Alcohol Swab Dispenser QUICKPAD®

Practical and efficient

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 patented "swab tear-off" system allows for the single use of the swab. This makes QUICKPAD® not only economical but also efficient in its use.

Quality and Endurance

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.

Please note that for pharmaceutical QUICKPAD®, the corresponding safety instruction is applicable.

Characteristics

- Single swab tear-off system allows for an efficient and economical use
- Fill Level control due to transparent container
- Retains moisture and sterility
- Physiologically harmless non-woven swab

- Available in three practical sizes (only as cosmetic)
- Suitable for self-application by the patient
- Ready for use
- Made in Germany Quality, CE Label

Range of Application

QUICKPAD® is supplied ready for use and with its simple operation, can be used by specialists as well as patients for disinfecting the skin. An ideal product for diabetics and other users of subcutaneous self-injection syringes.

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Date: 2020.12.12 10:49:35 EET
Reason: MoldSign Signature
Location: Moldova

Product range

The Quickpad® swap dispenser is available is available in three different sizes, MINIPAD®, QUICKPAD® und BIGPAD®.

	MINIPAD®	QUICKPAD®	BIGPAD®
size dispencer (L x W x H in mm)	50 x 50 x 50	**50 x 50 x 80**	62 x 62 x 75
Number of swabs per dispencer	50	**150**	100
size swabs(L x B in mm)	44 x 44	**44 x 44**	58 x 58

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 der Herstellungserlaubnis Nr. DE_SN_01_MIA_2012_0045 gemäß Art. 40 der Richtlinie 2001/83/EG umgesetzt in deutsches Recht durch § 13 Abs. 1 Arzneimittelgesetz.

Aufgrund der aus der letzten Inspektion vom 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 Herstellungspraxis gemäß
- Richtlinie 2003/94/EG

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 national inspection programme in connection with manufacturing authorisation no. DE_SN_01_MIA_2012_0045 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: Sec 13 para 1 Arzneimittelgesetz (German Drug Law).

From the knowledge gained during the inspection of 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

• the principles and guidelines of Good Manufacturing Practice laid down in
- Directive 2003/94/EC

FREISTAAT SACHSEN LANDESDIREKTION SACHSEN

Dieses Zertifikat bestätigt den Status der Betriebsstätte 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 2 gültig. Die Echtheit dieses Zertifikates kann ggf. durch die ausstellende Behörde bestätigt werden.

This certificate reflects the status of the manufacturing 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 and 2. The authenticity of this certificate may be verified with the issuing authority.

Teil 2

• Humanarzneimittel

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

Part 2

• Human Medicinal Products

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

FREISTAAT SACHSEN
LANDESDIREKTION SACHSEN

Name und Unterschrift des Bearbeiters der zuständigen Behörde

Klaus Hartmann
Landesdirektion Sachsen
Referat 24, Pharmazie, GMP-Inspektorat
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04107 Leipzig
Deutschland

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

13 January 2016

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

HOLTSCH Medizinprodukte GmbH

Material Safety Data Sheet

SECTION 1 - IDENTITY

NAME
HOLTSCH Medizinprodukte GmbH

ADRESS
In den Faltern 13 D-65232 Taunusstein GERMANY

TELEPHONE NUMBER	FOR ADDITIONAL INFORMATION CONTACT	DATE PREPARED
+49 6128 91717 822	Eveline Martin	November 23, 2011

COMMON NAME (USED ON LABEL)
70% Isopropyl Alcohol Preps

CHEMICAL FAMILY
Alcohol

CHEMICAL NAME
Propan 2-ol

FORMULA
$(CH_3)_2CHOH$

TRADE NAME
Quickpad

SECTION 2 - HAZARDOUS INGREDIENTS

HAZARDOUS COMPONENT	CAS#	% (WT)	TLV	PEL
Isopropyl Alcohol	67-63-0	70	980Mg/M3	980Mg/M3

PEL: Permissible Exposure Limit established by the Occupational Safety and Health Administration (OSHA).
TLV: Threshold Limit Value establihed by the American Conference of Governmental Industrial Hygenists, 1986-1987.

