# **HOLTSCH** Medizinprodukte GmbH

In den Faltern 13 • D – 65232 Taunusstein Germany

# **Declaration of conformity**

This is to confirm that

the swab dispenser **Quickpad**® containing fleece swabs, saturated with 70% isopropyl alcohol (V/V)

is

manufactured, packaged and sterilized in accordance with the rules of GMP and the paragraph 13 of the GERMAN MEDICAL LAW.

These swabs are equal to a

Medical Device Class I (UMNDS Code15-252)

and are checked and released

conform to

the German Medical Product Law according to

the

Medical Device Directive 93/42/EEC

of the European Counsel.

Taunusstein, November 17th, 2021

HOLTSCH Medizinprodukte GmbH

Malte Hertzberg

(Certified Biologist)



Zertifikat-Nr./Certificate no: DE SN 01 GMP 2016 0003

Aktenzeichen/Reference Number: L24-5117/90

#### BESTÄTIGUNG DER ÜBEREINSTIMMUNG EINES HERSTELLERS MIT GMP

#### Teil 1

#### Ausgestellt nach einer Inspektion gemäß

Art. 111 (5) der Richtlinie 2001/83/EG

Die zuständige deutsche Überwachungsbehörde bestätigt:

Der Hersteller **HOLTSCH Medizinprodukte GmbH** 

Anschrift der Betriebsstätte **HOLTSCH Medizinprodukte GmbH** Leipziger Straße 300 01139 Dresden Deutschland

· Sonstiges:

Der Hersteller wurde im Rahmen der nationalen Arzneimittelüberwachung inspiziert in Verbindung mit national inspection programme in connection with der Herstellungserlaubnis Nr. DE\_SN\_01\_MIA\_2012\_0045 gemäß Art. 40 der DE\_SN\_01\_MIA\_2012\_0045 in accordance with Art. Richtlinie 2001/83/EG umgesetzt in deutsches Recht durch § 13 Abs. 1 Arzneimittelgesetz.

Aufgrund der aus der letzten Inspektion vom From the knowledge gained during the inspection of 27. November 2015 gewonnenen Erkenntnisse wird für die oben genannte Betriebsstätte des Herstellers die Übereinstimmung mit den Anforderungen der Guten Herstellungspraxis festgestellt, die sich aus

 den Grundsätzen und Leitlinien der Guten
 the principles and guidelines of Good Manufacturing Herstellungspraxis gemäß

> FREISTAAT SACHSEN

- Richtlinie 2003/94/EG

DE\_SN\_01\_GMP\_2016\_0003 13.01.2016

ergeben.

# CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

#### Part 1

Issued following an inspection in accordance with

Art. 111 (5) of Directive 2001/83/EC

The competent authority of GERMANY confirms the following:

The manufacturer **HOLTSCH Medizinprodukte GmbH** 

Site address **HOLTSCH Medizinprodukte GmbH** Leipziger Straße 300 01139 Dresden Germany

· Other:

The manufacturer has been inspected under the manufacturing authorisation no. 40 of Directive 2001/83/EC transposed in the following national legislation: Sec 13 para 1 Arzneimittelgesetz (German Drug Law).

this manufacturer, the latest of which was conducted on 27 November 2015, it is considered that it complies with the Good Manufacturing Practice requirements referred to in

- Practice laid down in
  - Directive 2003/94/EC

Unterschrift: Klaus Hartmann

Dieses Zertifikat bestätigt den Status der Betriebsstätte This certificate reflects the status of the manufacturing zum Zeitpunkt der oben genannten Inspektion. Es sollte nicht zur Bestätigung der Übereinstimmung herangezogen werden, wenn seit der genannten Inspektion mehr als drei Jahre vergangen sind. Nach Ablauf dieser Zeit sollte mit der zuständigen Behörde Kontakt aufgenommen werden. Das Zertifikat ist nur bei Vorlage sämtlicher Seiten inklusive der Teile 1 und and 2. The authenticity of this certificate may be 2 gültig. Die Echtheit dieses Zertifikates kann ggf. verified with the issuing authority. durch die ausstellende Behörde bestätigt werden.

