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Welcome to CTFA's Product Labelling Training

Nadia Rashid
Technical & Regulatory Affairs Manager

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Introduction



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Regulatory Bodies - Labelling

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

The Department of Health is the executive department of the national government that is assigned to oversee healthcare in South Africa.

The NRCS is an entity of the Department of Trade, Industry, and Competition (the DTIC); established to administer compulsory specifications and other technical regulations with the view to protect human health, safety, the environment and ensure fair trade in accordance with government policies and guidelines.

NRCS national regulator for compulsory specifications

SABS
South African Bureau of Standards

The SABS is mandated to: develop, promote and maintain South African National Standards (SANS); promote quality in connection with commodities, products and services; and render conformity assessment services and assist in matters connected therewith. Overseen by DTIC.

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Current Regulatory Framework

NDoH

- Regulations relating to labelling, advertising and composition of cosmetics, R.1469

NRCS

- SANS 289:2022 Labelling requirements for prepackaged products (prepackages) and general requirements for the sale of goods subject to legal metrology control

SABS

- SANS 98:2012 Ingredient Labelling of Cosmetic Products

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Draft regulations relating to labelling, advertising and composition of cosmetics R. 1469, 22 December 2017

8. Labelling

- Cosmetic name
- Name & Business address - RP
- Country of origin – imported
- Nominal content - Legal Metrology Act
- Date of minimum durability / PAO (*)
- Precautions / warning statements (*)
- Batch/lot number
- INCI (*)
- Function if not clear

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Draft regulations relating to labelling, advertising and composition of cosmetics R. 1469, 22 December 2017

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

8. Labelling continued…

- Sample size and shape – leaflet, label, inlay, tape, tag, card
- Ingredients for small products
- Content marking exemption – free, <5g/ml, packs
- Date of minimum durability (*) – BB (dd/mm/yyyy), PAO >30 months
- Pressurised container – pressure, sun/high temp, pierced

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8. Labelling continued…

- **INGREDIENTS** – INCI, order
- Animal Testing
- Nano
- Language
- Prohibited claims

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NDoH

- Regulations relating to labelling, advertising and composition of cosmetics, R.1469

NRCS

- **SANS 289:2022** Labelling requirements for prepackaged products (prepackages) and general requirements for the sale of goods subject to legal metrology control

SABS

- **SANS 98:2012** Ingredient Labelling of Cosmetic Products

SANS 289:2022

Labelling requirements for prepackaged products (prepackages) and general requirements for the sale of goods subject to legal metrology control

1. Scope

- Identity of the product (name)
- Name and place of business of the manufacturer, packer, distributor, importer or retailer (physical or postal or both)
- Net quantity of product
- General requirements for sale of goods and prescribed sizes for certain products (annexes)

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SANS 289: 2022

3. Terms and definitions

- "**Pre-packaged**: any commodity that is made up as a unit or entity and for which its quantity has been determined and indicated on its label before being offered for sale, irrespective of whether such unit or entity is enclosed in a container, wrapped in any manner or unenclosed."

- "**Net quantity**: quantity of the identified product in the prepackage exclusive of wrappers and any other material packaged with such products, unless specifically allowed by these requirements"

SANS 289: 2022

3. Terms and definitions

- "**Label**: any written, printed or graphic matter affixed to, applied to, attached to, blown into, formed or moulded into, embossed on, or appearing upon a package containing any product for purposes of branding, identifying, or giving any information with respect to the product or to the contents of the package; however, an inspector's tag or other non-promotional text affixed to or appearing on a product is not deemed to be a label that requires the label information prescribed by these requirements."

- "**Principle display panel**: part of a package that is most likely to be displayed, presented, shown or examined under normal and customary conditions of display."

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SANS 289: 2022

4. Identity of Product

- The principal display panel on a prepackage shall bear a specification (description) of the identity of the product unless the wrapper is transparent, thus rendering the product easily identifiable.
- The identity of the product shall be a conspicuous feature of the principal display panel and shall be in such type size and so positioned as to make it easy to read and understand.
- The identity of the product shall be in terms of at least one of the following designations in the order of preference listed:

a) the name specified in or required by any applicable law or regulation;

b) the common or usual name of the product; and

c) the generic name or other appropriately descriptive term such as a specification which includes a statement of function.