SECTION 3 - PHYSICAL DATA

BOILING POINT	SPECIFIC GRAVITY (H_2O= 1)	VAPOR PRESSURE(mm Hg)
82.4° C	.869 - 879 at 25° C	33mm at 20° C

PERCENT VOLATILE BY VOLUME (%)	VAPOR DENSITY (AIR=1)	EVAPORATION RATE (Butyl Acetate = 1)
100%	2.07	2.88

SOLUBILITY IN WATER
Soluble

REACTIVITY IN WATER
Does not apply

APPEARNCE AND ODOR
Water white with an alcohol odor

SECTION 4- FIRE AND EXPLOSION DATA

FLASH POINT
12°C

FLAMMABLE LIMITS IN AIR(%by Volume)
LOWER: 2% UPPER: 12.7%

EXTINGUSHING MEDIA
Carbon Dioxid, alcohol foam or dry chemical

AUTO IGNITION TEMPERATURE
399°C

UNUSUAL FIRE AND EXPLOSION HAZARDS
None

SPECIAL FIRE FIGHTING PROCEDURES
None

SECTION 5 - HEALTH INFORMATION

PRIMARY ROUTES OF EXPOSURE
Skin, Eye, Inhalation or Ingestion

SIGNS AND SYMPTOMS OF EXPOSURE -
(1) ACUTE OVEREXPOSURE
Direct contact with eyes may result in irritaton. Target Organs: Eyes, skin and respiratory tract.

(2) CHRONIC OVEREXPOSURE
Prolonged contact with skin may result in drying or irritation. Prolonged inhalation of vapors may cause slight headaches or dizziness. Prolonged expusure to vapors may result in eye irritaton.

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE
Isopropyl alcohol is not a known liver or kidney toxin; persons with impaired liver or renal function should limit exposure.

CHEMICAL/COMPONENT LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN
None

OTHER EXPOSURE LIMITS
None determined

EMERGENCY & FIRST AID PROCEDURES
EYE CONTACT: Flush water for 15 minutes, seek medical attention. SKIN CONTACT: Flush with water for 15 minutes. INGESTION: Not likely; if ingestion occurs, do not induce vomiting, seek medical attention.

SECTION 6 - REACTIVITY DATA

STABILITY
Unstable ☐ Stable ☒

CONDITIONS TO AVOID
None Determined

INCOMPATIBILTY (MATERIALS TO AVOID)
Oxidizers

HAZARDOUS DECOMPOSITION PRODUCTS
Not determined

HAZARDOUS POLYMERIZATION
May Occur ☐ Will not Occur ☒

CONDITIONS TO AVOID
None

SECTION 7 - SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS LEAKED OR SPILLED
Not likely to spill or leak

WASTE DISPOSAL METHOD
Dispose of in accordance with applicable local, state and federal laws.

SECTION 8 - PERSONAL PROTECTION INFORMATION

RESPIRATORY PROTECTION
Respiratory protection is not required under normal use

VENTILATION
For normal use - use in a well ventilated area

PROTECTIVE GLOVES
Not rquired under normal use

EYE PROTECTION
Not required under normal use

OTHER PROTECTIVE CLOTHING OR EQUPMENT
Not required under normal use

SECTION 9 - SPECIAL PRECAUTIONS

Store away from heat and ignition sources

OTHER PRECAUTIONS
Not determined

THE INFORMATION CONTAINED WITHIN WAS OBTAINED FROM AUTHORITATIVE SOURCES AND IS BELIVED TO BE ACCURATE FOR THE MANNER IN WHICH THE PRODUCT IS INTENDED TO BE USED. OTHER USES COULD RESULT IN CONSEQUENCES WHICH ARE NOT CONSIDERED WITHIN THIS DOCUMENT.

HOLTSCH Medizinprodukte GmbH
In den Faltern 13 ● D-65232 Taunusstein ● Germany

To whom
it may concern

November 23, 2011

A Summarizing Evaluation of the Stability of Quickpad

The shelf-life of Quickpad is declared to be 18 months; this is reduced to 6 months after opening.