site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted. This certificate is valid only when presented with all pages and both parts 1



Humanarzneimittel

# · Human Medicinal Products

#### 1 HERSTELLUNGSTÄTIGKEITEN

- Die erlaubten Herstellungstätigkeiten umfassen vollständige und teilweise Herstellung (einschließlich verschiedener Prozesse wie Umfüllen, Abpacken oder Kennzeichnen), Chargenfreigabe und -zertifizierung, Lagerung und Vertrieb der genannten Darreichungsformen sofern nicht anders angegeben;
- Die Qualitätskontrolle und/oder Freigabe und/oder Chargenzertifizierung ohne Herstellungsschritte sollten unter den entsprechenden Punkten spezifiziert werden;
- Unter der relevanten Produktart und Darreichungsform sollte auch angegeben werden, wenn der Hersteller Produkte mit speziellen Anforderungen herstellt, z.B. radioaktive Arzneimittel oder Arzneimittel, die Penicilline, Sulfonamide, Zytostatika, Cephalosporine, Stoffe mit hormoneller Wirkung oder andere potenziell gefährliche Wirkstoffe enthalten (anwendbar für alle Bereiche des Teils 1 mit Ausnahme 1.5.2 und 1.6).

#### 1.1 Sterile Produkte

1.1.3 Ausschließlich Chargenfreigabe

#### 1.2 Nichtsterile Produkte

1.2.1 Nichtsterile Produkte

1.2.1.17 Andere nichtsterile Produkte Alkoholtupfer

#### 1 MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

#### 1.1 Sterile Products

1.1.3 Batch certification only

#### 1.2 Non-sterile products

1.2.1 Non-sterile products

1.2.1.17 Other non-sterile medicinal product alcoholic pads

13. Januar 2016



13 January 2016

Name und Unterschrift des Bearbeiters der zuständigen Name and signature of the authorised person of the

Behörde

Klaus Hartmann

Landesdirektion Sachsen

Referat 24, Pharmazie, GMP-Inspektorat

Braustraße 2 04107 Leipzig Deutschland

Tel.: +49(0)351 825-2411 Fax: +49(0)351 825-9201

Name and signature of the authorised person of the Competent Authority

Klaus Hartmann

Landesdirektion Sachsen
Referat 24, Pharmazie, GMP-Inspektorat

Braustraße 2 04107 Leipzig Deutschland

Tel.: +49(0)351 825-2411 Fax: +49(0)351 825-9201



LANDESDIREKTION SACHSEN 09105 Chemnitz

# MANUFACTURER'S AUTHORISATION

(This English translation is for reference only. It is not part of the official certificate.)

1. Authorisation number/file number DE\_SN\_01\_MIA\_2012\_0045/Nr. 6 / 24-5482.11/62

2. Name of authorisation holder HOLTSCH Medizinprodukte GmbH

Transcor additionador motor

3. Address(es) of manufacturing site(s) HOLTSCH Medizinprodukte GmbH Leipziger Straße 300

01139 Dresden

4. Legally registered address of authorisation In den Faltern 13 holder 65232 Taunusstein

5. Scope of authorisation and dosage forms ANNEX 1

6. Legal basis of authorisation Sect 13 para 1 Arzneimittelgesetz (German Drug Law)

7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

Edith Detlefsen

8. Signature

9. Date

10. Annexes attached

Annex 1

Annex 4 (Addresses of Contract Laboratories)

Annex 5 (Name of Qualified Person)

Annex 7 (Date of inspection on which authorisation

granted, scope of last inspection)

Annex 8 (Manufactured/ imported products authorised)

DE\_SN\_01\_MIA\_2012\_0045

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09/27/12 13:03:54

# SCOPE OF AUTHORISATION

Annex 1

Name and address of the site: HOLTSCH Medizinprodukte GmbH, Leipziger Straße 300, 01139 Dresden

Human Medicinal Products

#### AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

#### Part 1 - MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items:
- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.1	Sterile Products			
	1.1.3 Batch certification only			
1.2	Non-sterile products			
	1.2.1 Non-sterile products			
	1.2.1.17 Other non-sterile medicinal product alcoholic pads			

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

This Authorisation is according with the site plans of manufacturing rooms with list of room numbers and classification dated 16 July, 2009.



