

Circular No. HLME/ 008/20

March 26 , 2020

**Effective Hand Sanitizers Products for the Coronavirus (COVID-19) Pandemic  
فعالية منتجات معقمات اليدين خلال الوباء العالمي لفيروس الكورونا (كوفيد 19)**

To : All Healthcare Facilities

All Healthcare Professionals

Due to the Coronavirus Disease 2019 (COVID-19), the Department of Health Abu Dhabi (DoH) has received a number of queries concerning the effectiveness of hand sanitisers as a preventative measure for COVID-19.

As per international guidelines including those issued by the World Health Organisation (WHO), for a hand sanitiser to be effective against COVID-19 it must possess the following properties:

- Alcohol-based
- Manufactured using United States Pharmacopoeia (USP) or equivalent pharmaceutical grade ingredients
- Composed of either Ethanol (ethyl alcohol) or Isopropyl alcohol – most effective against viruses
- Should **not** contain toxic Methanol or Acetonitrile
- Must contain at least 60% alcohol – products found to be most effective had alcohol content of 60% to 90%
- Not be composed of more than 95% alcohol – higher concentrations of alcohol are less potent

Any products found to not conform to the above specifications may not offer effective prevention against COVID-19.

In case of shortage healthcare facilities can follow the attached FDA/ WHO guidelines as a temporary measure to

إلى: جميع منشآت الرعاية الصحية  
جميع ممارسي الرعاية الصحية

في الوضع الراهن والخاص بمرض فيروس كوفيد 19، تود دائرة الصحة ان تلفت انتباهكم بأننا تلقينا العديد من الاستفسارات بخصوص فعالية منتجات معقمات اليدين المستخدمة كإجراء احترازي للوقاية من فيروس كوفيد 19

ونود الايضاح بأنه حسب القواعد الارشادية العالمية، والتي من ضمنها تلك الموضوعه من قبل منظمة الصحة العالمية، يشترط لاي منتج يستخدم كمعقمات اليدين و فعال ضد فيروس كوفيد 19 ، ان تتوفر به المواصفات التالية :

- استخدام الكحول كمادة فعالة
- مصنع من مواد خام تتبع مواصفات دستور الادوية الامريكي او ما يعادله.
- تحتوي على الايثانول او كحول الايزوبروبيل - كونها فعالة ضد الفيروسات.
- لا يقل تركيز الكحول فيها عن 60% - حيث تبين أن أكثر المنتجات فعالية هي التي يتراوح تركيز الكحول فيها بين 60%-90%.
- لا يتجاوز تركيز الكحول فيها عن 95%، حيث تقل فعالية الكحول عند استخدامه بتركيزات مرتفعة.

ويعد أي منتج لا يتوافق مع المواصفات المذكورة أعلاه غير ملائم للوقاية من فيروس كوفيد 19.

في حالة وجود نقص في الامداد، تستطيع المنشآت الصحية تحضير معقمات اليدين باتباع الارشادات المرفقة لهذا التعميم

compound certain alcohol-based hand sanitizer products during this public health emergency.

We would also advise HCPs to be mindful that alcohol-based hand sanitisers are classified as flammable liquids, and to be cautious and not approach open flames immediately after use.

- For further information please contact Medical Devices Post Marketing Surveillance Program at Tel: 02- 4193643

Email: [medicaldevices@doh.gov.ae](mailto:medicaldevices@doh.gov.ae)

- Report any complaint on pharmaceutical products with suspected quality defect to us via:

Tel: **02 419 3589**

Email: [drugquality@doh.gov.ae](mailto:drugquality@doh.gov.ae)

Your cooperation is appreciated.

والصادرة عن إدارة الغذاء والدواء الأمريكية ومنظمة الصحة العالمية وذلك بشكل مؤقت خلال هذه الفترة الزمنية لمجابهة عدوى فيروس كوفيد 19.

كما نوجه عناية ممارسي الرعاية الصحية إلى أن معقمات اليدين المركبة من الكحول تعتبر من السوائل سهلة الاشتعال، لذلك يجب توخي الحيلة والحذر وتجنب اي مصدر حراري مشتعل بعد استخدام المعقمات.

- لمزيد من المعلومات بهذا الخصوص، الرجاء التواصل مع برنامج الرقابة على الوسائل الطبية ما بعد التسويق في دائرة الصحة على الرقم: 02 419 3643 بريد إلكتروني: [medicaldevices@doh.gov.ae](mailto:medicaldevices@doh.gov.ae)

- الإبلاغ عن أي شكوى متعلقة بجودة منتج صيدلاني عبر: الهاتف: **02 419 3589** البريد الإلكتروني: [drugquality@doh.gov.ae](mailto:drugquality@doh.gov.ae)

نقدر لكم تعاونكم.

This circular is designed for regulatory procedures and should not be used as content for media publication.

هذا التعميم للإجراءات التنظيمية وغير مخصص كمحتوى للنشر الإعلامي.

مدير دائرة تراخيص الرعاية الصحية والتعليم الطبي  
Director Healthcare Licensing and Medical Education



## Guide to Local Production: WHO-recommended Handrub Formulations

**Introduction:** This Guide to Local Production of WHO-recommended Handrub Formulations is separated into two discrete but interrelated sections:

**Part A** provides a practical guide for use at the pharmacy bench during the actual preparation of the formulation. Users may want to display the material on the wall of the production unit.