To confirm this stability different stability tests, which yielded the following results, were performed with Quickpad:

Completed Stability Tests

During these stability tests, which were performed on three production lots, the samples - after an initial inspection (0 value) - were stored under controlled conditions (climactic cabinet) for 24 months at 25° C and 60% relative humidity and for 6 months at 40° C and 75% relative humidity. After 3, 6, 9, 12, 18 and 24 months, the samples were checked for their content of 2-propanol 70% (v/v) per swab, whereby in each case swabs for the test were taken from the top, middle and bottom of the container. In addition to the 24-month value a sterility test was also performed.

The content determination was gravimetric and used the weight difference of a swab after removal from the donor box and after the evaporation of 2-propanol 70% (v/v) by drying the swab in a drying cabinet at 105° C for one hour.

To whom it may concern

A Summarizing Evaluation of the Stability of Quickpad

The individual results obtained during these stability tests confirm that, with regard to the content of 2-propanol 70% (v/v), the swabs remain within the production-related, technical tolerances for the 24-month duration of the testing period while under controlled storage conditions. After 24 months of storage, the samples were still sterile.

The samples stored at 40° C and 75% relative humidity were also checked with regard to the total weight of the containers after 1, 3 and 6 months of storage. This revealed that the total weights after these storage times were somewhat below the specified tolerance, which could be due to the effect of slight evaporation.

However, since in this case all the tested individual swabs from the top, middle and bottom of the container also fell within the specified tolerance with regard to the content of 2-propanol 70% (v/v), the decreased total weight of the container is of no significance for the stability evaluation of the finished product.

The stability test after opening was also performed on three production lots under practice-oriented removal conditions. The results obtained show that - after opening a container - storage is possible over a period of 6 months under normal room conditions (20 – 25° C; uncontrolled humidity 25- 55%). Here too, all of the tested swabs fell within the specified tolerances for the content of 2-propanol 70 % (v/v).

Overall, these stability tests confirmed that the finished product when stored at 25° C / 60% relative humidity for 24 months and at normal room conditions for 6 months after opening fulfills the parameters that determine quality.

Ongoing Stability Tests

Due to the fact that the initially used gravimetric method of content determination was replaced by a validated gas chromatography (GC) test method and an additional GC purity test was introduced to determine the content of acetone (≤ 5000 ppm) and benzene (≤ 2 ppm), follow-up stability tests were started with two production lots. The samples are stored under the controlled conditions (climactic cabinet) listed below and will be examined with regard to stability-relevant parameters at the specified testing intervals:

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A Summarizing Evaluation of the Stability of Quickpad

- Storage at 25° C ± 2° C / 60 % RH ± 5 % with the testing times of 0, 3, 6, 9, 12, 18 and 24 months.
- Storage at 30° C ± 2° C / 65 % RH ± 5 % with the testing times of 0, 3, 6 and 12 months.
- Storage at 40° C ± 2° C / 75 % RH ± 5 % with the testing times of 0, 3 and 6 months.

During this follow-up stability test, the following stability-relevant parameters will be checked at the specified testing times:

- Description, odor, tightness and intactness of the packaging.
- Identity and content of 2-propanol.
- Content of acetone (≤ 5000 ppm) and benzene (≤ 2 ppm) and the total of all degradation products (≤ 0.3 %).
- End weight of the final packaging (permeability of the container).
- Sterility test when placing into storage and in each case at the end of the planned duration of storage.

Presently, at the time of this evaluation the 6-month results for these follow-up stability tests are available.

In both lots the results obtained so far over 6 months and under the named storage conditions fall within the specified tolerances.

Based on the above-mentioned and already completed stability tests, it is expected that these follow-up stability tests will confirm the already established shelf-life of 24 months.

Overall, an expert opinion determines that the declared shelf-life for Quickpad of 18 months or 6 months after opening is justified without limitations in light of the stability tests that have been performed so far.

HOLTSCH Medizinprodukte GmbH
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To whom
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23 November 2011

Summary of Evaluation of the Efficacy and Safety of Quickpad

Product description

Quickpad is a set of ready-to-use swabs saturated with 70% propan-2-ol (v/v), for skin disinfection prior to injections. Each dispenser box contains 150 swabs made from non-woven fabric and filled in such a way that a single swab can be removed for every use. On each occasion, approximately 1/5 of the next swab is pulled out of the box. After each removal, the box, including the part of the next swab that has been pulled out, is closed tightly. In this way, the dispenser box encloses the next swab so securely that no evaporation of the pad's base (70% propan-2-ol v/v) takes place. The development of the swab dispenser is covered by a patent for the reliable single removal of swabs made from non-woven fabric.

