

Vitamin and mineral supplement labels marketed in São Paulo city: are they in compliance with Brazilian sanitary standards?

Rótulos de suplementos de vitaminas e minerais comercializados na cidade de São Paulo: atendem as normas sanitárias brasileiras?

ABSTRACT

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Introduction: The information provided on supplement labels contributes to consumer guidance on choosing the most suitable product for their needs; therefore, labels with nonconformity information to health legislation can negatively affect consumer health. **Objectives:** To evaluate the compliance of vitamin and mineral supplements labels marketed in the São Paulo city during the 2014-2017 period. **Method:** A checklist was drawn up covering the main items related to the labeling, which were verified in each package: name under which the product is sold; list of ingredients; composition; net quantity; identification of origin; batch identification; expiration date; warning and guidance statements; storage instructions; use of expressions; nutrition labeling; information on the presence of gluten and permitted additives. **Results:** The main irregularities observed were the presence of phrases or expressions inducing the consumer to mistake (29%), the incorrect description name (15%), and statement of active components not authorized for vitamin supplements (5%). **Conclusions:** The results highlight the problems related to the commercialization of vitamin and mineral supplements in Brazil, due to a complex legislation difficult to interpret that makes it possible for producing companies to create excuses to circumvent the law, damaging the health of the population.

KEYWORDS: Supplements; Vitamins; Labeling; Food Legislation

RESUMO

Introdução: As informações em rótulos de suplementos contribuem para a orientação do consumidor sobre a escolha do produto mais adequado às suas necessidades, no entanto, rótulos com informações não conformes à legislação sanitária podem afetar negativamente a saúde dos consumidores. **Objetivos:** Avaliar a conformidade de rótulos de suplementos de vitaminas e minerais comercializados na cidade de São Paulo no período de 2014 a 2017. **Método:** Foi elaborado um *checklist* com os principais itens relacionados à rotulagem, os quais foram verificados em cada embalagem: denominação de venda; lista de ingredientes; composição; conteúdo líquido; identificação de origem; identificação de lote; prazo de validade; frase de advertência e de orientação; cuidados de conservação; uso de expressões; rotulagem nutricional; informação sobre presença de glúten e aditivos permitidos. **Resultados:** As principais irregularidades observadas foram a presença de frases ou expressões induzindo o consumidor a engano (29%), a denominação de venda de forma incorreta (15%) e a declaração de componentes ativos não autorizados para suplementos vitamínicos (5%). **Conclusões:** Os resultados evidenciam os problemas relacionados à comercialização de suplementos vitamínicos e minerais no Brasil, em decorrência da complexa legislação, que dificulta sua interpretação gerando pretextos para as empresas produtoras burlarem a lei, prejudicando a saúde da população.

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INTRODUCTION

Labeling is defined as any inscription, caption, image, or any descriptive or graphic material written, printed, stamped, impressed, embossed-printed, lithographed, or stuck on a food packaging¹. The information provided by labeling is part of a set of rights provided for by the Brazilian Consumer Protection Code, which establishes that information on products must be clear and bring specific values regarding quantity, composition, and quality, as well as the risks foods may pose².

Vitamin and mineral supplements are classified as foods and consequently have to meet the requirements described in food labeling laws in addition to those established in the technical regulation on supplements. Vitamin and mineral supplements are categorized as isolated or associated vitamins, isolated or associated minerals, associations of vitamins with minerals, or products whose matrices are natural sources of vitamins and/or minerals, legally regulated by an Identity and Quality Standard in accordance with the pertinent legislation³. The main laws of the Brazilian Health Regulatory Agency of the Ministry of Health (Anvisa/MH) regarding the labeling of industrialized food in Brazil are the Board of Directors Resolution (BDR) no. 259, dated September 20, 2002, which approved the technical regulation on packaged food labeling¹; BDR no. 360, dated December 23, 2003, which approved the technical regulation on packaged food nutrition labeling⁴; BDR no. 359, dated December 23, 2003, which addressed the definition and establishment of food sizes and portions⁵; BDR no. 269, dated September 22, 2005, which established the recommended daily intake (RDI) values of protein, vitamins, and minerals⁶; and BDR no. 54, dated November 12, 2012, which approved the technical regulation on additional nutrition information⁷. Supplement labels must also present information on the presence of gluten, in accordance with Law no. 10,674, dated May 16, 2003, as a preventive and control measure against celiac disease⁸.

