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Cosmetics Europe Temporary Guidance on Personal-Hygiene Cleansing Hand Gels in the context of the ongoing CoVid-19 health crisis

1. Introduction

This guidance is meant for manufacturers who want to temporarily adapt their manufacturing to contribute to the solution to the ongoing health crisis by donating cosmetic hand cleansing gel products to their workers, health institutions and the public. The guidance is not aimed at the broad spectrum of hand gels that are already commercially placed on the market with a range of different compositions, intended benefits and use instructions.

The COVID-19 outbreak is impacting societies, citizens and economies in Europe and around the world. The World Health Organisation lists regular and thorough cleaning of hands with an alcohol-based hand rub or washing them with soap and water as the first basic protective measure against the new coronavirus. The European and US Centres for Disease Prevention and Control also point to cleansing hand hygiene as one of important preventive measures:

[1]*Hand hygiene refers to the frequent washing of hands with soap and water or cleaning of hands with alcoholic solutions, gels or tissues.*

[2]*Clean your hands often:*

- *Wash your hands often with soap and water for at least 20 seconds especially after you have been in a public place, or after blowing your nose, coughing, or sneezing.*
- *If soap and water are not readily available, use a hand sanitizer that contains at least 60% alcohol. Cover all surfaces of your hands and rub them together until they feel dry.*

Cosmetic and personal care manufacturers in Europe have raw materials and equipment at their disposal that allow to produce such hand cleansing and personal hygiene formulations. Many companies are ready to engage in this extraordinary crisis situation by making these products available not only within their companies (e.g. factories and shops) but also as donations to public institutions and the public. To support them in this effort, Cosmetics Europe, wishes to provide guidance on regulatory and technical aspects such as formulation, packaging compatibility, labelling, manufacturing and others in relation to such hand gels.

[1] ECDC TECHNICAL REPORT Guidelines for the use of non-pharmaceutical measures to delay and mitigate the impact of 2019-nCoV February 2020

[2] https://www.cdc.gov/coronavirus/2019-ncov/prepare/prevention.html

2. Scope

Note that ethanol, the main ingredient for Personal Hygiene Cleansing Hand Gels, is also an important raw material for institutional disinfection products used in hospitals. In the course of the ongoing health crisis, it may become a scarce raw material which needs to be directed towards the highest priority uses. Companies considering making available Personal-Hygiene Cleansing Hand Gels should therefore co-ordinate with local health authorities to identify their needs and priorities.

This guidance only addresses ethanol-based hand gel products that are made available as for company-internal use within the cosmetic sector (to ensure safety and hygiene in shops and factories and allow continued operation under GMP conditions) or as donations to public institutions and the public. It does not cover products that are placed on the market for commercial purposes.

The guidance also does not aim to provide comprehensive guidance on the borderline between the Cosmetic Products Regulation (EU No 1223/2009) and the Biocidal Product Regulation (Regulation (EU) No 528/2012) with regard to alcoholic hand gels. Whilst the guidance presents important product characteristics to be considered in order to ensure that the product falls in the scope of the Cosmetics Regulation, companies need to decide themselves on the regulatory status of their product and chose which regulatory framework is most appropriate, also in view of local considerations. In case of doubt, companies should contact the local trade association in the Member State where they want to donate the product or make it available in their factories or shops.

This guidance is to be considered as strictly temporary and it will be rescinded when the ongoing health crisis has ended, or when the need for increased production of such hand gels has ceased.

3. Guidance

Personal-hygiene cleansing hand gels made available as cosmetic products should fulfil the following conditions in order to ensure safety and to deliver the necessary end-user benefit:

a) Formulation

It is recognised in the EU Cosmetic Product Notification Portal CPNP[3] that hydroalcoholic skin gels can in principle be cosmetic products. The CPNP Frame Formula 1.9 describes the ingredient types and concentration ranges for a typical cosmetic hydroalcoholic gel formulation (see Annex I for full Frame Formula 1.9).

