CDC 11 (3968) DTZS

ICS:67.250

DRAFT TANZANIA STANDARD

Positive list of constituents of polyvinyl chloride (PVC) and its copolymer in contact with foodstuffs, pharmaceutical and drinking water

TANZANIA BUREAU OF STANDARDS

Second Edition 2026

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Foreword

This Tanzania Standard was published under the authority of the Board of Director of Tanzania Bureau of Standards.

Tanzania Bureau of Standards (TBS) is the statutory national standards body for Tanzania established by the Standards Act Cap. 130.

Tanzania Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. The Technical Committees work under the supervision of Divisional (sectoral) Committees. The Standards are developed in accordance with the Guide and Procedure for Development of Tanzania Standards and TZS 0, Guide for presentation of Tanzania Standards.

Tanzania Standards are subject to review, to keep pace with science and technological advances. Users of the Tanzania Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

This Tanzania Standard was developed under the supervision of the Chemicals Divisional Standards Committee [CDC]. The Technical Committee responsible for the standard is CDC 11 – Plastics and plastic products.

This second edition cancels and replaces the first edition (TZS 226:1984) which has been technically revised.

In preparing this Draft Tanzania Standard assistance has been derived from:

> IS 10148: 2023 — *Positive list of constituents of polyvinyl chloride (PVC) and its copolymer in contact with foodstuffs, pharmaceutical and drinking water,* published by India Bureau of Standards

Positive list of constituents of polyvinyl chloride (PVC) and its copolymer in contact with foodstuffs, pharmaceutical and drinking water

1 Scope

This Draft Tanzania Standard covers positive list of constituents of PVC, namely, the polymers, copolymers, manufacturing residues and necessary additives which may be regarded as safe for use, when properly processed in contact with food, pharmaceuticals and drinking water and when present in the prescribed limits of concentration.

This positive list does not purport to establish the suitability of the ingredient singly in a particular foodstuff from other than toxicological considerations.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this Draft Tanzania Standard, the following terms and definitions shall apply.

3.1
Polyvinyl chloride — shall mean:
3.1.1 The homopolymers of vinyl chloride.

3.1.2 Copolymers containing at least 50% by mass of vinyl chloride with one or several of the following monomers;

a) vinylidene chloride;

b) acrylonitrile;

c) styrene and substituted styrene:

d) butadiene;

e) ethylene;

f) propylene;

gl di-vinyl benzene;

h) vinyl acetate and vinyl propionate;

i) maleic, fumaric, itaconic, crotonic, acrylic and methacrylic acids; (Max limit of 8% by mass of all these monomers); and

j) esters of maleic, itaconic, crotonic, acrylic and methacrylic acids with saturated monohydric aliphatic alcohols;

k) modified PVC basic polymers and its analogous polymers: Chlorinated PVC (69 percent Cl. content *Max*) vinyl chloride co-polymerized with vinyl alcohol and vinyl acetate;

l) vinyl chloride – poly urethane graft copolymer (with *Min* 50 percent of vinyl chloride in the final polymer);

m) vinyl chloride – ethylene copolymer chlorinated (not exceeding 71 percent (w) Cl Content)

n) alfa olefins;

o) vinyl alcohol; and

p) alkyl vinyl ether.

3.1.3 Blending of homopolymers of vinyl chloride with one or several of the copolymers indicated in 3.1.2;

3.1.4 Blending of several copolymers indicated in 3.1.2 and

3.1.5 Chlorinated PVC resin and its compounds with chlorine content < =71 percent.

4 Requirements

4.1 Basic Resin

The polymers and copolymers defined in clause 3.1.1., 3.1.2 and 3.1.5 shall be made in such a way that they contain no ingredients or residues of ingredients used in their manufacture other than those listed in 4.1.1 and 4.2 to 4.8.4.

4.1.1 The following may be added to polyvinyl chloride (PVC), provided per cent by mass content of vinyl chloride of the mixture is at least equal to 30% and they conform to the concerned specification:

4.1.1.1 Homo and copolymers of monomers mentioned in 3 1.1 and 3.1.2.

4.1.1.2 Chlorinated polyolefin with a maximum chloride content of 56% by mass.

4.1.1.3 Copolymers of butyl acrylic and vinyl pyrrolidone (with 95% by mass of butyl acrylate);

4.1.1.4 Polyurethanes of molecular mass 40000 to 100000 obtained from:

a) Diisocyanate 1, 6 hexane;

b) Diisocyanate 2,4 toluene;

c) Diisocyanate 2,6 toluene and their mixtures,

d) Butane dihydric alcohol 1,4;

e) Polyester resulting from the action of adipic acid on a glycol:;and

f) Addition compounds of propylene or ethylene oxide and/or ethylene with ethylene glycol or poly propylene-glycol or glycerine or trimethylol propane or pentaerythritol or sorbitol.