The information provided on supplement labels is essential to inform and guide consumers quantitatively and qualitatively, provide consumption orientations when necessary, and help consumers choose the most suitable product for their needs. Therefore, it is fundamental that reliable data is shown clearly and is neither misleading nor mentions false advantages associated with the consumption of supplements.

Nutrition labeling is defined as any description oriented toward informing consumers about the nutritional properties of a certain food, encompassing the energy and main nutrient values⁴. It is necessary that this information is understood by all consumers of the product; however, they find it difficult to understand and apply label and nutrition information to safeguard their health. Some factors that hinder consumer understanding of products are excess advertising, use of technical language, abbreviations and/or acronyms and initialisms, lack of explanation about allergenic components, and use of insufficiently legible letters^{9,10}. The food industry must inform consumers about the benefits of using the products and clearly explain what will be consumed.

Taking into account the importance of labeling in guiding consumers, the present study aimed to carry out a critical analysis

of the labels of vitamin and mineral supplements marketed in the city of São Paulo, Brazil. The study considers the legislation currently in force in the country, mainly regarding the information that must necessarily be shown on labels and nutrition information panels. The presence of descriptive or graphic material that could mislead consumers was also evaluated.

METHODS

A set of 82 samples of vitamin and mineral supplements from different brands in the forms of pills, tablets, hard and soft gelatin capsules, suspensions, and solutions was analyzed. The samples were collected by the Health Regulatory Agency of the state of São Paulo and purchased randomly from drugstores and supplement stores in the city of São Paulo, according to the availability on the market, from 2014 to 2017. The set comprised 66 Brazilian products and 16 imported items, samples with different sources and compositions, and products manufactured by both multinational corporations and small-size Brazilian companies, which resulted in a variety of commercial samples.

Verification of labeling compliance was based on the following laws currently in force in Brazil:

- I. Law no. 8,078, dated September 11, 1990²;
- II. Law no. 10,674/2003⁸;
- III. BDR no. 259/2002byAnvisa/MH¹;
- IV. BDR no. 359/2003by Anvisa/MH⁵;
- V. BDR no. 360/2003 by Anvisa/MH⁴;
- VI. BDR no. 269/2005byAnvisa/MH⁶;
- VII. BDR no. 54/2012 byAnvisa/MH⁷;
- VIII. Administrative Rule by the Health Surveillance Secretariat/MH no. 32, dated January 13, 1998³.

A checklist with the main items related to labeling was prepared, and they were verified in each packaging:

1. Sales denomination: According to the legislation, one of the following terms must be included in the main panel: “*Vitamin Supplement*”, “*Mineral Supplement*”, “*Vitamin and Mineral Supplement*”, “*Vitamin-mineral Supplement*”, or “*Supplement based on...*” followed by the specification of the vitamin(s) or mineral(s) used.
2. List of ingredients: The list of ingredients must show the items in descending order of proportion.
3. Composition: All products must contain at least 25% and at most 100% of the RDI for each nutrient in the daily portion indicated by the manufacturer. The formula may be a mixture of vitamins and minerals, isolated or associated



vitamins, isolated or associated minerals, or products whose matrices are natural sources of vitamins and/or minerals, legally regulated by an Identity and Quality Standard in accordance with the pertinent legislation.

4. Net content: Must be clearly expressed according to specific regulations.
5. Identification of origin: The following items must be included: name (corporate name) of the manufacturer or producer or fractionator or brand holder (owner), full address, and country and municipality of origin.
6. Batch identification: Every label must have a printed, imprinted, or otherwise marked indicator using a code or plain language that allows to identify the batch to which the food belongs, in a way that is visible, legible, and indelible.
7. Expiration date: Must be indicated using one of the following expressions: “best before...”, “date of validity”, “expiration date”, “expiry date”, “period of validity”, “sell-by date”, “storage life”, “use-by date”, and “validity term”.
8. Warning sentence: The following sentence must be included, highlighted and in bold: “Consume this product according to the daily recommended intake shown in the packaging”.
9. Guidance sentence: The following sentence must be included, highlighted and in bold: “Pregnant and nursing women and children up to 3(three) years old should consume this product only under the supervision of a nutritionist or physician”.
10. Storage information: Measures to preserve and store the product before and after the packaging is open must be described whenever necessary.
11. Use of expressions: Any expression that refers to the use of supplements to prevent, ease, or treat a disease or to change of a physiological state is prohibited. Only information on the normal, scientifically proven functions of vitamins and minerals are allowed, e.g. describing the physiological role of these nutrients in the development or functioning of the body.
12. Nutrition labeling: Supplement labels must comply with food legislation if applicable, for instance regarding nutrition information.
13. Information on the presence of gluten: All industrialized foods must necessarily show on their label and in the package insert the inscriptions “contains gluten” or “gluten free”, depending on the characteristics of the product.
14. Allowed additives: The use of additives, technology adjuvants, and excipients that are approved by food legislation and other items attested in officially accepted pharmacopeias and compendiums is permitted, as long as their technological need is justified and their safe limits are met, if applicable.