**Part B** summarizes some essential background technical information and is taken from WHO Guidelines on Hand Hygiene in Health Care (2009). Within Part B the user has access to important safety and cost information and supplementary material relating to dispensers and distribution.



## PART A: GUIDE TO LOCAL PRODUCTION

Part A is intended to guide a local producer in the actual preparation of the formulation.

### Materials required (small volume production)

REAGENTS FOR FORMULATION 1:	REAGENTS FOR FORMULATION 2:
<ul style="list-style-type: none"> <li>Ethanol 96%</li> <li>Hydrogen peroxide 3%</li> <li>Glycerol 98%</li> <li>Sterile distilled or boiled cold water</li> </ul>	<ul style="list-style-type: none"> <li>Isopropyl alcohol 99.8%</li> <li>Hydrogen peroxide 3%</li> <li>Glycerol 98%</li> <li>Sterile distilled or boiled cold water</li> </ul>

- 10-litre glass or plastic bottles with screw-threaded stoppers ( 1 ), or
- 50-litre plastic tanks (preferably in polypropylene or high density polyethylene, translucent so as to see the liquid level) ( 2 ), or
- Stainless steel tanks with a capacity of 80–100 litres (for mixing without overflowing) ( 3 , 4 )
- Wooden, plastic or metal paddles for mixing ( 5 )
- Measuring cylinders and measuring jugs ( 6 , 7 )
- Plastic or metal funnel
- 100 ml plastic bottles with leak-proof tops ( 8 )
- 500 ml glass or plastic bottles with screw tops ( 8 )
- An alcoholometer: the temperature scale is at the bottom and the ethanol concentration (percentage v/v) at the top ( 9 , 10 , 11 )



#### NOTE

- Glycerol: used as humectant, but other emollients may be used for skin care, provided that they are cheap, widely available and miscible in water and alcohol and do not add to toxicity, or promote allergy.
- Hydrogen peroxide: used to inactivate contaminating bacterial spores in the solution and is not an active substance for hand antisepsis.
- Any further additive to both formulations should be clearly labelled and be non-toxic in case of accidental ingestion.
- A colorant may be added to allow differentiation from other fluids, but should not add to toxicity, promote allergy, or interfere with antimicrobial properties. The addition of perfumes or dyes is not recommended due to risk of allergic reactions.

## METHOD: 10-LITRE PREPARATIONS

These can be prepared in 10-litre glass or plastic bottles with screw-threaded stoppers.

### Recommended amounts of products:

FORMULATION 1	FORMULATION 2
<ul style="list-style-type: none"> <li>Ethanol 96%: <b>8333 ml</b></li> <li>Hydrogen peroxide 3%: <b>417 ml</b></li> <li>Glycerol 98%: <b>145 ml</b></li> </ul>	<ul style="list-style-type: none"> <li>Isopropyl alcohol 99.8%: <b>7515 ml</b></li> <li>Hydrogen peroxide 3%: <b>417 ml</b></li> <li>Glycerol 98%: <b>145 ml</b></li> </ul>

### Step by step preparation:



1. The alcohol for the formula to be used is poured into the large bottle or tank up to the graduated mark.



4. The bottle/tank is then topped up to the 10-litre mark with sterile distilled or cold boiled water.

5. The lid or the screw cap is placed on the tank/bottle as soon as possible after preparation, in order to prevent evaporation.



2. Hydrogen peroxide is added using the measuring cylinder.



6. The solution is mixed by shaking gently where appropriate or by using a paddle.



3. Glycerol is added using a measuring cylinder. As glycerol is very viscous and sticks to the wall of the measuring cylinder, it should be rinsed with some sterile distilled or cold boiled water and then emptied into the bottle/tank.



7. Immediately divide up the solution into its final containers (e.g. 500 or 100 ml plastic bottles), and place the bottles in quarantine for 72 hours before use. This allows time for any spores present in the alcohol or the new/re-used bottles to be destroyed.

## Final products

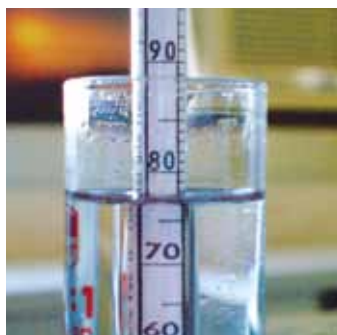
FORMULATION 1	FORMULATION 2
<b>Final concentrations:</b> <ul style="list-style-type: none"> <li>Ethanol 80% (v/v),</li> <li>Glycerol 1.45% (v/v),</li> <li>Hydrogen peroxide 0.125% (v/v)</li> </ul>	<b>Final concentrations:</b> <ul style="list-style-type: none"> <li>Isopropyl alcohol 75% (v/v),</li> <li>Glycerol 1.45% (v/v),</li> <li>Hydrogen peroxide 0.125% (v/v)</li> </ul>

## Quality control

1. Pre-production analysis should be made every time an analysis certificate is not available to guarantee the titration of alcohol (i.e. local production). Verify the alcohol concentration with the alcoholmeter and make the necessary adjustments in volume in the preparation formulation to obtain the final recommended concentration.



2. Post-production analysis is mandatory if either ethanol or an isopropanol solution is used. Use the alcoholmeter to control the alcohol concentration of the final use solution. The accepted limits should be fixed to  $\pm 5\%$  of the target concentration (75%–85% for ethanol).