NOTE — These products should be free from isocyanates and primary amines.

4.2 Catalysts/Initiators

The total residues of catalysts and their decomposition products shall be not more than 0.25% by

mass of the finished polymer. The residues as well as its decomposed products of the following catalysts may be present:

a) Benzoyl peroxide;
b) Aliphatic acid (C_3 to C_{16}) peroxide;
c) tert - Buty per benzoate;
d) *p-tert*-Butyl perpivalate;
e) Methyl ethyl ketone peroxide;
f) Persulphates of ammonium and potassium;
g) Percarbonates of the structure R_I OCOOOOCOR$_2$ where R_I and R_2 are alkly, aryl, alkylaryl, alkoxy or alkoxy alkyl or halogen substituted alkyl, aryl, alkylaryl, alkoxy or alkoxy alkyl (C_3 to C_{10});
h) Cycloalkyl (C_5 to C_8) peroxy dicarbonate;
i) bis-4-tert-Butyl cyclohexyl-peroxydicarbonate;
j) Acetyl cyclohexyl sulphonyl peroxide; and
k) Peresters of the structure R_ICOOOR$_2$ where R_I and R_2 are alkyl, aryl, alkylaryl, alkoxy or halogen substituted alkyl, aryl, alkylaryl, or alkoxy (C_2 to C_{10}).

4.3 Polymerization Inhibitors

The residue of polymerization inhibitors shall not exceed 0.01% by mass of the finished polymer.

4.4 Emulsifying agents

The total residues of emulsifying agents shall be not more than 3.0% by mass of the finished polymer. The residues of the following emulsifying may be present:

a) Alkyl, aryl and alkylaryl sulphates of sodium, potassium and ammonium, the alkyl group containing C_{10} to C_{20};
b) Alpha hydroxy octadecane sodium sulphonate;
c) Sodium, potassium, and ammonium salts of sulpho-succinic acid and its mono and di-esters with saturated monohydric aliphatic alcohols C_4 to C_{20};
d) Sodium potassium and ammonium salts of saturated aliphatic acids above C_7;
e) Esters of sorbitol or of sorbitan with saturated or unsaturated aliphatic acids above C_7;
f) Calcium; sodium, potassium and ammonium salts of hydroxylic fatty acids C_{12} to C_{20} and their sulphonyl or acetyl derivatives;
g) Products of condensation of ethylene oxide with monobasic aliphatic acids C_{12} to C_{20} and their ammonium sulphates;
h) Products of condensation of ethylene oxide with monohydric aliphatic alcohols C_{12} to C_{20} and their sodium and ammonium sulphates;
i) Products of condensation of ethylene oxide with alkylphenols having alkyl groups C_7 and

above and their sodium and ammonium sulphate;

j) Products of condensation of ethylene oxide with alkyl, dialkyl amines C_1 to C_{20};

k) Fatty alcohols C_{10} to C_{20}; and

l) Alkyl, aryl, alkylaryl, acyl, polyethoxy ethanol and their sulphates.

4.5 Suspension Agents

The total residues shall not be more than 1.0% by mass of the finished polymer. The residues of the following may be present:

a) Methylcellulose;

b) Hydroxy ethyl cellulose;

c) Hydroxy-propyl methyl cellulose;

d) Sodium carboxy methyl cellulose;

e) Methyl ethyl cellulose;

f) Polyvinyl alcohol (having a viscosity of at least 4 centipoises at 20°C in 4% aqueous solution;

g) Polyvinyl pyrrolidone and copolymers of vinyl pyrrolidone with vinyl ethers or esters; and

h) Copolymers of vinyl alkyl (C_1 toC_{12}) ethers with maleic acid or alkyl alcohol.

4.6 Chain transfer agents

The total residue shall not constitute more than 0.5% by mass of the finished polymer. The residues of the following may be present:

a) Trichloroethylene;
b) Perchloroethylene;
c) trans Dichloroethylene;
d) Isobutylene;
e) Xylene;
f) Chloroform;
g) Mono thio ethylene glycol;
h) Tri ethylene glycol;
i) Propionates; and
j) Polyether polyol

4.7 Miscellaneous Additives

The residues of the following additives may be present:

a) Sodium carbonate and bicarbonate;

b) Sodium chloride;

c) Organ polysiloxanes;

d) Calcium and sodium phosphates and phosphoric acid;

e) sodium dialkyl sulphonamides up to a maximum of 0.05% by mass of the finished polymer;

f) Aluminium sulphate;

g) Magnesium sulphate;

h) Sodium sulphate;

i) Calcium acetate; and

j) Sodium sulphite and sodium hydrogen sulphite.