RESULTS AND DISCUSSION

In the evaluated samples, 48% of the items presented labels with at least one item that did not comply with the legislation. Among these, 11% had two or more items that did not comply with the legislation (Figure).

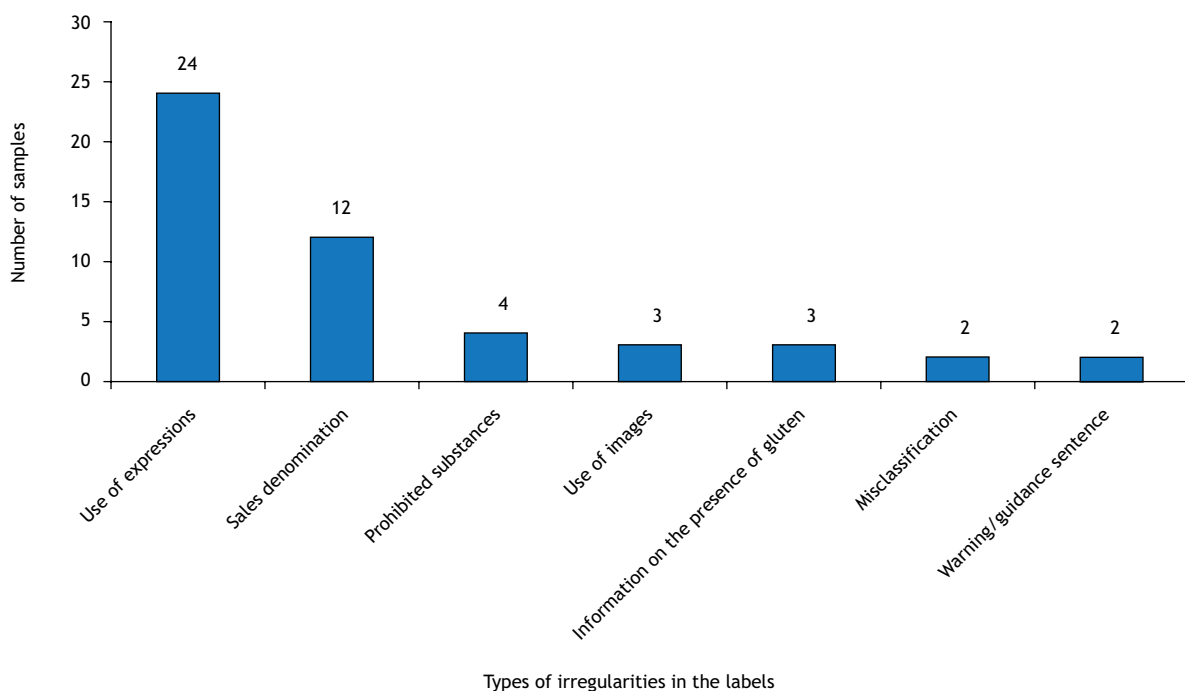


Figure. Main irregularities identified in labels of vitamin supplements and their respective numbers in the 82 analyzed samples.



Irregularities were found regarding the sales denomination in 12 samples. Two presented the sales denomination in the side panel, one showed the denomination as nutrition supplement made up of vitamins and minerals, and five had the denomination multivitamins and multiminerals. Additionally, four samples showed the sales denomination polyvitamins, although this is the denomination used in vitamin-based medicines¹¹. Vitamin-based supplements and medicines have similar presentation forms and appearance but represent different categories because they contain different levels of micronutrients in their composition. An incorrect sales denomination of vitamin supplements may mislead consumers, making it difficult for them to distinguish between the two types of products.