3. The alcoholmeter shown in this information pamphlet is for use with ethanol; if used to control an isopropanol solution, a 75% solution will show 77% ( $\pm 1\%$ ) on the scale at 25°C.

## General information

Labelling should be in accordance with national guidelines and should include the following:

- Name of institution
- WHO-recommended handrub formulation
- For external use only
- Avoid contact with eyes
- Keep out of the reach of children
- Date of production and batch number
- Use: Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry
- Composition: ethanol or isopropanol, glycerol and hydrogen peroxide
- Flammable: keep away from flame and heat

## Production and storage facilities:

- Production and storage facilities should ideally be air conditioned or cool rooms. No naked flames or smoking should be permitted in these areas.
- WHO-recommended handrub formulations should not be produced in quantities exceeding 50-litres locally or in central pharmacies lacking specialised air conditioning and ventilation.
- Since undiluted ethanol is highly flammable and may ignite at temperatures as low as 10°C, production facilities should directly dilute it to the above-mentioned concentration. The flashpoints of ethanol 80% (v/v) and of isopropyl alcohol 75% (v/v) are 17.5°C and 19°C, respectively.
- National safety guidelines and local legal requirements must be adhered to the storage of ingredients and the final product.
- Additional safety information is presented in Part B of this Guide.

## PART B: SUPPLEMENTARY TECHNICAL, SAFETY AND COST INFORMATION:

Part B contains important safety and cost information and incorporates information from the WHO Guidelines on Hand Hygiene in Health Care (2009).

### The case for alcohol-based handrubs in health care

At present, alcohol-based handrubs are the only known means for rapidly and effectively inactivating a wide array of potentially harmful microorganisms on hands.

#### WHO recommends alcohol-based handrubs based on the following factors:

1. Evidence-based, intrinsic advantages of fast-acting and broad-spectrum microbicidal activity with a minimal risk of generating resistance to antimicrobial agents;
2. Suitability for use in resource-limited or remote areas with lack of accessibility to sinks or other facilities for hand hygiene (including clean water, towels, etc.);
3. Capacity to promote improved compliance with hand hygiene by making the process faster, more convenient and immediately accessible at the point of patient care;
4. Economic benefit by reducing annual costs for hand hygiene, representing approximately 1% of extra-costs generated by health care-associated infection
5. Minimization of risks from adverse events because of increased safety associated with better acceptability and tolerance than other products.

(Source: WHO Guidelines on Hand Hygiene in Health Care 2009)

### Background to WHO alcohol-based handrub formulations

According to the available evidence on efficacy, tolerability and cost-effectiveness, WHO recommends using an alcohol-based handrub for routine hand antisepsis in most clinical situations. Health-care facilities currently using commercially-available handrubs, liquid soaps and skin care products sold in disposable containers should continue this practice, provided that the handrubs meet recognised standards for microbicidal efficacy (ASTM or EN standards) and are well accepted/tolerated by the health-care workers. It is obvious that these products should be regarded as acceptable, even if their contents differ from those of WHO-recommended formulations described within this document. WHO recommends the local production of the following formulations as an alternative when suitable commercial products are either unavailable or too costly.

To help countries and health-care facilities to achieve system change and adopt alcohol-based handrubs, WHO has identified formulations for their local preparation. Logistic, economic, safety, cultural and religious factors have all been carefully considered by WHO before recommending such formulations for use worldwide.

### Efficacy

It is the consensus opinion of a WHO expert group that WHO-recommended handrub formulations can be used both for hygienic hand antisepsis and for presurgical hand preparation.

### Hygienic handrub

The microbicidal activity of the two WHO-recommended formulations was tested by WHO reference laboratories according to EN standards (EN 1500). Their activity was found to be equivalent to the reference substance (isopropanol 60% v/v) for hygienic hand antisepsis.

### Presurgical hand preparation

Both WHO-recommended handrub formulations were tested by two independent reference laboratories in different European countries to assess their suitability for use for pre-surgical hand preparation, according to the European Standard EN 12791. Although formulation I did not pass the test in both laboratories and formulation II in only one of them, the expert group is, nevertheless, of the opinion that the microbicidal activity of surgical antisepsis is still an ongoing issue for research as due to the lack of epidemiological data there is no indication that the efficacy of n-propanol (propan-1-ol) 60% v/v as a reference in EN 12791 finds a clinical correlate. It is the consensus opinion of a WHO expert group that the choice of n-propanol is inappropriate as the reference alcohol for the validation process because of its safety profile and the lack of evidence-based studies related to its potential harmfulness for humans. Indeed, only a few formulations worldwide have incorporated n-propanol for hand antisepsis.

Considering that other properties of WHO recommended formulations, such as their excellent tolerability, good acceptance by health-care workers and low cost are of high importance for a sustained clinical effect, the above results are considered acceptable and it is the consensus opinion of a WHO expert group that the two formulations can be used for surgical hand preparation. Institutions opting to use WHO-recommended formulations for surgical hand preparation should ensure that a minimum of three applications are used, if not more, for a period of 3–5 minutes. For surgical procedures of more than 2 hours duration, ideally surgeons should practise a second handrub of approximately 1 minute, even though more research is needed on this aspect.