SANS 289: 2022

5. Name & place of business

- The label of a prepackaged product shall specify conspicuously the name and address of business of the person responsible for any of the following: manufacturing, packing, distributing, importing or retailing the product. When the product is not manufactured or packaged by the person whose name appears on the label, the name may be qualified by a phrase that reveals the connection such person has with the product, for example: “manufactured for ...","distributed by ... ", "marketed by ... ", "imported by ... " or "sold by ... “
- The statement of the place of business shall include a complete physical address or a mailing address (or both). This may be an address of a head office, provided that the responsible person at such head office is able to identify the address of the packaging plant. In cases where a code is used to identify a packaging plant, the manufacturer shall disclose the meaning of the code to any inspector requiring it.

SANS 289: 2022

6. Net quantity

- Pre-packages shall each be marked with a quantity indication in accordance with SANS 289

- Where a package contains a number of items (kit or gift pack) – outer container must declare the number of items and their individual quantity
- e.g. 1 x 50 ml Hand cream
- 1 x 25 ml Hand scrub

- Outer container shall comply with requirements for product identification and details of final packer

SANS 289: 2022

- Net quantity statement for a specific product shall be expressed in the most appropriate measuring unit:
  - Volume / Mass
  - Annex E – expression of quantity and prescribed quantities

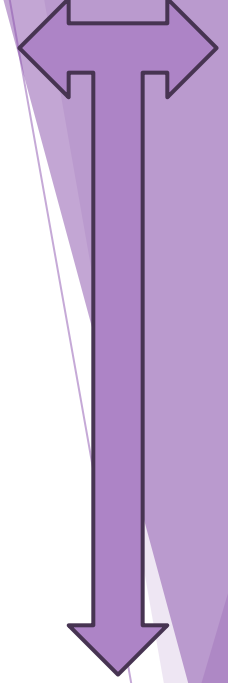
*Cosmetics and toiletries	(See D.1.2(c))
a) In the form of pastes, crèmes and viscous or other liquids	Volume
b) In the form of solids or powders	Mass
c) Deodorant sticks	Mass or volume

- Aerosol products – net quantity declared as mass or volume that will be expelled when instructions of use are followed.
  - If propellant is expelled with the product – propellant included in net quantity declared
  - Shall be filled to at least 60% of available capacity with product (including propellant) in its liquid phase

SANS 289: 2022

- **Free quantity** of same type of products as an integral part of the contents:
  - Declare on the packaging:
    - the quantity to be paid for excluding free quantity,
    - the free quantity, and
    - the total quantity contained in the package
  - Quantities declared above shall be in the same unit of measure or multiples or submultiples thereof
  - If free quantity is a separate component attached to pre-package:
    - quantity of package exclusive of free quantity must be declared

SANS 289: 2022



- Quantity expressed in whole number
- Presentation shall be easily legible **boldface** type or print that **contrasts** with background and other information on a package
- Annex B - Minimum type size requirements

SANS 289: 2022

Annex A:
Units of measurement and symbol

- No full stop after unit of measure (UOM)
- No “s” after UOM
- A single space to separate number from UOM

200 ml

- Words “Approximately” and “when packed” shall not be used

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Annex A:
Units of measurement and symbol

A.1 Units of measurement shall be expressed in either words or symbols. Table A.1 provides the units and the appropriate symbols for measurements. If it becomes necessary to use units other than those specified in table A.1, they shall comply with applicable national legislation prescribing requirements for measuring units.

Table A.1 — Units of measurement

1	2
Unit	**Symbol**
milligram gram kilogram	mg g kg
ton hectolitre litre	t hL or hl L or l
centilitre millilitre micrometre	cL or cl mL or ml µm
millimetre centimetre decimetre	mm cm dm
metre square millimetre square centimetre	m mm^2 cm^2
square metre cubic centimetre cubic decimetre cubic metre	m^2 cm^3 dm^3 m^3
NOTE 1 The alternative symbol for litre, L, was adopted by the General Conference of Weights and Measures (CGPM) in order to avoid the risk of confusion of the letter l and the number 1.	
NOTE 2 The script letters ℓ for litre and g for gram are acceptable within the SADC region but these symbols might not be accepted in countries outside the region and packers should be informed accordingly.	