Address(es) of Contract Laboratories

Li-iL GmbH Arzneimittel Arzneibäder Leipziger Strasse 300 01139 Dresden

- total quality control without sterility and microbiological testing

SGS Institut Fresenius GmbH Im Maisel 14 65232 Taunusstein

- Sterility Testing in accordance with Pharm Europ. 2.6.1
- Microbiological Testing non-steril products in accordance with Pharm Europ. 2.6.12 Total viable aerobic count of non-sterile intermediate



Name(s) of Qualified Person(s)

Mrs. Dr. Karin Beck-Piotraschke

Mr. Malte Hertzberg



Date of Inspection on which authorisation was granted

09/01/2011

Scope of last Inspection

Quality Management, Personnel, Premises and Equipment, Documentation, Contract Manufactore and Analysis, Complaints and Product Recall, Self Inspection



Products authorised to be manufactured/imported (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 45 and 46 of Directive 2001/82/EC, as amended).

Quickpad® Tupfer





# HOLTSCH Medizinprodukte GmbH D 65323 Taunusstein • Germany

# To whom it may concern

The product line of our swab dispenser is ruled differently according to the claim which is posted on the product. In Germany both is possible.

It depends on the claim you choose. If the claim is for **disinfecting** the skin before an injection, etc, it is ruled by the **AMG** (German Drug Law). If we sell Quickpad just for **cleaning** the skin Quickpad is ruled as a **cosmetic** (for example like make up remover).

We produce and sell "Quickpad" in Germany under the regulations of the German Drug Law (Arzneimittelgesetz **AMG**).

The European market and the European regulations (i.e. Guideline-for medical items-93/42/EWG), are converted in Germany into the Medizinproduktegesetz (**MPG**).

#### There is a difference between these two regulations.

The **AMG** (strictly national) covers all products which have a pharmaceutical effect. The **MPG** covers all products which are not drugs but support drugs or have a **physical** (not a pharmaceutical) effect, like for example our tourniquet. The MPG fulfils the guideline 93/42/EWG. MPG, items have to bear the CE signet.

As mentioned before it depends on the claim you choose. If the claim is for disinfecting the skin before an injection, etc., it is a drug and ruled by the AMG. For this reason we have the permission to produce and to market this product under AMG (CE-signet is not possible in this case). The product has to be labeled strictly with the original HOLTSCH label

If your claim is for **cleaning** the skin, it is considered as a cosmetic item and is ruled by the cosmetic act and has no CE signet and no special permission as per the AMG is necessary. This is also possible in Germany.

Most of our customers do not declare Quickpad as a drug because they might run through some kind of registration with their ministry of health. They prefer to use Quickpad like a cosmetic and as explained above there is no possibility of a CE-signet on the product.

Maybe the regulations in other countries are different.

If so, please let us know.

Taunsstein, September 07, 2021

Malte Hertzberg Qualified Person AMG HOLTSCH MED

Quality. Safety. Trust.

# Quickpad

The Quickpad alcohol swab dispenser, being sterile and physiologically verified as harmless, is ideal for cleaning and disinfecting the skin.

The active agent 2 propanol acts as an effective, "mild on skin" disinfecting agent. The "swab tear-off" ready to use system allows for the single use of the swab. This makes Quickpad not only economical but also efficient in its use.

The lid of the Quickpad alcohol swab dispenser container seals air-tight, keeping the alcohol swabs moist and sterile. As a result, the swab dispenser has a particularly long shelf life of 24 months.

Quickpad is supplied ready for use and with its simple operation, can be used by specialists as well as patients for cleaning/disinfecting the skin. An ideal product for diabetics and other users of self-injection syringes. Additionally, it is always possible through the transparent container to see the fill level and it is suitable for self-application by the patient.