### Key lessons learned from around the world

Many settings around the world successfully undertook local production of the two WHO-recommended formulations. Throughout Part B, additional information is presented where relevant, in table form, based on feedback from 11 sites located in Bangladesh, Costa Rica, Egypt, Hong Kong SAR, Kenya, Mali, Mongolia, Pakistan (two sites), Saudi Arabia, and Spain. Further, detailed information is available within the WHO Guidelines on Hand Hygiene in Health Care (2009)

## Composition of alcohol-based formulations for in-house/local production

The choice of components for WHO handrubs takes into account both cost constraints and microbiological efficacy. The procurement of raw ingredients will be influenced by the availability of sub-standard materials on the market and it is important to select local sources with care.

The following two alcohol-based handrub formulations are recommended for preparation in-house or in a local production facility, up to a maximum of 50 litres:

### Formulation 1

To produce final concentrations of ethanol 80% v/v, glycerol 1.45% v/v, hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) 0.125% v/v.

### Formulation 2

To produce final concentrations of isopropyl alcohol 75% v/v, glycerol 1.45% v/v, hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) 0.125% v/v:

Only pharmacopoeial quality reagents should be used (e.g. The International Pharmacopoeia) and not technical grade products.

## Raw materials:

While alcohol is the active component in the formulations, certain aspects of other components should be respected. All raw materials used should be preferably free of viable bacterial spores. The raw materials for inclusion/consideration are listed in the table below:

<b>H<sub>2</sub>O<sub>2</sub></b>	<ul style="list-style-type: none"> <li>The low concentration of H<sub>2</sub>O<sub>2</sub> is intended to help eliminate contaminating spores in the bulk solutions and recipients and is not an active substance for hand antisepsis.</li> <li>H<sub>2</sub>O<sub>2</sub> adds an important safety aspect, however the use of 3–6% for the production might be complicated by its corrosive nature and by difficult procurement in some countries.</li> <li>Further investigation is needed to assess H<sub>2</sub>O<sub>2</sub> availability in different countries as well as the possibility of using a stock solution with a lower concentration.</li> </ul>
<b>Glycerol and other humectants or emollients</b>	<ul style="list-style-type: none"> <li>Glycerol is added as a humectant to increase the acceptability of the product.</li> <li>Other humectants or emollients may be used for skin care, provided that they are affordable, available locally, miscible (mixable) in water and alcohol, non-toxic, and hypoallergenic.</li> <li>Glycerol has been chosen because it is safe and relatively inexpensive. Lowering the percentage of glycerol may be considered to further reduce stickiness of the handrub.</li> </ul>
<b>Use of proper water</b>	<ul style="list-style-type: none"> <li>While sterile distilled water is preferred for making the formulations, boiled and cooled tap water may also be used as long as it is free of visible particules.</li> </ul>
<b>Addition of other additives</b>	<ul style="list-style-type: none"> <li>It is strongly recommended that no ingredients other than those specified here be added to the formulations.</li> <li>In the case of any additions, full justification must be provided together with documented safety of the additive, its compatibility with the other ingredients, and all relevant details should be given on the product label.</li> </ul>
<b>Gelling agents</b>	<ul style="list-style-type: none"> <li>No data are available to assess the suitability of adding gelling agents to WHO-recommended liquid formulations, but this could increase potentially both production difficulties and costs, and may compromise antimicrobial efficacy.</li> </ul>
<b>Fragrances</b>	<ul style="list-style-type: none"> <li>The addition of fragrances is not recommended because of the risk of allergic reactions.</li> </ul>

All handrub containers must be labelled in accordance with national and international guidelines.



### Cleansing and disinfection process for reusable handrub bottles:

1. Bring empty bottles to a central point for reprocessing by standard operational protocols;
2. Wash bottles thoroughly with detergent and tap water to eliminate any residual liquid;
3. If heat-resistant, thermally disinfect bottles by boiling in water. Whenever possible, thermal disinfection should be chosen in preference to chemical disinfection. The latter may increase costs and introduces an extra step to flush out the remains of the disinfectant. Chemical disinfection should include soaking the bottles in a solution containing 1000 ppm of chlorine for a minimum of 15 minutes and then rinsing with sterile/cooled boiled water;
4. After thermal or chemical disinfection, leave bottles to dry completely upside-down in a bottle rack. Dry bottles should be closed with a lid and stored, protected from dust, until use.

Procurement of components: key learning from around the world (based on feedback from the field)	
<b>Ethanol</b>	Easier to procure from local suppliers due to cost in some countries. <ul style="list-style-type: none"> <li>• Can be derived from sugar cane or wheat.</li> <li>• Subject to licensing restrictions and strict record-keeping – an important consideration prior to embarking on production.</li> </ul>
<b>Isopropyl</b>	Easier to procure in some countries.
<b>Glycerol</b>	Produced by local suppliers in most cases.
<b>Hydrogen peroxide</b>	Difficulties sourcing satisfactory H <sub>2</sub> O <sub>2</sub> resulted in the need to import in five sites.

### Production and storage

Manufacture of WHO-recommended handrub formulations is feasible in central pharmacies or dispensaries. Whenever possible and according to local policies, governments should encourage local production, support the quality assessment process, and keep production costs as low as possible. Special requirements apply for the production and stock piling of the formulations, as well as for the storage of the raw materials.