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Annex B:
Type size of letters and numerals for statements of net quantity on consumer packages

B.1 For prepackaged products bearing a net quantity indication in units of mass, volume or volume in cubic measure, letters and numerals used in the net quantity indication shall have a minimum height as prescribed in table B.1, except if clause B.2 is applicable.

NOTE The heights required for the quantity indication are minimum heights and packers are encouraged to increase the specified size to avoid contravening the national legislation of other countries.

Table B.1 — Minimum height of numbers and letters applicable to clause B.1

1	2
Net contents (*C*)	**Minimum height of numbers and letters** mm
$C \leq 50$ g or mL	2
50 g or mL $< C \leq 200$ g or mL	3
200 g or mL $< C \leq 1$ kg or L	4
1 kg or L $< C$	6

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Annex D:
Goods exempted from quantity indication

- Free sample mark as “free sample” or “not for sale”
- Quantities MUST be < 5 g/ 5 ml
- Transparent package which is a combined package containing items of goods of the same kind or different kind of the same quantity or different quantity:
  - Number of such items must not exceed 12
  - Such item should bear a quantity statement and at least be clearly visible on one such unit

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SANS 98: 2012

Ingredient Labelling of Cosmetic Products

- What is the purpose of Ingredient labelling?
  - ensures transparency to consumer
  - provides adequate information about the product
  - avoids purchase of product that contains ingredient/s the consumer does not wish to use

- International Nomenclature Cosmetic Ingredients (INCI)?
  - Ingredient descriptions used are uniform throughout the world to allow consumers to identify the same ingredient in products manufactured in different countries

- Appear on outermost packaging of product preceded by the word "**Ingredients**"

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Ingredient Labelling of Cosmetic Products

- If packaging is too small or has a shape that precludes labelling, ingredient listing shall be given on a label, tag or card fixed to or enclosed within product OR in a notice in close proximity to the display in which the product is offered

- Specific requirements:
  - Ingredient 1% or more – descending order of listing
  - Ingredient <1% - list in any order
  - Fragrance allergens – before colourants
  - Colourants – in any order at the end of the list

- If raw material is a blend - list each ingredient separately considering percentage concentration in finished product.

- Warning or caution statements required when restricted ingredients are used

Example of INCI description of ingredient

EU ONLY

AQUA, ALCOHOL DENAT., HAMAMELIS VIRGINIA EXTRACT, SODIUM PCA, MEL, PRUNUS AMYGDALUS DULCIS OIL, PARAFFINUM LIQUIDUM, MELALEUCA ALTERFOLIA LEAF OIL, PARFUM, PHENOXYETHANOL, METHYLPARABEN, PROPYLPARABEN, LIMONENE, LINALOOL, CI 42090

HARMONISED

AQUA (WATER), ALCOHOL DENAT., HAMAMELIS VIRGINIANA (WITCH HAZEL) EXTRACT, SODIUM PCA, MEL (HONEY), PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL, PARAFFINUM LIQUIDUM (MINERAL OIL), MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL, PARFUM (FRAGRANCE), PHENOXYETHANOL, METHYLPARABEN, PROPYLPARABEN, LIMONENE, LINALOOL, CI 42090 (BLUE 1)

Specific cases

- General terms – Perfume and Flavour
- Trivial names – Aqua
- Colourants
- Decorative Cosmetics - **+/- or MAY CONTAIN**
- Botanicals
- Alcohol – denatured/undenatured
- Hydrocarbon propellants
- Soap
- Fragrance & Flavour – 0,001% leave on / 0,01% rinse off

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STEPS TO DECLARATION

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STEP ONE: FORMULATION AS IS WITH TRADE NAMES

STEP TWO: INCI NAMES BREAKDOWN

STEP THREE: COMPLEX AMOUNTS

STEP FOUR: ACTUAL AMOUNTS (IN 100)