All the evaluated samples presented the list of ingredients in a logical order, according to what is expected for supplements. However, only a complete physicochemical analysis would make it possible to certify that the list of ingredients matches the order described in the label. In fatty matrices, the first announced component was the carrier, and the soybean oil stood out as the most common item in this function. In solid supplements containing vitamins and minerals, the first listed ingredient was calcium, in the form of calcium carbonate or phosphate, probably because this is the micronutrient with the highest RDI (1,000 mg).

Regarding the composition of the evaluated vitamin supplements, a sample with the denomination "vitamin C supplement" was made up of dehydrated camucamu pulp. Another sample was denominated as a "selenium, vitamin B5 and vitamin C supplement," but it presented the word "graviola" with the fruit's illustration. The regulation for the commercialization of fruit pulp capsules should be better clarified. Examples of products known as vitamin supplements consisting of fruit pulps were *goji berry, cranberry, and blueberry, which have now been made commercially available*. When commercialized as vitamin supplements, they become exempt from registration with the MH, which makes their trading easier. Capsules containing pulp from the mentioned fruits should be marketed as "New food" to meet the requirements of Resolution no. 16 dated April 30, 1999 by Anvisa/MH, which classifies them as foods or substances with no history of consumption in the country, or foods with substances already consumed that may be used or added at levels significantly higher compared to those currently found in foods included in a regular diet¹².

These foods may also be marketed in nonconventional presentation forms such as capsules, pills, tablets, and others. Some examples of fruits commercialized in the capsule format included in the list of foods recently approved by Anvisa are pineapple, acai, and Barbados cherry¹².

The labels of two samples revealed active components that are prohibited in vitamin supplements. One presented guarana in the list of ingredients, but this element is classified as a herbal medicine and consequently must be registered with the MH before being marketed¹³. The same is assumed for capsules made up of fruit pulp, which the manufacturer categorized as a vitamin supplement to begin the commercialization process

without the need of a previous registration, in an attempt to circumvent the law. The main panel of this product showed the expression "more energy from guarana" stressing the energy effect of this component with the image of an athlete. The other sample included caffeine in the list of ingredients, together with vitamins and minerals, and it was called vitamin and mineral supplement. A caffeine supplement is a product that aims to increase the aerobic capacity in prolonged physical activity and belongs to the category of products oriented toward athletes. However, the addition of nutrients in this type of supplement is prohibited¹⁴. The product under discussion had a commercial name that resembled the word "anti-cellulite" which can be construed as a marketing strategy to induce consumers to believe that its consumption might help fight cellulite. There are scientific reports on the effect of caffeine on the reduction of cellulite, but this evidence was obtained when the substance was used in topical applications¹⁵.

Still regarding the supplement composition, two imported samples showed indications of the presence of anabolic steroids, with the presentation of the following sentences in the main panel: "*World's most potent natural steroidal product available*" in one sample and "*Maximum muscular development and strength gains*" in the other. Both showed the label message in Portuguese over the original text on the back of the packaging, which is mandatory, given that this type of information must be written in the official language of the consumer country according to the legislation¹. Nevertheless, these products were denominated vitamin and mineral supplements on the label translated into Portuguese, with the list of ingredients showing vitamins, minerals, and excipients and no mention of steroids, probably because the commercialization of such substances is prohibited. In cases like this, importers commit a sanitary infraction by not complying with the standards in force, because commercializing the product as a vitamin and mineral supplement implies being exempt from registering the item with the MH. The consumption of high doses of anabolic steroids may lead to liver toxicity and be related to an increased incidence of cardiovascular diseases. Consequently, the use of these supplements poses a health risk to consumers, who often will not be aware of this fact¹⁶.

The net content in solid samples was presented as the quantity of supplement units on the package, and for liquid samples the net content in each container was expressed in milliliters. A sample of vitamin C supplement indicated "500 mg" in the main panel, without specifying what this value referred to. Nutrition information revealed that this number corresponded to the mass of one capsule, which contained 45 mg of vitamin C. The label information could lead consumers to think that the product as a whole had 500 mg of vitamin C, and it would be clearer if the text indicated that the written mass referred to a single capsule, as observed in other analyzed samples.

All the examined packaging showed the name (corporate name) of the manufacturer, producer, fractionator, or brand holder (owner), full address, country of origin, municipality, and registration number or identification code of the manufacturing company with the competent institution (CNPJ). The labels of



the imported products had the name or corporate name and the importer's address, in accordance with the legislation¹.