Because undiluted ethanol is highly flammable and may ignite at temperatures as low as 10°C, production facilities should directly dilute it to the concentrations detailed within this guide. (Refer to *Summary table of risks and mitigation measures concerning the use of alcohol-based hand hygiene preparations*)

WHO is exploring the development of additional guidance on large-scale production to facilitate scale-up.

### Quality Control:

If concentrated alcohol is obtained from local production, verify the alcohol concentration and make the necessary adjustments in volume to obtain the final recommended concentration. An alcoholmeter can be used to control the alcohol concentration of the final use solution; H<sub>2</sub>O<sub>2</sub> concentration can be measured by titrimetry (oxydo-reduction reaction by iodine in acidic conditions). A higher level quality control can be performed using gas chromatography and the titrimetric method to control the alcohol and the hydrogen peroxide content, respectively. Moreover, the absence of microbial contamination (including spores) can be checked by filtration, according to the European Pharmacopeia specifications.

Production facilities and personnel: key learning from around the world (based on feedback from the field)	
<b>Who are the main producers?</b>	<ul style="list-style-type: none"> <li>• Qualified pharmacists.</li> </ul>
<b>How much is produced?</b>	<ul style="list-style-type: none"> <li>• 10 litres to 600,000 litres per month was produced in test-sites.</li> </ul>
<b>Where does production occur?</b>	<ul style="list-style-type: none"> <li>• Hospital pharmacy.</li> <li>• National drug companies.</li> </ul>
<b>Production equipment</b>	<ul style="list-style-type: none"> <li>• Plastic, stainless steel and glass containers were used for mixing.</li> </ul>
<b>Dispensers for final product</b>	<ul style="list-style-type: none"> <li>• Ranges used:                             <ul style="list-style-type: none"> <li>– 100 ml pocket bottles</li> <li>– 385 ml bottles</li> <li>– 500 ml wall-mounted dispensers</li> <li>– 1 litre wall mounted bottles or bags</li> </ul> </li> </ul>
<b>Sources of dispensers</b>	<ul style="list-style-type: none"> <li>• Local sourcing can prove problematic, some countries had success working with local private sector suppliers.</li> </ul>

Quality control: key learning from around the world (based on feedback from the field)	
<b>Method</b>	<ul style="list-style-type: none"> <li>• Local alcoholmeters used in majority of sites.</li> <li>• Seven sites sent samples to the University of Geneva Hospitals, Geneva, Switzerland, for quality checks by gas chromatography and the titrimetric method to control the alcohol and the hydrogen peroxide content.</li> </ul>
<b>Addition of fragrance</b>	<ul style="list-style-type: none"> <li>• Quality was optimal for three formulations in which either a fragrance or special humectants were added to WHO formulation I.</li> </ul>
<b>Extremes of climate</b>	<ul style="list-style-type: none"> <li>• Samples from Mali, which were kept in a tropical climate without air conditioning or special ventilation, were in accordance with the optimal quality parameters in all samples up to 19 months after production.</li> </ul>

### Storage volumes:

Special requirements are applicable for the production and storage of the formulations, as well as the storage of the primary products. The quantity of locally-produced WHO handrub should not exceed 50 litres, or possibly less if regulated by local and/or national guidelines and regulations.

## Distribution

To avoid contamination with spore-forming organisms, disposable bottles should preferably be used although reusable sterilizable bottles may reduce production costs and waste management. To prevent evaporation, containers should have a maximum capacity of 500 ml on ward and 1 litre in operating theatres, and ideally fit into a wall dispenser. Leakage-free pocket bottles with a capacity of no more than 100 ml should also be available and distributed individually to health-care workers, but it should be emphasized that the use of these products should be confined to health care only. The production or re-filling unit should follow norms on how to clean and disinfect the bottles (e.g. autoclaving, boiling, or chemical disinfection with chlorine). Autoclaving is considered the most suitable procedure. Reusable bottles should never be refilled until they have been completely emptied and then cleansed and disinfected.

### Cleaning and recycling: key learning from around the world (based on feedback from the field)

Cleaning and recycling of dispensers	<ul style="list-style-type: none"> <li>The cleaning and recycling process outlined in this document was applied in six sites. Methods used for disinfection varied and included treatment with chlorine or alcohol.</li> </ul>
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## Cost issues:

The costs of WHO handrub formulations may vary according to country, resources and labour costs; studies to evaluate costs and resource use are necessary. As a comparison, examples of actual prices of commercially available alcohol-based handrubs in different countries are detailed within the Guidelines.

### Costs: Key learning from around the world (based on feedback from the field)

Production cost (including salaries but not the dispenser) per 100 ml	Formulation 1: <ul style="list-style-type: none"> <li>US\$ 0.37 (Kenya)</li> <li>US\$ 0.30 (Mali)</li> </ul> Formulation 2: <ul style="list-style-type: none"> <li>US\$ 0.30 (Bangladesh).</li> </ul>
Production cost (including the pocket bottle) per 100 ml	Formulation 1: <ul style="list-style-type: none"> <li>US\$ 0.50 (Hong Kong)</li> </ul> Formulation 2: <ul style="list-style-type: none"> <li>US\$ 0.44 (Pakistan)</li> </ul>
Range of cost of commercially available products per 100 ml	<ul style="list-style-type: none"> <li>US\$ 2.50–5.40 (liquid)</li> <li>US\$ 8 (gel)</li> </ul>

## Safety Standards

With regard to skin reactions, handrubbing with alcohol based solutions is better tolerated than handwashing with soap and water. In a recent study conducted among ICU health-care workers, the short-term skin tolerability and acceptability of WHO-recommended handrub formulations were significantly higher than those of a reference product. Any additive should be as non-toxic as possible in case of accidental or intentional ingestion.