STEP FIVE: CONSOLIDATE

STEP SIX: RANK IN ORDER

STEP SEVEN: ARRANGE AS PER ORDER

1	2	3	4	5	6	7
Raw material trade name	**Raw material INCI description**	**Complex %**	**Actual %**	**Theoretical make-up %**	**Theoretical %**	**Listing order**
Deionized water	Aqua (water)	N/A	50,037	50,0370 + 8,400 + 7,200 + 0,8295 + 0,900	67,367	1
Hampene Na4	Tetrasodium EDTA	N/A	0,100	0,100	0,100	Random after 7
SF 1288	PEG-12 dimethicone	N/A	1,050	1,050	1,050	7
Mackernium 006	Polyquaternium-6	N/A	0,750	0,750	0,750	Random after 7
Propylene glycol	Propylene glycol	N/A	0,960	0,960 + 0,560 + 0,555	2,075	4
Empicol ESB3/X	Sodium C12-15 pareth sulfate	30	12,000	3,600 (+ 8,400 water)	3,600	3
Empicol ESB 70	Sodium laureth sulfate	70	24,000	16,800 (+ 7,200 water) + 0,355	17,155	2
Euperlan PK771	Glycol distearate (and) Sodium laureth sulfate (and) Cocamide MEA (and) Laureth-10	50 30 10 10	3,950	1,975 1,185 (30 %) = 0,355 (+ 0,8295 water) 0,395 0,395	1,975 0,000 0,395 0,395	5 Random after 7 Random after 7
Lipocol HCO 60	PEG-60 hydrogenated castor oil	N/A	1,250	1,250	1,250	6
Fragrance	Parfum (fragrance)	N/A	0,600	0,600	0,600	Random after 7
Carbopol ETD 2020	Acrylates/C10-30 alkyl acrylate crosspolymer	N/A	0,200	0,200	0,200	Random after 7
Crovol AP10G	PEG-14 avocado glycerides	N/A	0,800	0,800	0,800	Random after 7
Microcare DMP	Propylene glycol (and) Diazolidinyl urea (and) Methylparaben Propylparaben	56 30 11 3	1,000	0,560 0,300 0,110 0,030	0,000 0,300 0,110 0,030	 Random after 7 Random after 7 Random after 7
Triethanolamine 99 %	Triethanolamine	N/A	0,300	0,300	0,300	Random after 7
Encapsulate white pearl	Aloe barbadensis leaf extract (and) Paraffinum liquidum (mineral oil) (and) Gelatin	45 45 10	1,500	0,675 0,675 0,150	0,675 0,675 0,150	Random after 7 Random after 7 Random after 7
Herbasol extract cucumber	Water (and) Propylene glycol (and) Cucumis sativus (cucumber) fruit extract	60 37 3	1,500	0,900 0,555 0,045	0,000 0,000 0,045	 Random after 7
FCF Blue 1	CI 42090 (Blue 1)	N/A	0,003	0,003	0,003	Last
TOTAL			**100,000**		**100,000**	

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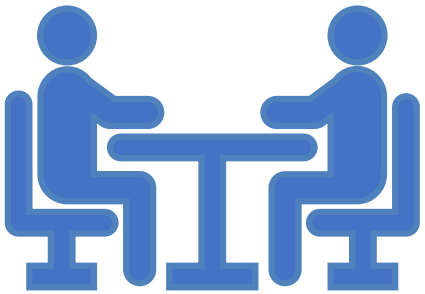
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INGREDIENTS:
AQUA (WATER), SODIUM LAURETH SULFATE, SODIUM C12-15 PARETH SULFATE, PROPYLENE GLYCOL, GLYCOL DISTEARATE, PEG-60 HYDROGENATED CASTOR OIL, PEG-12 DIMETHICONE, ALOE BARBADENSIS LEAF EXTRACT, CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT, PEG-14 AVOCADO GLYCERIDES, POLYQUATERNIUM-6, PARAFFINUM LIQUIDUM (MINERAL OIL), GELATIN, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, COCAMIDE MEA, LAURETH-10, TRIETHANOLAMINE, TETRASODIUM EDTA, PARFUM (FRAGRANCE), LIMONENE, LINALOOL, CINNAMAL, ALPHA-ISOMETHYL IONONE, DIAZOLIDINYL UREA, METHYLPARABEN, PROPYLPARABEN, CI 42090 (BLUE 1)

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QUESTION & ANSWER SESSION



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Thank you for your attendance!

For ARTWORK REVIEWS please send an email to samantha@ctfa.co.za