The active ingredient in Quickpad is the disinfectant 70% propan-2-ol (v/v), described in the literature.

The basis of the pads is tear-resistant non-woven fabric containing polypropylene with a slightly porous, haptically solid surface.

The pads are gamma-sterilised in the closed dispenser box after saturation of the pack contents (150 swabs) with 70 ml 70% propan-2-ol (v/v).

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To whom it may concern

Summary of Evaluation of the Efficacy and Safety of Quickpad

Indications

Quickpad is designed for “skin antisepsis (skin disinfection) prior to injections”. To achieve this, the relevant area of skin is rubbed thoroughly with a single swab.

Evaluation of microbicidal efficacy

Antiseptic efficacy in the practical test

The skin antisepsis test was carried out on the upper arm and forehead. In accordance with the specified directions, the area of skin at the test site was rubbed with a single Quickpad and the reduction in the microbial count was determined at the end of the contact time. As a reference product 70% propan-2-ol 70 (v/v) was applied once with a swabstick.

Summary of results

With reference to efficacy on skin containing few sebaceous glands (upper arm), the test procedure with pads just removed from the box was significantly more effective than the reference product when considering the immediate value after 15 sec. After 30 sec and 1 min, both procedures were equivalent, i.e. there was no significant difference in effect.

On skin without any sebaceous glands (forehead), the test procedure using pads was significantly superior to the reference product after both 10 min and 30 min. This proves the efficacy of Quickpad for skin antisepsis.

To investigate the possibility of a loss of effect due to the volatility of the alcohol with continued removal of the pads, 5 pads were taken out of the box during the course of each working day over a 2-week period, and the efficacy test was repeated on skin containing few sebaceous glands at the end of this application period. The test was limited to skin containing few sebaceous glands because the differences between Quickpad and 70% propan-2-ol (v/v) were generally less marked than on skin containing a large number of sebaceous glands.

In this test, Quickpad was significantly more effective than the reference product after 15 and 30 sec. After 1 min, as in the previous test, Quickpad showed a tendency to be less effective than the reference product, but not significantly so.

To whom it may concern

Summary of Evaluation of the Efficacy and Safety of Quickpad

Similarly, after 4 weeks of daily removal of 5 pads on each occasion, the efficacy test was carried out on the upper arm and forehead. With this test, Quickpad fared significantly better than the reference product at all three test times, i.e. after 15, 30 and 60 sec. The situation on skin containing a large number of sebaceous glands was similar. Therefore, the conclusion can be drawn that there is no loss of efficacy with Quickpad, even with continued use.

Since the test and reference procedures are based on the use of 70% propan-2-ol (v/v), the tendential, and in many cases significant, superiority of Quickpad should be due to the more intensive mechanical effect of the pad compared with wetting the area of skin with a saturated cotton wool swab.

The opinion on the efficacy of 70% propan-2-ol (v/v) from the literature is as follows:

- The following ranking in terms of the bactericidal effect of short-chain alcohols, in descending order, is generally accepted: propan-1-ol > propan-2-ol > ethanol. The optimum effect is cited as 60-70% for propan-2-ol and 50-60% for propan-1-ol. For hygienic hand disinfection, 77% ethanol, 60% propan-2-ol and 42% propan-1-ol are equally effective.

To summarise, the active ingredient propan-2-ol in a 70% concentration (v/v) can be regarded, alongside propan-1-ol, as the active ingredient of choice in skin antisepsis before injections.

Toxicity: Evaluation of an interaction between 70% propan-2-ol (v/v) and the pad substrate based on the results of cytotoxicity tests

The examination of the in vitro cytotoxicity of propan-2-ol and pad extracts containing propan-2-ol and cell culture medium clearly showed that propan-2-ol in an end-concentration of ≥ 10 % (v/v) has a very strong cytotoxic effect on L929 mouse fibroblasts. On extraction of the pad substrate with 3 ml extracting agent per single-sided surface, substances with a weak cytotoxic effect can be extracted. However, this does not result in preferential extraction of these substances from the pad substrate containing 70% propan-2-ol (v/v) compared with extraction in a cell culture medium.