In the context of the ongoing public health crisis, personal-hygiene cosmetic hand gels in the scope of this guidance should be formulated with a minimum ethanol content of 52 % wt/wt or 60 % vol/vol to fulfil necessary hand hygienic requirements[4]. At the same time, in order to fall within the CPNP Frame Formulation 1.9, the ethanol content should not exceed 70 % wt/wt (approx. 88 % vol/vol).

[3] Web-based system implementing the notification requirement under Art. 13 of Regulation 1223/2009/EC

[4] http://www.who.int/gpsc/5may/tools/who_guidelines-handhygiene_summary.pdf

With regard to other ingredients, the formulation should be kept as simple as possible to facilitate manufacture and minimise the need for compatibility testing. An example of a basic formulation for a personal-hygiene cosmetic hand gel within the scope of CPNP FF 1.9 is given in Annex II. A template Product Information File and Safety Assessment are also provided for this formulation.

b) Packaging Compatibility

Compatibility between the formulation and the packaging is particularly important for products with high solvent (alcohol) content to ensure stability of both the product and the packaging.

The following are examples of materials that are widely used and have proven suitable for the primary packaging (container) of hydroalcoholic gels:

- Container in PET or HDPE
- Pumps in PBT or in PP, dip tube in PEBD, pushbutton in PP or PE, lid/ reducer in PP or PE, Tubes in PEHD

Packaging should be in accordance with to transport regulations for dangerous goods ADR / RID / IMDG (Road, rail and waterway)

- e.g. ADR 4.1.1 for limited quantities (Filling Level, Proper Packaging Material, tightness etc.)

c) Labelling

Personal-hygiene cleansing hand gels should be labelled according to the Cosmetics Regulation (Regulation 1223/2009/EC, Article 19).

With regard to the product function terms should be used which are easily understandable by the end user, such as for example 'Hydroalcoholic Cleansing Hand Gel' or 'Personal Hygiene Cleansing Hand Gel'. Note that, due to language and cultural differences, the translation of the function may need to be adapted to specific local markets. In case of doubt, the local cosmetic association should be contacted for advice.

Use instructions should be given to convey the following meaning: "*Apply enough product on hands to cover all surfaces. Rub hands together, until hands feel dry.*"

Given the high alcohol content, flammability warnings may be required to ensure safe use. Cosmetic Europe's Recommendation of flammability warnings can be found here: https://cosmeticseurope.eu/library/guidelines (search for 'flammability').

No claims going beyond personal hygiene should be made on the product. In particular, claims should be avoided that, in the Member State where the product is made available company internal or as a donation, would be lead to the classification as biocidal product (e.g. "disinfecting", "sterilising", "antiviral", "anti CoViD-19", …). Note that there may be national differences in the acceptance of certain terms. If a company wishes to make any non-cosmetic claims, it should check with local association to assess whether the product

would fall under the Cosmetic Products Regulation or other legal frameworks like in particular the Biocidal Products Regulation. Note that, due to the ongoing health crisis, several EU Member States have issued temporary decrees that simplify placing on the market of biocidal hand sanitisers. You can find the Commission's collection of notified Member States decrees here:

https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b

d) Product Information File (PIF) and Safety Assessment

A template PIF and Safety Assessment for the above standard formulation are given in Annex II. Please note that these are templates only. The valid safety assessment will need to be obtained from a suitably qualified safety assessor prior to making the specific product available, according to the EU Cosmetics Regulation. Also note that these documents are only valid for this specific standard formulation and for raw materials with within the purity specifications listed therein. In case of a different formulation or different raw material specifications, the safety assessment needs to be adapted accordingly.

e) Other requirements under the Cosmetics Regulation

All requirements under the Cosmetics Regulation, including CPNP notification, apply to personal-hygiene cosmetic hand gels, even if they are made available as a donation.

f) Manufacturing

Besides the compliance with cosmetics GMP, manufacturing hydroalcoholic products with a high ethanol content poses specific technical and occupational safety challenges. In particular, the equipment must comply with ATEX Directives:

- the ATEX 95 equipment Directive 2014/34/EU on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres
- the ATEX 137 workplace directive 99/92/EC, Minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres.