## General Safety Issues:

The main safety issues relate to the flammability of alcohol-based handrubs and the adverse effects associated with accidental or deliberate ingestion. These are summarised in the *Summary table of risks and mitigation measures concerning the use of alcohol-based hand hygiene preparations*.

## Flammability – Flash-points:

The flash points of ethanol 80% (v/v) and isopropyl alcohol 75% (v/v) are 17.5°C and 19°C, respectively, and special attention should be given to proper storage in tropical climates. Production and storage facilities should be ideally air-conditioned or cool rooms. Open flames and smoking must be strictly prohibited in production and storage areas. Pharmacies and small-scale production centres supplying WHO-recommended handrub formulations are advised not to manufacture locally batches of more than 50 litres at a time.

## Accidental ingestion:

In general, it is not recommended to add any bittering agents to reduce the risk of ingestion of the handrubs. Nevertheless, in exceptional cases where the risk of ingestion might be very high (paediatric or confused patients), substances such as methylethylketone and denatonium benzoate, added to some household products to make them less palatable, may be added to alcohol-based handrubs in order to reduce the risk of accidental or deliberate ingestion. However, there is no published information on the compatibility and deterrent potential of such chemicals when used in alcohol-based handrubs to discourage their abuse. It is important to note that such additives may make the products toxic and add to production costs. In addition, the bitter taste may be transferred from hands to food being handled by individuals using handrubs containing such agents. Therefore, compatibility and suitability, as well as cost, must be carefully considered before deciding on the use of such bittering agents.

A colorant may be incorporated to differentiate the handrub from other fluids as long as such an additive is safe and compatible with the essential components of the handrubs. However, the H<sub>2</sub>O<sub>2</sub> in the handrubs may tend to fade any colouring agent used and prior testing is recommended.

## Summary table of risks and mitigation measures concerning the use of alcohol-based hand hygiene preparations

Risk	Mitigation	Risk	Mitigation
<b>Fire – general</b>	<ul style="list-style-type: none"> <li>Do not produce in quantities exceeding 50 litres locally. If producing in excess of 50 litres, produce only in central pharmacies with specialized air conditioning and ventilation.</li> <li>Since undiluted ethanol is highly flammable production facilities should directly dilute it to the concentrations outlined in this Guide.</li> <li>Involve fire officers, fire safety advisers, risk managers, and health and safety and infection control professionals in risk assessments prior to embarking on system change</li> <li>Risk assessment should take into account: <ul style="list-style-type: none"> <li>The location of dispensers</li> <li>The storage of stock</li> <li>The disposal of used containers/ dispensers and expired stock.</li> </ul> </li> <li>Store away from high temperatures or flames</li> <li>Water or aqueous (water) film-forming foam (AFFF) should be used in case of fire; other types of extinguishers may be ineffective and may spread the fire over a larger area rather than put it out.</li> <li>Health-care workers should be advised to rub hands until dry (once dry – hands are safe).</li> </ul>	<b>Fire – storage (local)</b>	<ul style="list-style-type: none"> <li>The quantity of handrub kept in a ward or department should be as small as is reasonably practicable for day-to-day purposes.</li> </ul>
		<b>Fire – disposal</b>	<ul style="list-style-type: none"> <li>Rinse out used containers with copious amounts of cold water to reduce the risk of fire (the containers may then be recycled or disposed of in general waste).</li> </ul>
		<b>Fire – location of dispensers</b>	<ul style="list-style-type: none"> <li>Handrub dispensers should not be placed above or close to potential sources of ignition, such as light switches and electrical outlets, or next to oxygen or other medical gas outlets (because of the increased risk of vapours igniting).</li> </ul>
		<b>Fire – spillage</b>	<ul style="list-style-type: none"> <li>Significant spillages should be dealt with immediately by removing all sources of ignition, ventilating the area, and diluting the spillage with water (to at least 10-times the volume).</li> <li>The fluid should then be absorbed by an inert material such as dry sand (not a combustible material such as sawdust), which should be disposed of in a chemical waste container.</li> <li>Vapours should be dispersed by ventilating the room (or vehicle), and the contaminated item should be put in a plastic bag until it can be washed and/or dried safely.</li> </ul>
<b>Fire – production and storage (central)</b>	<ul style="list-style-type: none"> <li>Local and central (bulk) storage must comply with fire regulations regarding the type of cabinet and store, respectively.</li> <li>Production and storage facilities should ideally be air-conditioned or cool rooms.</li> <li>No naked flames or smoking should be permitted in these areas.</li> <li>National safety guidelines and local legal requirements must be adhered to for the storage of ingredients and the final product.</li> <li>Containers/dispensers should be stored in a cool place and care should be taken regarding the securing of tops/lids.</li> <li>A designated ‘highly flammables’ store will be required for situations where it is necessary to store more than 50 litres.</li> <li>Containers and dispenser cartridges containing handrub should be stored in a cool place away from sources of ignition. This applies also to used containers that have not been rinsed with water.</li> </ul>	<b>Ingestion</b>	<ul style="list-style-type: none"> <li>In areas where there is thought to be a high risk of ingestion, a staff-carried product is advised.</li> <li>If a wall-mounted product is used, consideration should be given to small bottles.</li> <li>If bottles with a greater capacity than 500 ml are used, consideration should be given to providing them in secured containers.</li> <li>Product containers may be labelled simply as “antimicrobial handrubs” with a warning of dangers associated with ingestion.</li> <li>National and local toxicology specialists should be involved in developing and issuing national/ local guidance on how to deal with ingestion (based on products available within a country).</li> </ul>
		<b>Other</b>	<ul style="list-style-type: none"> <li>Consideration should be given to the risks associated with spillage onto floor coverings, including the risk of pedestrian slips – it is important to deal with spillages immediately.</li> <li>The siting of handrub dispensers above carpets is not recommended, because of the risk of damage and lifting/warping of carpets.</li> </ul>