Holtsch Medizinprodukte GmbH In den Faltern 13 D-65232 Taunusstein T +49 6128 91717-7 F +49 6128 44742 M info@holtsch-med.com



according to Regulation (EC) No 1907/2006

## Quickpads

Product code: 10692-0001 Revision date: 03.07.2020 Page 1 of 9

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

#### 1.1. Product identifier

Quickpads

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

#### Use of the substance/mixture

Disposable alcohol swabs for cleansing the skin

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

Company name: Holtsch Medizinprodukte GmbH

Street: In den Faltern 13 Place: D-65232 Taunusstein

Telephone: +49(0)6128 917 177 Telefax: +49(0)6128 447 42

e-mail: info@holtsch-med.com Contact person: Malte Hertzberg www.holtsch-med.com Internet:

Responsible Department: Responsible for the safety data sheet: sds@gbk-ingelheim.de

+49 (0) 172 6123 572 1.4. Emergency telephone

In England and Wales: NHS 111 In Scotland: NHS 24 - dial 111 number:

#### **SECTION 2: Hazards identification**

#### 2.1. Classification of the substance or mixture

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

Hazard categories:

Flammable liquid: Flam. Liq. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Specific target organ toxicity - single exposure: STOT SE 3

Hazard Statements:

Highly flammable liquid and vapour. Causes serious eve irritation.

May cause drowsiness or dizziness.

# 2.2. Label elements

#### **Regulation (EC) No. 1272/2008** Signal word: Danger

Pictograms:





#### **Hazard statements**

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

#### Additional advice on labelling

According to the EC hazardous substance regulations in compliance with the EC cosmetic product regulations this product must not be labelled as a hazardous substance.

# 2.3. Other hazards

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT / vPvB substance.

If swallowed in higher quantities risk of intestinal passage obstruction.

according to Regulation (EC) No 1907/2006

## Quickpads

Revision date: 03.07.2020 Product code: 10692-0001 Page 2 of 9

## **SECTION 3: Composition/information on ingredients**

#### 3.2. Mixtures

#### **Chemical characterization**

Disposable swab impregnated with 70%-Isopropanol (0,46 ml per swab).

#### **Hazardous components**

CAS No	Chemical name				
	EC No	Index No	REACH No		
	GHS Classification				
67-63-0	Propan-2-ol			0,46 ml %	
	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.

#### **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

#### **General information**

No specific precautions required.

#### After inhalation

Move to fresh air in case of accidental inhalation of vapours or decomposition products.

In the event of symptoms refer for medical treatment.

#### After contact with skin

No specific precautions required.

# After contact with eyes

Rinse immediately with plenty of water, also under the eyelids.

If eye irritation persists, consult a specialist.

#### After ingestion

Consult a physician.

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

Causes serious eye irritation.

May cause drowsiness or dizziness.

If swallowed in higher quantities risk of intestinal passage obstruction.

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

Treat symptoms.

# **SECTION 5: Firefighting measures**

# 5.1. Extinguishing media

#### Suitable extinguishing media

Alcohol-resistant foam, dry chemical, carbon dioxide (CO2), water-spray.

#### Unsuitable extinguishing media

Full water jet

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

Fire may produce:

carbon monoxide and carbon dioxide

#### 5.3. Advice for firefighters

Use breathing apparatus with independent air supply.

Protective suit.

according to Regulation (EC) No 1907/2006

# Quickpads

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#### Additional information

Vapours are heavier than air and spread along ground.

The vapour/air mixture is explosive, even in empty, uncleaned receptacles.

Cool containers at risk with water spray jet.

Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

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

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

In case of vapour formation use respirator.

Ensure adequate ventilation.

Use personal protective clothing.

Keep away sources of ignition.

Avoid contact with skin, eyes and clothing.

#### 6.2. Environmental precautions

Do not discharge into the drains/surface waters/ground water.

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

Take up mechanically and collect in suitable container for disposal.

#### 6.4. Reference to other sections

Observe protective instructions (see Sections 7 and 8).

Information for disposal see section 13.

# **SECTION 7: Handling and storage**

# 7.1. Precautions for safe handling

#### Advice on safe handling

When using do not eat, drink or smoke.

Avoid contact with eyes.

#### Advice on protection against fire and explosion

Keep away from heat and sources of ignition.

Don't smoke.