4.8 Auxiliary items for working.

4.8.1 ***Plasticizers***

The following plasticizers may be present to the uses for which the total migration in foodstuffs including oils and fats does not exceed the maximum permitted in the standard extraction test:

4.8.1.1 Adipates

1) Di-(normal-octyl)-adipate;
2) Di-(2-ethyl-hexyl)-adipate;
3) Di-iso butyl adipate.
4) Di-decyl adipates – 30% *Max* in finished polymer; and
5) Di-iso-nonyl adipates with level of 5% (weight) and film thickness not exceed 1.5 mm for food product with product not exceeding fat and oil content beyond 40% (weight).

4.8.1.2 Sebacates

1) Di-(normal-octyl) sebacate; 2-(ethyl-hexyl)-sebacate;
2) Di-n-butyl-sebacte; and
3) Di-octyl sebacate (DOS).

4.8.1.3 Azelates;

1) Di-n-octyl-azelate;
2) Di-2-ethyl-hexyl-azelate; and
3) Di-n-hexyl azelate.

4.8.1.4 (2 ethyl-hexyl)-diphenyl-phosphate

4.8.1.5 Citrates

a) Acetyl-tributyl-citrate;
b) Stearyl (mono. di, tri) citrate;
c) iso Propyl (mono) citrate;
d) Triethyl citrate;
e) Tri Butyl Citrate (TBC)

4.8.1.6 Esters of alkyl sulphonic acids of phenol and/or cresol C_{12} to C_{20}

4.8.1.7 Polyesters obtained from di-acids like adipic, azelaic, glutaric, sebacic

4.8.1.8 Succinic acids and polyols (excluding ethylene-glycol and 1, 3 propylene glycol). The terminal groups may be esterified with:

4.8.1.9 Epoxidized oils

1) Epoxidized castor oil Max 5% to be used	Not less than 2.5% of oxirane of oxygen and less than 6% of iodine value.
2) Epoxidized Linseed oil *Max* 10%	Not less than 2.5% of oxirane of oxygen and less than 6% of iodine value.
3) Epoxidized Soyabean oil, *Max* 8%	Not less than 2.5% of oxirane of oxygen and less than 6% of iodine value.
4) Chlorinated paraffin Hydrogenated poly butane	

4.8.1.10 Glycerol, pure and glycerol triacetate;

4.8.1.11 Glycerol esters of saturated and unsaturated natural fatty acids;

4.8.1.12 Triethylene and polyethylene (Molecular mass greater than 400) glycols;

4.8.1.13 P-tert-Butylphenyl salicylate; and

4.8.1.14 1,2 cyclohexane acid diisononyl ester.

4.8.2 ***Stabilizers***

The following stabilizers may be present in the finished polymers to the extent of permitted limits:

4.8.2.1 Organic derivatives of tin:

a) Acid-butyl-thiostanic (Maximum 0.5%);
b) Di-n-octyl-tin-di-laurate;
c) Di-n-octyl-tin-di-maleate;
d) Di-(n-octyl) bis (methyl-1-heptyl) oxy-carbonyl- methyl-thiotin;
e) Di-(n-octyl) bis (methyl-1-heptyl) oxy-carbonyl-phenyl-thiotin;
f) Bis (ethyl, 2-hexoxy-carbonyl-methyl-thio) di-n- octyl tin.
g) Bis (ethyl, 2-hexoxy-carbonyl-phenyl-thio) di-n- octyl tin;
h) Di-n-octyl (tin s-s' bis iso-octylmercapto acetate);
i) Bis (ethyl-2 hexoxy carbonyl methythio) di-m-octyl tin; and
j) Di-n-octyltin-s-bis, iso octylmercapto acetate.

NOTE: - The above organic salts of tin may be used up to a maximum total dose of 1.5% of which the content of di-n-octylic derivatives of tin are at least 95%. If these derivatives of tin are used, the maximum doses of the other liquid auxiliary items should be limited to 1.5% on the whole. The use of plasticizers is then not allowed.

1) Acetic acid
2) Coconut oil tally acid;
3) Octyl alcohol; and

4) Decyl alcohol.