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# Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2). Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact FDA's human drug compounding team (CDER) at [compounding@fda.hhs.gov](mailto:compounding@fda.hhs.gov).

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)**

**March 2020  
Compounding**

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# Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry

*Additional copies are available from:  
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<https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>*

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)**

**March 2020  
Compounding**

**TABLE OF CONTENTS**

<b>I.</b>	<b>INTRODUCTION.....</b>	<b>1</b>
<b>II.</b>	<b>BACKGROUND .....</b>	<b>2</b>
<b>III.</b>	<b>DISCUSSION .....</b>	<b>2</b>

## **Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry<sup>1</sup>**

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

### **I. INTRODUCTION**

Due to the Coronavirus Disease 2019 (COVID-19) pandemic, the Food and Drug Administration (FDA or Agency) has received a number of queries concerning compounding of alcohol-based hand sanitizers. The Agency is issuing this guidance to communicate its policy for the temporary compounding of certain alcohol-based hand sanitizer products by pharmacists in State-licensed pharmacies or Federal facilities and registered outsourcing facilities (referred to collectively in this guidance as compounders) for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020.<sup>2</sup>

In light of the public health emergency posed by COVID-19, this guidance is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)(i)) and 21 CFR 10.115(g)(2)). This guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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<sup>1</sup> This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research at the Food and Drug Administration.

<sup>2</sup> The HHS Public Health Emergency Declaration is available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

## *Contains Nonbinding Recommendations*

### **II. BACKGROUND**

There is currently an outbreak of respiratory disease caused by a novel coronavirus that was first detected in Wuhan City, Hubei Province, China, and that has now been detected in many locations internationally, including cases in the United States. The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). SARS-CoV-2 has demonstrated the capability to rapidly spread, leading to significant impacts on healthcare systems and causing societal disruption. The potential public health threat posed by COVID-19 is high, both globally and to the United States. On January 31, 2020, the Secretary of HHS determined that a public health emergency exists.

Hand hygiene is an important part of the U.S. response to COVID-19. Washing hands often with soap and water for at least 20 seconds is essential, especially after going to the bathroom, before eating, and after coughing, sneezing or blowing one’s nose. If soap and water are not readily available, the Centers for Disease Control and Prevention (CDC) recommends consumers use an alcohol-based hand sanitizer that contains at least 60 percent alcohol (also referred to as ethanol or ethyl alcohol).<sup>3</sup>

### **III. DISCUSSION**

We understand that some consumers and health care professionals are currently experiencing difficulties accessing alcohol-based hand sanitizers. We are also aware of reports that some consumers are producing hand sanitizers for personal use; the Agency lacks information on the methods being used to prepare such products and whether they are safe for use on human skin. We further recognize that compounders, relative to untrained consumers, are more familiar with standards and methods for producing drug products.

Because of the public health emergency posed by COVID-19, FDA does not intend to take action against compounders<sup>4</sup> that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, provided the following circumstances are present:

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<sup>3</sup> Isopropyl alcohol and ethyl alcohol are two of the active ingredients currently being evaluated by FDA as part of its review of over-the-counter (OTC) monographs for hand sanitizers for use in reducing bacteria on the skin that potentially can cause disease or decreasing bacteria on the skin. See “Safety and Effectiveness of Consumer Antiseptic Rubs; Topical Antimicrobial Drug Products for Over-the-Counter Human Use,” Final Rule, 84 FR 14847 (April 12, 2019); Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use Final Rule, 82 FR 60474 (December 20, 2017); “Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products,” Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM).

<sup>4</sup> Specifically, FDA does not intend to take action against pharmacists in State-licensed pharmacies or Federal facilities, for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, for violations of sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act (21 U.S.C. 351(a)(2)(B), 352(f)(1), and 355), or against outsourcing facilities for violations of sections 502(f)(1), 505, or 582 of the FD&C Act (21 U.S.C. 352(f)(1), 355, and 360eee-1).



## *Contains Nonbinding Recommendations*

1. The hand sanitizer is compounded using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:<sup>5</sup>
  - a. Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20; **or** Isopropyl Alcohol (75%, v/v) in an aqueous solution.<sup>6</sup>
  - b. Glycerol (1.45% v/v).<sup>7</sup>
  - c. Hydrogen peroxide (0.125% v/v).
  - d. Sterile distilled water or boiled cold water.