# 7.2. Conditions for safe storage, including any incompatibilities

#### Requirements for storage rooms and vessels

Protect against direct sun radiation.

Keep containers tightly closed in a cool, well-ventilated place.

#### Hints on joint storage

Incompatible with:

Oxidizing agents

Alkaline metals and earth alkaline metals.

#### Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

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

Disposable alcohol swabs for cleansing the skin

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

#### 8.1. Control parameters

according to Regulation (EC) No 1907/2006

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#### **Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
67-63-0	Propan-2-ol	400	999		TWA (8 h)	WEL
		500	1250		STEL (15 min)	WEL

# 8.2. Exposure controls

#### Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas.

#### Protective and hygiene measures

When using do not eat, drink or smoke.

Do not inhale vapours.

Avoid contact with eyes.

#### Eye/face protection

Not required under normal use.

#### Hand protection

Not required under normal use.

#### Skin protection

Not required under normal use.

# Respiratory protection

No personal respiratory protective equipment normally required.

# **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

Physical state: Tissue, tinctured with clear disinfectant solution

Colour:

Odour: Alcoholic

Test method

pH-Value: n.d.

Changes in the physical state

Melting point:

n.d.
Initial boiling point and boiling range:

sublimation point:

n.a.

Softening point:

n.d.

Flash point:

12 °C \*)

**Flammability** 

Solid: Combustible.
Gas: n.a.

#### **Explosive properties**

The product is considered non-explosive; nevertheless explosive vapour/air mixture can be generated

Lower explosion limits: 2,0 vol. % \*) Upper explosion limits: 12 vol. % \*) Ignition temperature: 425 °C \*)

**Auto-ignition temperature** 

Solid: The product is not self-igniting Gas: n.a.

according to Regulation (EC) No 1907/2006

Quickpads								
Revision date: 03.07.2020	Product code: 10692-0001	Page 5 of 9						
Decomposition temperature:	n.d.							
Oxidizing properties  Not oxidising.								
Vapour pressure: (at 20 °C)	43 hPa *)							
Density (at 20 °C):	0,87 g/cm³ *)							
Bulk density:	n.d.							
Water solubility: (at 20 °C)	Miscible *)							
Solubility in other solvents n.d.								
Viscosity / dynamic:	n.a.							
Viscosity / kinematic:	n.a.							
Flow time:	n.a.							
Vapour density:	n.d.							
Evaporation rate:	n.d.							
Solvent separation test:	n.d.							
Solvent content:	n.d.							
9.2. Other information								
*) All data refer to the solution								

# SECTION 10: Stability and reactivity

# 10.1. Reactivity

No decomposition if stored and applied as directed.

#### 10.2. Chemical stability

Stable under normal conditions.

# 10.3. Possibility of hazardous reactions

No hazardous reactions known.

#### 10.4. Conditions to avoid

Heating can release vapours which can be ignited.

#### 10.5. Incompatible materials

Oxidizing agents

Alkaline metals and earth alkaline metals.

# 10.6. Hazardous decomposition products

No hazardous decomposition products known.

Fire may produce:

Carbon monoxide and carbon dioxide

# **SECTION 11: Toxicological information**

# 11.1. Information on toxicological effects

#### **Acute toxicity**

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

Propan-2-ol

LD50/oral/rat: 5045 mg/kg [RTECS] LD50/dermal/rabbit: 12800 mg/kg

LC50/inhalation/rat: 46,5 mg/l/4h [RTECS]

according to Regulation (EC) No 1907/2006

## Quickpads

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#### Irritation and corrosivity

Causes serious eye irritation.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

#### Sensitising effects

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

#### Carcinogenic/mutagenic/toxic effects for reproduction

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

#### STOT-single exposure

May cause drowsiness or dizziness.

#### 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.

#### Additional information on tests

Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

#### **Practical experience**

#### Other observations

If appropriately handled and if in accordance with the general hygienic rules, no damages to health have become known.

Sometimes short-term reddening of skin may occur.

May cause irritation of the mucous membranes.

If swallowed in higher quantities risk of intestinal passage obstruction.