All the products had batch identification and expiration date displayed in a visible and legible way. Most evaluated supplements had an expiration date of 24 months. The date of manufacture was not included in 12% of the samples, but this information is not mandatory¹.

Concerning the obligatory warning and guidance sentences, it was found that this information was not present in two samples of the vitamin and mineral supplements, which instead had the sentences: "This product does not replace a balanced diet and its consumption must be supervised by a nutritionist or physician" and "This product must not be consumed by children, pregnant women, elderly people, and people with diseases", this is not appropriate, given that they are mandatory on the labels of foods for athletes¹⁷. In other two samples, the warning sentence was neither highlighted nor boldfaced, but was placed in a visible place, right below the nutrition information.

Exposure to light, heat, and humidity interferes with the stability of vitamins. Therefore, it is important to guide consumers on storage procedures by providing such information on the label. Most examined samples had the following instructions: keep the product protected from light (sun, sun light, incidence of sun light) (67%), store it in a cool place (temperatures lower than 25 °C, lower than 30 °C, 15°C-30°C, room temperature) (91%), and protect it from humidity (dry place) (85%). Indicating the storage temperature is important, because in Brazil, especially in the North and Northeast regions, temperatures are usually higher than 30 °C. Guidance on the period of consumption after the product package is opened was found in only 9% of the samples, which showed a 30 to 90 day period of consumption. This information should be included in all products, because after the package is opened, the item becomes more susceptible to the effect of oxygen and air humidity, which may cause the degradation of vitamins¹⁷. Consequently, the expiration date shown on the label would probably change after the opening of the product package.

Although the supplement legislation prohibits the use of expressions that imply that the consumption of these products could prevent, ease, or treat a disease or a change one's physiological state, the same legislation allows the use of expressions that define the normal, scientifically proven functions of vitamins and minerals, describing the physiological role of these nutrients in the development or functioning of the body³. Some examples of accepted sentences are: "Vitamin A is necessary for a normal sight"; "Iron is necessary for the formation of red blood cells"; and "Calcium and vitamin D are nutrients necessary for the normal structure of bones and teeth". However, several functions of vitamins are extensively studied, and for the purposes of label evaluation and supplement inspection, this item of the legislation should be explained better and the regulation should include a list with sentences and expressions permitted on labels of vitamin and mineral supplements.

According to the legislation, 32 labels (39%) showed irregular sentences and expressions. These were transcribed in the chart: "Does not cause weight gain"; "More energy for you daily routine"; "Invigorating"; "Fights stress"; "Complete nutrition at the right dose"; and "Recommended to fight hair loss, provide it with volume, growth, and shine". The inclusion of this information on labels, in addition to making the product seem to be of higher quality compared to similar items, raises consumers' mistaken expectations regarding its real properties, and may even lead to loss of health.

Analysis of some samples revealed images that may induce consumers to develop a false impression about the real effects and/or properties of the product. Three supplements presented images that created the impression that their consumption could improve the skin, nails, and hair, and listed references to scientific articles on these vitamin-related effects. However, this is false advertising, given that it is impossible to verify whether the effects promised on the labels occur at the doses prescribed on these supplements (at most 100% of the RDI).

Nutrition information must be presented by portion and as a percentage of the daily value (% DV). The BDR no. 360/2003 by Anvisa/MH made nutrition labeling mandatory, and establishes, among other specifications, the mandatory listing of energy value, content of carbohydrates, protein, total fat, saturated fat, trans fat, dietary fiber, and sodium on industrialized food labels⁴. Over 50% of the examined samples reported a quantity equivalent to 100% of the RDI of vitamins, and the other samples showed values in the recommend interval of 25% to 100%. Consequently, noncompliance was not observed regarding the description of nutrition information, but the real values of the vitamins can be confirmed only with laboratory analyses using validated analytical methods.

Six samples (7%) had expressions related to the absence of sugar or calories, such as "zero sugar", "does not contain sugar", "zero calorie", and "calorie free". According to the BDR no. 54/2012⁷, the absence of calories and sugar may be expressed as complementary nutrition information on the label of the product, as soon as their values in one portion are lower than 4 kcal and 0.5 g, respectively. Only the tablet samples contained sugar, and similarly to what was observed in other products, its content was classified as negligible in the nutrition information, probably because one portion of this supplement had less than 0.5 g of sugar.