The flash point of the product could be very low (around 13°) therefore the welding of tubes must be carefully controlled.

Note that the above aspects, whilst particularly relevant for the manufacturing of ethanol-based gels, are not an exhaustive list of manufacturing requirements. Companies should thoroughly check EU and local manufacturing rules and requirements.

Annex I

CPNP Frame Formula 1.9

SKIN GEL (HYDRO-ALCOHOL BASED)

Ingredient	Maximum level (%w/w)
Ethanol and/or isopropanol (alcohol, alcohol denat, isopropyl alcohol)	70
Emollients, humectants (e.g. propylene glycol, glycerin)	20
Additional ingredients (e.g. vitamins, plant extracts)	10
Emulsifying agents, anionic / amphoteric / non-ionic surfactants (e.g. fatty acid polyglycolethers)	6
Thickeners (e.g. carbomer)	5
Preservatives, antimicrobials	3.5
Colorants	1
Parfum	1
Aqua	to 100

Annex II

Template PIF and Safety Assessment

Example of a basic personal-hygiene cosmetic hand gel within the scope of CPNP FF 1.9:

Ingredient (INCI)	Amount % wt/wt
Alcohol (or Alcohol denat.)	63,09457 (calculated as pure ethanol)
Glycerin	2,0000
Propanediol	2,0000
Carbomer	0,20000
Aminomethyl Propanediol	0,03500
Aqua (Water)	32,67043

A template PIF and Safety Assessment for the above standard formulation are given below.

Please note that these are templates only. The valid safety assessment will need to be obtained from They need to be validated by a suitably qualified safety assessor prior to making the specific product available, according to the EU Cosmetics Regulation. Also note that these documents are only valid for this specific formulation and for raw materials with within the purity specifications listed therein. In case of a different formulation or different raw material specifications, the safety assessment needs to be adapted accordingly.

Example Product Information File

a) Description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product

Name and address of the Responsible Person:_____

Name, Brand and company reference of the product: _____

Company Reference of the formula : _____

Copy of the product label

b) Cosmetic product safety report

(See separate document below)

c) Description of the method of manufacturing and a statement on compliance with good manufacturing practice

1. Specifications during the process

- Temperature : 25°C measured with an accuracy of +/-3°C.
- pH : 5,7 to 6,3
- The stirring times and stirring speeds in the overview are to be adjusted according to the equipment and batch size.

2. Process

- lower water and glycerin into the tank
- lower polymer into the tank and disperse until a grain-free phase is obtained (10 minutes)
- lower ethanol and disperse until a homogenous phase (10 minutes)

The product is manufactured according to ISO GMP Standard 22716.

d) Proof of the effect claimed for the cosmetic product

No specific claims are made beyond the product function 'hydroalcoholic cleansing hand gel'

The product formulation is in line with WHO recommendation on hydroalcoholic hand cleansing gels. No specific additional efficacy tests are necessary.

http://www.who.int/gpsc/5may/tools/who_guidelines-handhygiene_summary.pdf

e) Data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.

Neither the manufacturer, nor his agents and nor any of the raw material suppliers have tested the finished product or any of the raw materials on animals after March 2009.

