

38.22

38.22 - Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, other than those of heading 30.02 or 30.06; certified reference materials.

This heading covers **diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents, other than** diagnostic reagents of heading 30.02 or diagnostic reagents designed to be administered to the patient and blood grouping reagents 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 immuno-assay 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. However, diagnostic kits having the essential character of products of heading 30.02 or 30.06 (e.g., those based on monoclonal or polyclonal antibodies) are **excluded**.

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).

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) Colouring matter 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**).