The proportion of extractable substances in the in vitro cytotoxicity test can be completely disregarded because the main in vitro cytotoxic effect is produced by propan-2-ol.

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 23 November 2011

To whom it may concern

Summary of Evaluation of the Efficacy and Safety of Quickpad

Resorption

The resorption of propan-2-ol (test preparation: polyalcohol hand antiseptic containing 70% propan-2-ol) was tested as a worst-case scenario in volunteer test subjects in a monocentre controlled randomised blinded comparative study versus a further 4 alcohol-based hand disinfectants in situations of both hygienic and surgical hand disinfection.

Despite extensive exposure, the results produced only mild, toxicologically insignificant resorption.

Considering the excessive dermal exposure in the study design selected, compared with the localised application of Quickpad for skin antisepsis (at least 150 times greater than with use of a pad), the use of Quickpad can be regarded as absolutely safe.

Besides the fact that resorption can be disregarded due to the low exposure, the following reasons also support this opinion:

- The half-life of propan-2-ol is 0.6 – 2 h in the mammalian body. Therefore, rapid metabolism of any alcohol absorbed during application for the purposes of skin antisepsis, presumably in analytically non-measurable trace amounts, would be guaranteed.

- Animal-experimental studies have shown no evidence of a risk from dermal or inhaled exposure to propan-2-ol. During 90 days‘ dermal application of a hand disinfectant containing 70% propan-2-ol, with approximately 20 to 25 times more exposure than in a real situation of hand disinfection, there was no evidence of an effect on the particularly sensitive nervous system. During inhaled exposure of rats to 8575 mg/m^3 for 7h/d over 19 d, no blood levels were measurable.

- In terms of industrial medicine, there is also no evidence of a risk from inhalation of propan-2-ol. In printers exposed to between 8 and 647 mg/m^3 for 7 days, blood and urine propanol-2 levels were non-measurable.

HOLTSCH Medizinprodukte GmbH
In den Faltern 13 ● D-65232 Taunusstein ● Germany

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To whom it may concern

Summary of Evaluation of the Efficacy and Safety of Quickpad

Toxicological data

The analysis of the current literature on propan-2-ol leads to the following conclusions:

- With local application of propan-2-ol-based skin disinfectants, there is no risk to the skin, and no systemic side effects, including long-term side effects (mutagenicity, carcinogenicity, or teratogenicity), are to be feared.

- When the assessment of acute toxicity is based on the classification by LD_{50} values, the classification for propan-2-ol is “virtually non-toxic”.

Local tolerance

Skin

In rabbits, guinea pigs and humans, the primary dermal irritation test produces the classification of non-irritating.

In humans, tolerance as a hand disinfectant is comparable to ethanol and propan-1-ol.

Eye

In the Draize test in the rabbit, the classification “corrosive” with persistent eye damage for > 21 days after application was achieved in conformity with US EPA criteria. After application of 70% propan-2-ol, complete regeneration was achieved after 14 or 7 days, depending on the amount applied.

Wound

In the explant test, 60% propan-2-ol did not achieve the tolerance of 70% ethanol, but significantly exceeded that of mucous membrane antiseptics, such as those with a chlorhexidine base, in terms of tolerance, so even from this viewpoint the tolerance of lower alcohols is confirmed.

To whom it may concern

Summary of Evaluation of the Efficacy and Safety of Quickpad

Sensitisation potential

Propan-2-ol is non-allergenic in animal studies. However, there are difficult-to-interpret isolated cases of positive patch tests, exhibiting contact dermatitis, involving exposure in 4 of the 5 cases to propan-2-ol in combination with other active ingredients; admittedly, the patch test reaction was triggered by chemically pure propan-2-ol.

In a recent literature search, no reports of sensitisation to propan-2-ol could be found.

Summarising evaluation

Quickpad fulfils the requirements of a skin antiseptic according to current requirements with a contact time of 15 s.

Skin tolerance is good and free from allergenic potential.

Propan-2-ol is resorbed through the skin to a very low, toxicologically insignificant extent. There is no evidence of significant systemic toxicity.