Example Cosmetic Product Safety Report

PART A – Cosmetic product safety information

1) Quantitative and qualitative composition of the cosmetic product

Ingredient INCI(CTFA) Name	% RM in formula	% ingredient in RM	% Ingredient in formula	Purpose of use	CAS N°
ALCOHOL	67.00	94.171	63.09457	SOLVENT	64-17-5
AQUA (WATER)		5.829	3.90543		7732-18-5
AQUA (WATER)	28.765	100.00	28.765	SOLVENT	7732-18-5
GLYCERIN	2.00	100.00	2.00	HUMECTANT	56-81-5
PROPANEDIOL	2.00	100.00	2.00	SOLVENT	504-63-2
CARBOMER	0.20	100.00	0.20	VISCOSITY INCREASING AGENT	9003-01-4
AMINOMETHYL PROPANEDIOL	0.035	100.00	0.035	pH ADJUSTER	115-69-5
	100.00		**100.00**		

2) Physical/chemical characteristics and stability

a. Cosmetic product

Appearance	fluid gel
Odour	alcohol odour
Colour	clear, colourless
pH	5.5 – 5.9
Viscosity	280 – 550 cPs

The physical/chemical properties of the product of the finished product are consistent with the historical data observed for this type of cosmetic product.

The physical/chemical properties of the finished product are not affected by centrifugation and/or under accelerated ageing conditions demonstrating that the product is considered as stable over time.

b. Raw materials

All raw materials are simple, well characterised chemicals which are stable under normal storage conditions. Nature and levels of impurities are known and are not expected to impact the stability of the raw materials. See attachment for raw material specifications.

3) Microbiological quality

The microbiological quality of all raw materials is systematically controlled against the following specification: < 100 CFU/g (Colony-Forming Unit/g).

The formulation is considered as having a low microbiological risk according to EN ISO Standard 29621 due to its high alcohol content. A microbiological challenge test is not necessary.

The formulation meets the microbiological requirements specified in the SCCS Notes of guidance, 8th Revision, Section 4-4.2

4) Impurities, traces, information about the packaging material

For impurity levels in the raw materials, see raw material specifications (attached). The control on the residual traces of impurities on each raw material allows to estimate the potential maximum amount of each impurity in the finished product. Impurity levels remain within safe limits.

Impurity

Impurity	Max. possible concentration, based on raw material specifications
Aldehydes	0.32 %
Methanol	1.9 %
Esters	73 ppm
Higher alcohols	0.32 %
Volatile nitrogenous bases	0.06 %
Heavy metals (Pb, As, Hg, Sb, Cd)	0.32 ppm
Cyclohexane	10 ppm
Halogenated compounds	0.7 ppm
Diethylene glycol	2 ppm
Secondary amines	1.8 ppm
Nitrosamines	0.018 ppb
Other impurities	2 ppm

Information on packaging material :

Packaging component in direct contact with the formulation	Code and/or supplier	Material
Flask	123456	PET
Pump	54321	PP
Dip Tube	246810	LDPE
Pushbutton	13579	PP
Lid/reducer	235711	PP
Tubes	951357	HDPE

In line with the Cosmetics Europe Advisory Document[5], relevant compositional information according to the was obtained from the suppliers on packaging components that are in direct contact with the formulation (see supplier certificates in attachment).

After data analysis, it appears that the composition of all packaging components

- complies with EU legislation on Food Contact Materials and its migration limits for Food Simulant D1 (50 % ethanol)
- does not contain SVHC substances at or above 0.1%
- does not contain heavy metals at or above 100 ppm (sum of concentration levels of lead, cadmium, mercury and hexavalent chromium)
- does not contain substances banned for use in cosmetics in Annex II of Regulation (EC) 1223/2009 or classified as skin sensitisers in Regulation (EC) No 1272/2008 at or above 10 ppm

5) Normal and reasonably foreseeable use

Defined by use instructions:	"*Apply enough product on hands to cover all surfaces. Rub hands together, until hands feel dry."*

6) Exposure to the cosmetic product

a)	Site(s) of application	Hands
b)	Surface area(s) of application	860 cm²
c)	Amount of product applied	3 g
d)	Duration and frequency of use	10/day, leave-on fast evaporation of ethanol
e)	Normal and reasonably foreseeable exposure route(s)	dermal
f)	Targeted (or exposed) population(s)	adults & children > 3 years