#### **SECTION 12: Ecological information**

#### 12.1. Toxicity

Propan-2-ol

LC50/Lepomis macrochirus/96 h = 1400 mg/l [ECOTOX DATABASE]

EC50/Daphnia magna/48 h = 13299 mg/l [IUCLID]

EC50/Desmodesmus subspicatus/72 h > 1000 mg/l [IUCLID]

#### 12.2. Persistence and degradability

Propan-2-ol

Biodegradable (OECD): 95% [OECD 301 E]

#### 12.3. Bioaccumulative potential

Propan-2-ol

Product has a low bioaccumulating potential. Log Pow: 0,05 [OECD 107]

# 12.4. Mobility in soil

No data available

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

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT / vPvB substance.

#### 12.6. Other adverse effects

Low hazard to waters.

#### **Further information**

Product is not allowed to be discharged into aquatic environment.

#### **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

#### **Disposal recommendations**

Can be incinerated, when in compliance with local regulations.

according to Regulation (EC) No 1907/2006

# Quickpads

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#### List of Wastes Code - residues/unused products

180106 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals consisting of or containing hazardous substances; hazardous waste

#### Contaminated packaging

Empty containers should be taken for local recycling, recovery or waste disposal.

Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse.

Packaging that cannot be cleaned should be disposed of like the product.

# **SECTION 14: Transport information**

#### Land transport (ADR/RID)

**14.1. UN number:** UN 3175

**14.2. UN proper shipping name:** SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)

14.3. Transport hazard class(es):4.114.4. Packing group:IIHazard label:4.1



Classification code: F1

Limited quantity: 1 kg / 30 kg

Excepted quantity: E2
Transport category: 2
Hazard No: 40
Tunnel restriction code: E

# Inland waterways transport (ADN)

**14.1. UN number:** UN 3175

14.2. UN proper shipping name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)

14.3. Transport hazard class(es):4.114.4. Packing group:IIHazard label:4.1



Classification code: F1

Limited quantity: 1 kg / 30 kg

Excepted quantity: E2

Marine transport (IMDG)

**14.1. UN number:** UN 3175

**14.2. UN proper shipping name:** SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)

14.3. Transport hazard class(es):4.114.4. Packing group:IIHazard label:4.1

according to Regulation (EC) No 1907/2006

## Quickpads

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Marine pollutant: No

Limited quantity: 1 kg / 30 kg
Excepted quantity: E2
EmS: F-A, S-I

Air transport (ICAO-TI/IATA-DGR)

**14.1. UN number:** UN 3175

**14.2. UN proper shipping name:** SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)

14.3. Transport hazard class(es):4.114.4. Packing group:IIHazard label:4.1



Limited quantity Passenger: 5 kg
Passenger LQ: Y441
Excepted quantity: E2

IATA-packing instructions - Passenger: 445
IATA-max. quantity - Passenger: 15 kg
IATA-packing instructions - Cargo: 448
IATA-max. quantity - Cargo: 50 kg

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

# 14.6. Special precautions for user

Take the usual precautions when handling with chemicals.

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

The transport takes place only in approved and appropriate packaging.

#### **SECTION 15: Regulatory information**

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

#### **EU** regulatory information

2004/42/EC (VOC): 0.46 ml

Information according to 2012/18/EU P5c FLAMMABLE LIQUIDS

(SEVESO III):

# National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile

work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or

nursing mothers.

# 15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

# **SECTION 16: Other information**

according to Regulation (EC) No 1907/2006

# Quickpads

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#### Abbreviations and acronyms

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intér IMDG = International Maritime Code for Dangerous Goods

IATA/ICAO = International Air Transport Association / International Civil Aviation Organization

MARPOL = International Convention for the Prevention of Pollution from Ships

IBC-Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

REACH = Registration, Evaluation, Authorization and Restriction of Chemicals

CAS = Chemical Abstract Service

EN = European norm

ISO = International Organization for Standardization

DIN = Deutsche Industrie Norm

PBT = Persistent Bioaccumulative and Toxic

vPvB = Very Persistent and very Bio-accumulative

LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

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

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

#### **Further Information**

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities.

The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge.

The delivery specifications are contained in the corresponding product sheet.

This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

(n.a. = not applicable; n.d. = not determined)

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