The information on the presence of gluten was not found in two liquid samples and in one sample in the form of pills. Although the presence of gluten is unlikely in vitamin supplements, this information is mandatory and must be shown on the label of these products, because the ingestion of this protein may result in problems for people with celiac disease, such as chronic diarrhea, constipation, anemia, loss of appetite, mood swings, abdominal distension, and abdominal pain, among others¹⁸. The message indicating the presence or absence of gluten in foods must be available in Portuguese, written clearly and accurately. In the case of imported items, importers must ensure that the information is in conformity with Brazilian legislation⁸.



Chart. Transcription of sentences and expressions used in the labels of the analyzed supplement samples.

Sales denomination	Expressions
Vitamin and mineral supplement	Does not cause weight gain, more stamina and vitality for your day.
Vitamin and mineral supplement	Zero sugar. Its exclusive formula was developed to supply the daily needs of these nutrients, which are considered essential and have to be obtained from external sources, given that they are not produced by the human body.
Vitamin and mineral supplement	Helps prevent vitamin and mineral deficiency. Helps keep a balanced life rhythm. It is suitable in situations that demand high energy expenditure.
Vitamin supplement	Does not contain sugar. Does not cause weight gain. Helps prevent vitamin deficiencies.
Vitamin and mineral supplement	Does not cause weight gain.
Vitamin and mineral supplement	Zero calorie.
Vitamin and mineral supplement	Zero sugar. Does not cause weight gain.
Vitamin and mineral supplement	Especially developed for men. Energy. Antioxidant action. Immunity. Muscle health.
Vitamin-mineral supplement	More energy for your daily routine. Fights stress. Does not cause weight gain.
Vitamin-mineral supplement	More energy for your daily routine. Balanced formula. Does not cause weight gain.
Vitamin-mineral supplement	More energy for your daily routine. Antioxidant substances.
Vitamin-mineral supplement	Fights stress. Does not cause weight gain. Supplies nutritional deficiencies.
Vitamin-mineral supplement	Does not increase appetite. Calorie free.
Vitamin + mineral supplement	Invigorating. Antioxidant. Does not cause weight gain.
Vitamin and mineral supplement	Celluli Solution and an associated image.
Supplement of zinc, selenium, molybdenum, iron, vitamins C, E, B6, biotin, riboflavin, niacin, pantothenic acid, and folic acid	The original formula provides nutrients which are essential to hair bulb cells, including iron. Biotin, selenium, and zinc contribute to keeping healthy hair. Vitamins B6 and B9 and molybdenum contribute to a complete synthesis of sulfur-containing amino acids, which are essential to keratin. Contains an effective antioxidant complex (riboflavin, vitamins C and E, selenium, and zinc) that helps protect cells against oxidative stress.
Vitamin and mineral supplement	Complete nutrition at the right dose.
Vitamin and mineral supplement	Daily care for a healthy body and mind.
Vitamin and mineral supplement	Hair & nail solution and an associated image.
Hair polyvitamin	Indicated to fight hair loss and give it volume, growth, and shine.
Multivitamin and multimineral supplement	Supplies nutritional deficiencies of the body. Antioxidant. Does not cause weight gain.
Vitamin supplement	For people who do extreme physical exercises or in special environmental conditions, vitamins are essential to complementing a healthy diet.
Supplement containing calcium, vitamins D, K, B ₁₂ and C, and magnesium	Strong bones.
Vitamin and mineral supplement	Contributes to the normal production of collagen.
Vitamin and mineral supplement	Skin integrity and strengthening of hair and nails. Fights the symptoms of PMS.
Vitamin and mineral supplement	High antioxidant power, helps prevent heart diseases and strengthens the immune system.
Vitamin and mineral supplement containing magnesium, zinc, and vitamin B ₆	Maximum performance, maximum results.
Vitamin and mineral supplement	Zero sugar.
Vitamin and mineral supplement	Rejuvenating, stimulates the production of collagen, gives the skin firmness and elasticity, strengthens hair and nails.
Vitamin and mineral supplement	Helps grow and strengthen hair and nails.
Vitamin and mineral supplement	The most powerful natural steroid product available in the world*.
Vitamin and mineral supplement	Maximum muscle development and strength gain*.