[5] INFORMATION EXCHANGE ON COSMETIC PACKAGING MATERIALS ALONG THE VALUE CHAIN IN THE CONTEXT OF THE EU COSMETICS REGULATION EC 1223/2009

7) Exposure to the substances

Ingredient	Dermal Exposure g/day	Dermal penetration (%)	Systemic exposure mg/kg bw/day
Alcohol	18.93 g/day	3	0.57
Glycerin	0.6 g/day	80	0.48
Propanediol	0.6 g/day	80	0.48
Carbomer	0.06 g/day	80	0.048
Aminomethyl Propanediol	0.0105 g/day	80	0.0084
Aqua (Water)	9.80 g/day	80	7.84

8) Toxicological profile of the substances

Ingredient	Reference	Conclusion	NOAEL	MoS
Alcohol	ECHA, REACh Registration dossier of Ethanol The percutaneous absorption taken up for the MoS calculation is the highest result obtained experimentally (2.3%) rounded up to the next highest whole percentage i.e. 3%.	Safe (MoS>100)	1280	2254
Glycerin	Cosmetic Ingredient Review (CIR) Safety Assessment of Glycerin as Used in Cosmetics, 2015. OECD SIDS Initial Assessment Report for GLYCEROL, 2002. Kroes R. et al., Application of the threshold of toxicological concern (TTC) to the safety evaluation of cosmetic ingredients, Food and Chemical Toxicology 45:2533-2562, 2007.	Safe (MoS>100)	10000	20833
Propanediol	ECHA website. Propane-1,3-diol (CAS number: 504-63-2) registration dossier	Safe (MoS>100)	1000	2083
Carbomer	Cosmetic Ingredient Review (CIR), Final Report on the Safety Assessment of Carbomers-934, -910, -934P, -940, -941, and -962, International Journal of Toxicology, 1(2):109-141, 1982.	Safe (MoS>100)	250	5208

	Kroes R. et al., Application of the threshold of toxicological concern (TTC) to the safety evaluation of cosmetic ingredients, Food and Chemical Toxicology 45:2533-2562, 2007.			
Aminomethyl Propanediol	Cosmetic Ingredient Report (CIR) final Amended Report on Safety Assessment on Aminomethyl Propanol and Aminomethyl Propanediol, International Journal of Toxicology 28(6S) 141S-161S, 2009. Kroes R. et al., Application of the threshold of toxicological concern (TTC) to the safety evaluation of cosmetic ingredients, Food and Chemical Toxicology 45:2533-2562, 2007.	Safe (MoS>100)	100	11905

9) Undesirable effects and serious undesirable effects

Since the launching date, no undesirable effect has been reported. If an abnormally high number of adverse events is recorded or if a serious adverse effect is found, or if changes occur (new scientific findings, conditions of use, legal requirements, formula, specifications of raw material) the safety of the product will be reassessed.

PART B – Cosmetic product safety information

1) Assessment conclusion
   After the analysis of the cosmetic product information (Part A), I undersigned (*name of safety assessor)* consider that the skin care product *(name of product)* fulfils the safety requirements of Cosmetic Regulation n°1223/2009 and is not expected to cause damage to human health when applied under normal and reasonably foreseeable conditions of use.

2) Labelled warnings and instructions of use
   Use instruction: "*Apply enough product on hands to cover all surfaces. Rub hands together, until hands feel dry."*

   Warnings : *"Only for external use on healthy skin. Avoid contact with the eyes. Keep out of reach of children."*

3) Reasoning
   All the raw materials comply with the current Regulation (EC) No 1223/2009 meaning that the formula does not contain any forbidden raw materials, nor any restricted chemical substances used at an unauthorised concentration (Annex II to VI).

   All ingredients are simple chemical substances that are stable under reasonable storage conditions. The physical/chemical properties of the finished product are not affected by centrifugation and/or under accelerated ageing conditions demonstrating that the product is considered as stable over time.