4.8.2.2. Calcium, zinc and magnesium salts of aliphatic mono and polyacids, saturated or not. Note - The finished PVC product should not contain more than 1% of zinc.

4.8.2.3 Di-phenyl-thio-urea, *Max.* 1% by mass and 2-phenyl- indol, *Max.* 1% by mass.

4.8.2.4 Manganese compounds;

a) manganese hydroxide; and

b) manganese salts of aliphatic mono and polyacids, saturated or not.

4.8.2.5 Di-epoxy-cylo-dodecene and Tri-epoxy-cycle dodecene.

NOTE: The epoxidized products mentioned in 4.8.2.5 are limited to 5% on the whole.

4.8.2.6 The epoxidized resins obtained from 4-4' dihydroxy diphenyl alkane (bisphenol A) and from epichlorohydrine with a mass per epoxy equivalent value greater than 175 in so far as they meet the specification concerning them.

4.8.2.7 Stearate, palmitate and myristate of lithium.

4.8.2.8 Polyvinyl-ethyl-ether

4.8.2.9 N, N' -di-stearyl and/or palmityl-ethylene-diamine (Max. 1 percent)

4.8.2.10 Sodium compounds: Carbonates, phosphates, polyphosphates, stearates, laurates, oleates, myristates and ricinoleates;

4.8.2.11 Esters of β-amino-crotonic acid with mono or dibasic alcohols.

4.8.2.12 Sorbitol, manitol, pentaerythritol and their esters with the fatty acids and sorbitan.

4.8.2.13 Hexanetriol

4.8.2.14 Di-tert-butyl-p-cresol:

1) 2-4 dinoylphenyl, di (4-mono-nonylphenyl) phosphite with a max 20% content of di-*iso*-octyl-nonyl-phenyl phosphite and products of oxidation; and

2) Thio-bis (methyl-*tert*-butyl-n-phenol) otherwise called 4,4' - Thio-bis (6-tert-butyl-m-cresol).

NOTE - The above three products (Clause 4.8.2.14) are limited to a total of 0.5%

3.8.2.15 *4, 4' di-hydroxv-di--phenyl propane*

4.8.3 **Lubricants**

The following lubricants may be permitted:

a) Aliphatic fatty acids, saturated or not (C_8 to C_{20});

b) Aliphatic alcohols (C_8 to C_{20});

c) Fatty alcohols with at least 12 atoms of carbon, with a Max. 3%

d) Amides of oleic, palmitic, myristic, stearic, ricinoleic and linoleic acid with a maximum of

0.3%;

e) Natural waxes;

f) Microcrystalline waxes, paraffin, and paraffin oil containing less than 0.1 ppm of noxious polycyclic aromatic hydrocarbons;

g) Polyethylene waxes;

h) Esters of montanic acids with glycol or 1,3 butane dihydric alcohol;

i) Esters of saturated aliphatic acids (C_{12} to C_{24}) with monovalent saturated aliphatic alcohols (C_{12} to C_{20}) with a maximum of of 3%.

j) Esters of glycerine with fatty acids, saturated or not, with a maximum of 3%.

k) Esters of polyethylene glycol;

l) Esters of polypropylene glycol;

m) Polyethylene and polypropylene glycols;

n) Esters of sorbital and sorbitan with fatty acids, saturated or not C_8 to C_{20});

o) Edible vegetable oils;

p) Products of condensation of ethylene oxide with fatty acids C_8 to $C_{20;}$ and

q) Butyl stearate;

r) White mineral oil (of saybolt with *Min* 20)

s) PTFE Powder

t) Poly propylene

u) Petroleum wax

v) Organo poly siloxane; and

w) Tridesyl alcohol – Max level 30%

x) Montan wax (Triglycerides);

y) Carnauba wax;

z) Bees wax; and

aa) Hydrogenated castor oil.

4.8.4 *Other additives*

Copolymers, polyblends and terpolymers of styrene acrylonitrile, butadiene and esters of acrylate, methacrylate to a maximum of 20% by mass of the total polymer only. For foaming of PVC or its blend, following blowing agents can be considered:

a) Azodi carbonamide – levels not exceeding 2%; and
b) Sodium bicarbonate (food grade)

4.9 Fillers

a) Calcium Carbonate (chalk and natural)
b) Clay;
c) Kaolin;
d) Calcium silicate;
e) Magnesium silicate (Talc);

f) Silica;
g) Diatomaceous earth;
h) Aluminium silicate;
i) Bentonite (Colloidal clay)
j) Aluminium Hydroxide; and
k) Magnesium hydroxide.

