

Title : Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 30.06; certified reference materials.

38.22 - Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 30.06; certified reference materials.

- Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits :

3822.11 - - For malaria

3822.12 - - For Zika and other diseases transmitted by mosquitoes of the genus *Aedes*

3822.13 - - For blood-grouping

3822.19 - - Other

3822.90 - Other

This heading covers **diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, including** blood grouping reagents, **other than** diagnostic reagents designed to be administered to the patient of **heading 30.06**. It also covers **certified reference materials**.

Diagnostic reagents are used in the evaluation of physical, biophysical or biochemical processes and states in animals and humans; their function is based upon a measurable or observable change in the biological or chemical substances constituting the reagent. Prepared diagnostic reagents of this heading may be similar in function to those designed to be administered to patients (subheading 3006.30), with the exception that they are used for *in vitro*, rather than for *in vivo*, applications. Prepared laboratory reagents include not only diagnostic reagents, but also other analytical reagents used for purposes other than detection or diagnosis. Prepared diagnostic and laboratory reagents may be used in medical, veterinary, scientific or industrial laboratories, in hospitals, in industry, in the field or, in some cases, in the home.

Reagents of this heading are either on a backing or in the form of preparations and thus comprise more than a single constituent. For example, they may consist of admixtures of two or more reagents or of single reagents dissolved in solvents other than water. They may also be in the form of paper, plastics or other materials (used as backings or support), impregnated or coated with one or more diagnostic or laboratory reagents, such as litmus, pH or pole-finding papers or pre-coated immunoassay plates. Reagents of this heading may also be put up in the form of kits, consisting of several components, even if one or more components are separate chemically defined compounds of Chapter 28 or Chapter 29, synthetic colouring matter of heading 32.04 or any other substance which, when presented separately, would be classifiable under another heading. Examples of such kits are those for testing glucose in blood, ketones in urine, etc., and those based on enzymes.

The reagents of this heading should be clearly identifiable as being for use only as diagnostic or laboratory reagents. This must be clear from their composition, labelling, instructions for *in vitro* or laboratory use, indication of the specific diagnostic test to be performed or physical form (e.g., presented on a backing or support).

Diagnostic kits based on reactions such as agglutination, precipitation, neutralization, binding of complement, haemagglutination, enzyme-linked immunosorbent assay (ELISA), etc are classified here. Malaria diagnostic kits, for example those based on monoclonal antibodies to pLDH (plasmodium lactate dehydrogenase), are also classified here.

However, diagnostic kits having the essential character of products of **heading 30.06** (e.g., blinded (or double-blinded) clinical trial kits for a recognized clinical trial, put up in measured doses) are **excluded**.

Blood-grouping reagents are also classified here. The reagents under this heading must be suitable for direct use in blood-grouping. They are either sera of human or animal origin, or vegetable extracts of seeds or other parts of plants (phytagglutinins). These reagents are used in the determination of blood-groups by reference to the characteristics of the blood

corpuscles or of the blood serum. In addition to the active principle(s), they may contain substances to strengthen their activity or stabilize them (antiseptics, antibiotics, etc.).

A. The following are to be regarded as reagents for determining blood-group by reference to the **characteristics of blood corpuscles** :

- (i) Preparations for determining the A, B, O and AB groups, A₁ and A₂ sub-groups and Factor H.
- (ii) Preparations for determining the M, N, S and P groups and other groups such as Lu, K and Le.
- (iii) Preparations for determining the Rh groups and C^w, F, V, etc. sub-groups.
- (iv) Preparations for determining the blood-groups of animals.

B. The preparations to be regarded as reagents for determining the **characteristics of sera** are those used to determine :

- (i) characteristics of Gm, Km, etc., systems;
- (ii) serum groups Gc, Ag, etc.

C. Anti-human globulin serum (Coombs serum), which is essential in certain bloodgrouping techniques, is also to be regarded as a reagent of this heading.

Crude sera and other semi-finished substances which require further treatment before becoming suitable for use as reagents are to be classified by reference to their constituent material.

D. Reagents for the determination of HLA properties (HLA antigens) fall in this heading; they must be directly applicable. They are sera of either human or animal origin. These reagents react with peripheral blood lymphocytes of the test subject for the determination of the HLA antigens. The HLA antigens of the test subject may be determined on the basis of the reaction pattern of different HLA test sera. Besides the active ingredients the reagents contain additives for stabilisation and conservation.

These include :

1. Preparations for the determination of the HLA A, B and C antigens.
2. Preparations for the determination of the HLA DR antigens.
3. Preparations for the determination of the HLA D antigens.
4. Finished reagents for the determination of the HLA A, B and C antigens which contain a range of different HLA antisera (e.g., test plates).
5. Finished reagents for the determination of the HLA DR locus (e.g., test plates).

With the **exception** of the products of **Chapter 28** or **29**, for the classification of certified reference materials, heading 38.22 shall take precedence over any other heading in the Nomenclature.

The **certified reference materials** of this heading are reference materials prepared for the calibration of an apparatus, the assessment of a measurement method or the assignment of values to a material. These reference materials may consist of the following :

- (a) Substrate materials containing added analytes, the concentration of which has been accurately determined;

- (b) Unmixed materials, the concentration of certain components of which has been accurately determined (e.g., the protein and fat content of milk powder);
- (c) Materials, whether natural or synthetic, certain properties of which have been accurately determined (e.g., tensile strength, specific gravity).

These reference materials must be accompanied by a certificate which indicates the values of the certified properties, the methods used to determine the values and the degree of certainty associated with each value, and the certifying authority.

The heading also **excludes** the following reagents, whether or not put up in forms for use as diagnostic or laboratory reagents :

- (a) Goods of **headings 28.43 to 28.46 and 28.52** (see Note 1 to Section VI);
- (b) Products covered by Note 1 to Chapter 28 or Note 1 to Chapter 29;
- (c) Synthetic organic products of a kind used as luminophores of heading 32.04, including preparations mentioned in Note 3 to Chapter 32
- (d) Prepared culture media for the development or maintenance of micro-organisms (including viruses and the like) or of plant, human or animal cells (**heading 38.21**).