World Health Organization | Patient Safety — A World Alliance for Safer Health Care | SAVE LIVES Clean Your Hands

Guia de Produção Local:
WHO-Formulações recomendadas de álcool-gel.

O download do arquivo original pode ser feito em:
https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf

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Introdução: Este guia para a produção local de formulações recomendadas de álcool-gel para as mãos pela OMS e é separado em duas seções distintas, mas inter-relacionadas:

Parte A fornece um guia prático para uso na bancada da farmácia durante a preparação real da formulação. Os usuários podem exibir o material na parede da unidade de produção.

Parte B resume algumas informações técnicas básicas e é retirada das Diretrizes da OMS sobre Higiene das Mãos nos Cuidados com a Saúde (2009). Na Parte B, o usuário tem acesso a informações importantes sobre segurança e custos e material suplementar relacionado a distribuidores e distribuição.

MÉTODO: PREPARAÇÕES DE 10 LITROS

Estes podem ser preparados em garrafas de vidro ou plástico de 10 litros com rolhas de rosca.

Quantidades recomendadas de produtos:

FORMULAÇÃO 1	FORMULAÇÃO 2
• Etanol 96%: **8333 ml** • Peróxido de hidrogênio 3%: **417 ml** • Glicerol 98%: **145 ml**	• Alcool isopropilico 99.8%: **7515 ml** • Peróxido de hidrogênio 3%: **417 ml** • Glicerol 98%: **145 ml**

Preparação passo-a-passo:

1. O álcool da fórmula a ser utilizada é derramado no grande frasco ou tanque até a marca graduada.

2. O peroxido de hidrogênio é adicionado usando o cilindro de medição.

3. O glicerol é adicionado usando um cilindro de medição. Como o glicerol é muito viscoso e adere à parede do cilindro de medição, ele deve ser lavado com água fervida estéril ou destilada a frio e depois esvaziado no frasco / tanque.

4. O frasco / tanque é depois enchido até a marca de 10 litros com água fervida estéril ou destilada a frio.

5. A tampa ou a tampa de rosca é colocado no tanque / garrafa logo que possível após a preparação, a fim de evitar a evaporação
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6. A solução é misturada agitando suavemente onde apropriado ou usando uma pá.

7. Divida imediatamente a solução em seus recipientes finais (por exemplo, garrafas de plástico de 500 ou 100 ml) e coloque-as em quarentena por 72 horas antes do uso. Isso permite que os esporos presentes no álcool ou nas garrafas novas / reutilizadas sejam destruídos.

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)

Procurement of components: key learning from around the world (based on feedback from the field)	
Ethanol	Easier to procure from local suppliers due to cost in some countries. • Can be derived from sugar cane or wheat. • Subject to licensing restrictions and strict record-keeping – an important consideration prior to embarking on production.
Isopropyl	Easier to procure in some countries.
Glycerol	Produced by local suppliers in most cases.
Hydrogen peroxide	Difficulties sourcing satisfactory H_2O_2 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.

Production facilities and personnel: key learning from around the world (based on feedback from the field)	
Who are the main producers?	• Qualified pharmacists.
How much is produced?	• 10 litres to 600,000 litres per month was produced in test-sites.
Where does production occur?	• Hospital pharmacy. • National drug companies.
Production equipment	• Plastic, stainless steel and glass containers were used for mixing.
Dispensers for final product	• Ranges used: – 100 ml pocket bottles – 385 ml bottles – 500 ml wall-mounted dispensers – 1 litre wall mounted bottles or bags
Sources of dispensers	• Local sourcing can prove problematic, some countries had success working with local private sector suppliers.

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.

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.

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_2O_2 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.

Quality control: key learning from around the world (based on feedback from the field)	
Method	• Local alcoholmeters used in majority of sites. • 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.
Addition of fragrance	• Quality was optimal for three formulations in which either a fragrance or special humectants were added to WHO formulation I.
Extremes of climate	• 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.

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

Risk	Mitigation
Fire – general	• 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. • Since undiluted ethanol is highly flammable production facilities should directly dilute it to the concentrations outlined in this Guide. • 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 • Risk assessment should take into account: – The location of dispensers – The storage of stock – The disposal of used containers/ dispensers and expired stock. • Store away from high temperatures or flames • 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. • Health-care workers should be advised to rub hands until dry (once dry – hands are safe).
Fire – production and storage (central)	• Local and central (bulk) storage must comply with fire regulations regarding the type of cabinet and store, respectively. • Production and storage facilities should ideally be air-conditioned or cool rooms. • No naked flames or smoking should be permitted in these areas. • National safety guidelines and local legal requirements must be adhered to for the storage of ingredients and the final product. • Containers/dispensers should be stored in a cool place and care should be taken regarding the securing of tops/lids. • A designated 'highly flammables' store will be required for situations where it is necessary to store more than 50 litres. • 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.

Risk	Mitigation
Fire – storage (local)	• The quantity of handrub kept in a ward or department should be as small as is reasonably practicable for day-to-day purposes.
Fire – disposal	• 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).
Fire – location of dispensers	• 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).
Fire – spillage	• 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). • 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. • 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.
Ingestion	• In areas where there is thought to be a high risk of ingestion, a staff-carried product is advised. • If a wall-mounted product is used, consideration should be given to small bottles. • If bottles with a greater capacity than 500 ml are used, consideration should be given to providing them in secured containers. • Product containers may be labelled simply as "antimicrobial handrubs" with a warning of dangers associated with ingestion. • 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).
Other	• 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. • The siting of handrub dispensers above carpets is not recommended, because of the risk of damage and lifting/warping of carpets.