   The microbiological quality of all raw materials is systematically controlled to remain < 100 CFU/g (Colony-Forming Unit/g). The formulation is considered as having a low microbiological risk according to EN ISO Standard 29621 due to its high alcohol content. The formulation meets the microbiological requirements specified in the SCCS Notes of guidance, 8th Revision, Section 4-4.2

   Maximum levels of relevant impurities are controlled via raw material specifications and are below the safe level. The packaging material is compatible with the formulation and does not lead to toxicologically relevant migration of material from the packaging into the formulation.

   The available toxicological profile of the ingredients allows an assessment of both local and systemic toxicity. For all ingredients, the Margin of Safety MoS is significantly above 100 under the expected exposure and use scenario. The high ethanol content makes the product irritant for the eyes and potentially irritant on damaged skin. It is also carries a risk of acute toxicity in case of ingestion of larger amounts by small children. Appropriate warning statements are therefore necessary.

   Since the launching date, no undesirable effect has been reported.

4) Assessor's credentials and approval of part B

   Name and address of the safety assessor_____
   Proof of qualification of safety assessor _____
   Date and signature of safety assessor _____

Raw material specifications

Alcohol

Appearance	liquid
Odour	alcohol odour
Colour	clear, colourless

Ethanol content	> 96 %

Impurities

	g/hl ethanol (100% vol)
Acid content, expressed as acetic acid	≤ 0.4
Ester content, expressed as ethylacetate	≤ 0.01
Aldehyde content, expressed as acetaldehyde	≤ 0.5
Methanol	≤ 3
Higher alcohols, expressed as 2-methylpropan-1-ol	≤ 0.5
Dry extract	≤ 1.5
Volatile nitrogenous bases, expressed as nitrogen	≤ 0.1
Furfural	not detectable

Permanganate Test	≥ 18 minutes at 20°C

UV Spectrophotometric assay

Quartz cuvette (10mm) against water: Smooth , regular curve

270 nm	< 0.02
240 nm	< 0.08
230 nm	< 0.18
220 nm	< 0.30

Carbomer

Appearance	powder
Odour	slightly acetic
Colour	white
Wetting time	8 min (0,5 % dispersion)
Transmission clarity	88% at 420 nm (0,5 % dispersion)
Brookfield viscosity(mPa*s) (20 rpm, 25°C, #7)	45.000-65.000 (0,5 % dispersion)

Impurities	% wt
Water	≤ 2
Heavy metals (Pb, As, Hg, Sb)	≤ 0.001 (10 ppm)
Ethylacetate & Cyclohexane	≤ 0.5

Glycerin

Appearance	liquid
Odour	odourless
Colour	clear, colourless
Refractive index	1.470-1.475 n D 20
Density 20°C	≥ 1.262
Glycerin content	> 99.5 %

Impurities	% wt
Sulphate ash test	≤ 0.01
Chlorides	≤ 0.001 (10 ppm)
Halogenated compounds	≤ 0.0035 (35 ppm)
Heavy metals	≤ 0.0005 (5 ppm)
Diethylenglycol	≤ 0.1
Aldehydes	≤ 0.001 (10 ppm)
Any other impurity	≤ 0.1
Water	≤ 0.5
Acidity or alkalinity	≤ 0.1 ml 0.1 M NaOH
Sugar	negative

Aminomethyl Propanediol

Appearance	crystalline
Odour	slightly amine
Colour	white
Aminomethyl Propanediol content, anhydrous	> 99 %

Impurities	% wt
Secondary amines, anhydrous	≤ 0.5
Nitrosamines	≤ 0.005 (50 ppb)
Water	0.5

Propanediol

Appearance	liquid
Odour	slightly alcoholic
Colour	clear, colourless
Aminomethyl Propanediol content, anhydrous	> 99.5 %

Impurities	% wt
Water	0.5 (Karl Fischer titration)
Heavy metals (Pb, As, Hg, Cd)	≤ 0.001 (10 ppm)