The use of additives, technology adjuvants, and excipients included in the food legislation and other items attested in officially accepted pharmacopeias and compendiums is permitted, as long as their technological need is justified and their safe limits are met³. The guarantee that the added excipients are present at doses lower than the safe limits can be obtained only through laboratorial analysis. All the components in the list of ingredients were permitted¹⁹.

Information on artificial colorings was identified in 68% of the samples. Although all the mentioned colorings were permitted by the legislation, its excess use is questioned. The most cited artificial colorings were sunset yellow, brilliant blue, red no. 40, erythrosine (red), and titanium dioxide, and 51% of the evaluated samples had a combination of two to five colorings. The labels of two samples of infant formula indicated the presence of artificial



colorings, including erythrosine, red no. 40, and indigotine (blue). In the other children-oriented samples (eight items), no artificial colorings were present in the list of ingredients, which may be considered a positive, given that children are more likely to develop allergic reactions to this type of additive²⁰.

Food color influences consumer choices, a fact that justifies the use of colorings in several types of food products²¹. Because supplements must be kept away from light and thus are stored in opaque containers, consumers cannot see the content when the products are being chosen. Therefore, there is no reasonable explanation for adding colorings to vitamin and mineral supplements. Additionally, the excess ingestion of colorings may pose a health risks to consumers because these substances have toxicological and mutagenic potential, especially amaranth, erythrosine, and tartrazine, the latter also has allergenic properties. Consequently, caution must be exercised in the application and legalization of these substances in foods, and their use more restricted and controlled^{22,23}.

Recent evaluations revealed a high percentage (between 35% and 51%) of nonconformities in labels of foods for athletes and vitamin and mineral supplements, taking into account only the specific laws of each category: the BDR no. 18 dated April 27, 2010 by Anvisa/MH and the Administrative Rule no. 32/1998 by the Health Surveillance Secretariat/MH. The main nonconformities reported in both studies were the incorrect denomination of the examined products and mistakes in the warning sentences^{24,25}. These facts show the importance and need to expose data on labeling inadequacy to the scientific community and the population itself, letting people know that supplement labels do not always comply with the legislation in force.

CONCLUSIONS

The evaluation of the composition of vitamin supplements stands out among the examined items. Irregularities by the manufacturer regarding this aspect were found, which might have been caused by a lack of knowledge of technical regulations and/or a deliberate intention to gain financial advantages. The current Brazilian legislation on food supplements is comprehensive and complex, which results in difficulties to interpret the standards²⁶. These laws are specific to each product category: vitamin and mineral supplements, bioactive substances and probiotics, new foods, foods with alleged functional properties, supplements

for athletes, supplements for pregnant and nursing women, and specific medications that do not require medical prescription. According to Anvisa, the regulation of these products is under review, and the new regulatory proposal aims to put the products that currently belong to the categories mentioned previously into a single category named food supplements²⁷. The current legislation determines that, among these categories, only vitamin and mineral supplements and foods for athletes are exempt from acquiring a health license, in accordance with the BDR no. 27 dated August 6, 2010 by Anvisa/MH²⁸. With the new proposal, other categories that require registration with the MH before being marketed will probably become exempt from previous registration. Exemption from health license requirements makes it easier for companies to release their products on the market, leading to an increased number of available items and hindering their inspection²⁶.

The labels of 48% of vitamin and mineral supplement samples evaluated in the present study presented at least one item that did not comply with the legislation. This result indicates that many manufacturers commercialize their products without following the standards required by the law. Some irregularities may be a consequence of a lack of knowledge of the legislation, and others may result from attempts to circumvent the law, avoiding the registration of the product with the MH or using deceptive marketing strategies to attract consumers. These findings emphasize the need to intensify inspections in order to identify and correct potential irregularities, and guarantee that the choices consumers make about supplements are based on reliable and authentic information.

It is important that new regulations are developed and that the current ones are reviewed to guarantee the provision of more reliable and detailed labels, which allow consumers to choose products more suitable to their needs. Health authorities and regulatory agencies must question the improvements that this new legislation will bring because, if more categories become exempt from registration, the inspection and scrutiny of these products will become more difficult, a fact that is already observed. In case of health violation, the penalties provided by the law range from warnings, fines, and product seizures to the interdictions of managers and/or owners of commercial establishments. However a better legislation will not work without a more rigid inspection regime and the effective application of penalties.

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Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.



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