All Kind of Surfaces Including Glass, wooden, upholstery, etc.,

Furthermore, we have attached the proposals in Soft (CD) and hard (BOX File) together with their Business Contact for your kind peruse and further Approval.

This is for your positive response and usual support.

Thank you and best regards,

**Mahboub Farhan Alqahtani**

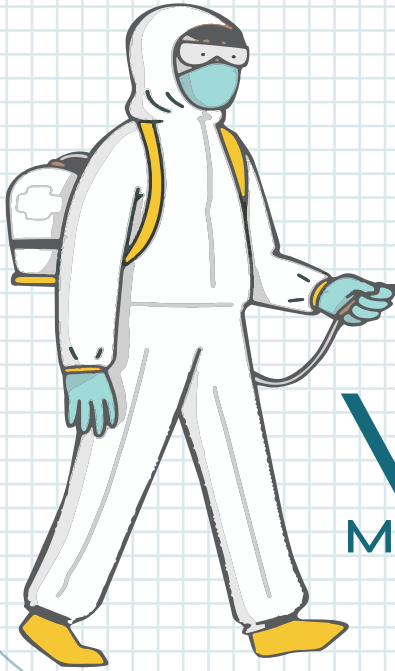
Project Manager

GACA Group-II Airports



نعود بحذر

نحن جاهزون لتعقيم منشاتكم  
We are ready to disinfect your organization



VITALITY  
MEDICAL TRADING CO.

www.vitality-bh.com

✉ info@vitality-bh.com



اتصلو/ اكتبو رسالة.. نصلكم

05097 888 10