**The compounder does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.**

2. The compounder pays particular attention to ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used.
3. The hand sanitizer is prepared under conditions routinely used by the compounder to compound similar nonsterile drugs.<sup>8</sup>
4. The hand sanitizer is labeled consistent with the attached labeling in Appendix A (Labeling for Ethyl Alcohol Formulation Consumer Use), Appendix B (Labeling for Isopropyl Alcohol Formulation Consumer Use), Appendix C (Labeling for Ethyl Alcohol Formulation Health Care Personnel Handrub Use), or Appendix D (Labeling for Isopropyl Alcohol Formulation Health Care Personnel Handrub Use).

This policy does not extend to other types of products, such as products that use different active ingredients, whose potency falls above or below the formulation described above, that are marketed with claims that do not conform to the “Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products,” Proposed Rule, 59 FR 31402 (June 17, 1994) (e.g., pathogen-specific disease claims), that are surgical hand rubs, or whose advertising or promotion is false or misleading in any particular.

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<sup>5</sup>The 1994 TFM is available at <https://www.gpo.gov/fdsys/pkg/FR-1994-06-17/html/94-14503.htm>. WHO’s recommendations, titled “Guide to Local Production: WHO-recommended Handrub Formulations,” are available at [https://www.who.int/gpsc/5may/Guide\\_to\\_Local\\_Production.pdf](https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf).

<sup>6</sup> Consistent with the 1994 TFM, alcohol should be used in a final product concentration between 60-95% (v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20; isopropyl alcohol should be used in a concentration between 70-91.3% (v/v). This guidance is consistent with WHO’s recommended formulation specifications of 80% alcohol and 75% isopropyl alcohol.

<sup>7</sup> Although WHO’s recommended formulation includes glycerol 1.45% (v/v), reports indicate that glycerol negatively impacts effectiveness of isopropyl alcohol (<https://www.ncbi.nlm.nih.gov/pubmed/28670452>), and reports studying the effectiveness of WHO’s formulation have suggested a reduction from 1.45% to 0.725% (<https://www.ncbi.nlm.nih.gov/pubmed/23388358/>).

<sup>8</sup> In particular, outsourcing facilities compound drugs subject to current Good Manufacturing Practice requirements, and other pharmacy compounders generally prepare nonsterile drug products from bulk drug substances in compliance with United States Pharmacopoeia chapter 795. Both outsourcing facilities and other pharmacy compounders must also avoid insanitary conditions as set forth in section 501(a)(2)(A) of the FD&C Act (21 U.S.C. 351(a)(2)(A)).

*Contains Nonbinding Recommendations*

FDA encourages consumers and health care professionals to report adverse events experienced with the use of hand sanitizers to FDA's [MedWatch Adverse Event Reporting](#) program:

- Complete and submit the report [online](#); or
- Download and complete the [form](#), then submit it via fax at 1-800-FDA-0178.

Outsourcing facilities can see [Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act](#) for more information.

*Contains Nonbinding Recommendations*

**Appendix A. Labeling for Ethyl Alcohol Formulation Consumer Use**

**PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):**

**Alcohol Antiseptic 80%  
Topical Solution**

**Hand Sanitizer  
Non-sterile Solution**

**[Insert Volume of Product in mL]**

**DRUG FACTS LABEL**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 80% v/v.....	Antiseptic
<b>Use[s]</b>	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
<ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>	
<b>Other information</b>	
<ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

*Contains Nonbinding Recommendations*

**Appendix B. Labeling for Isopropyl Alcohol Formulation Consumer Use**

**PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):**

**Isopropyl Alcohol Antiseptic 75%  
Topical Solution**

**Hand Sanitizer  
Non-sterile Solution**

**[Insert Volume of Product in mL]**

**DRUG FACTS LABEL**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Isopropyl alcohol 75% v/v.....	Antiseptic
<b>Use[s]</b>	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
<ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>	
<b>Other information</b>	
<ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

*Contains Nonbinding Recommendations*

**Appendix C. Labeling for Ethyl Alcohol Formulation Health Care Personnel Handrub Use**

**PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):**

**Alcohol Antiseptic 80%  
Topical Solution**

**Antiseptic Hand Rub  
Non-sterile Solution**

**[Insert Volume of Product in mL]**

**DRUG FACTS LABEL**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 80% v/v.....	Antiseptic
<b>Use[s]</b>	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
• in children less than 2 months of age	
• on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
• Place enough product on hands to cover all surfaces. Rub hands together until dry.	
• Supervise children under 6 years of age when using this product to avoid swallowing.	
<b>Other information</b>	
• Store between 15-30C (59-86F)	
• Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

*Contains Nonbinding Recommendations*

**Appendix D. Labeling for Isopropyl Alcohol Formulation Health Care Personnel Handrub Use**

**PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):**

**Isopropyl Alcohol Antiseptic 75%  
Topical Solution**

**Antiseptic Hand Rub  
Non-sterile Solution**

**[Insert Volume of Product in mL]**

**DRUG FACTS LABEL**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Isopropyl alcohol 75% v/v.....	Antiseptic
<b>Use[s]</b>	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b>	
<b>For external use only. Flammable. Keep away from heat or flame</b>	
<b>Do not use</b>	
• in children less than 2 months of age	
• on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
• Place enough product on hands to cover all surfaces. Rub hands together until dry.	
• Supervise children under 6 years of age when using this product to avoid swallowing.	
<b>Other information</b>	
• Store between 15-30C (59-86F)	
• Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	