

Vivarin Tablets

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015 (Revision Date: 11/8/23)

SECTION 1: IDENTIFICATION

Product Identifier

Product Form: Mixture

Product Name: Vivarin Tablets, 200 mg

Synonyms: Caffeine Tablets, 200 mg

Intended Use of the Product

Use of the substance/mixture: Caffeine alertness aid

Name and Address of the Supplier of the Safety Data Sheet Vespyr Brands, Inc.

279 Princeton Highstown Road

East Windsor, NJ 08520 USA

T 732-839-9400

vespyrbrands.com

Emergency Telephone Number 1-855-874-0970

Emergency Email - Dr. Kanwaljit Uppal - Kuppal@aurobindousa.com

SECTION 2: HAZARDS IDENTIFICATION

Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information

about this product when used according to the physician's directions

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and by Canada's Food and Drugs Act.

It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(5)(iii) and in Canada's Hazardous Products Act.

Classification of the Substance or Mixture

Classification

Not classified

Label Elements

Not classified

Other Hazards

NA

Unknown Acute Toxicity

NA

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Substance NA

Mixture

Name	Product Identifier
Caffeine 200mg 28%	(CAS No) 58-08-2
D&C Yellow #10 Lake 4.63 mg .64%	(CAS No) 8004-92-0
Croscarmellose sodium 20 mg 2.8%	(CAS No) 74811-65-7
Dicalcium Phosphate 272.80 mg 37.88%	(CAS No) 7757-93-9
Magnesium stearate 10 mg 1.4%	(CAS No) 557-04-0
Starch 5 mg .69%	(CAS No) 9005-25-8
Calcium 62.74 mg 8.7%	(CAS No) 7440-70-2
Magnesium .4 mg .06%	(CAS No) 7439-95-4
Sodium 1 mg .14%	(CAS No) 7647-14-5

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Titanium dioxide 4.63mg .64%	(CAS No) 13463-67-7
Polyethylene glycol 2.5mg .35%	(CAS No) 25322-68-3
Silica, amorphous 5mg .28%	(CAS No) 7631-86-9
FD and C Yellow No. 6 Lake .04mg .006%	(CAS No) 2783-94-0
Polysorbate 80 .02mg .003%	(CAS No) 9005-65-6
Carnauba wax <1mg .1%	(CAS No) 8015-86-9
Hypromellose 13.8mg 1.9%	(CAS No) 9004-65-3
Microcrystalline Cellulose 130.2mg 18%	(CAS No) 9004-34-6

SECTION 4: FIRST AID MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Description of First Aid Measures

Overdose: Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away.

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: Using proper respiratory protection, move the exposed person to fresh air at once. Encourage exposed person to cough, spit out, and blow nose to remove dust. Immediately call a poison center, physician, or emergency medical service. **Skin**

Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms: No information available.

Indication of Any Immediate Medical Attention and Special Treatment Needed

Treat symptomatically. In case accident or if you feel unwell, get medical advice immediately (show product label).

SECTION 5: FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media: None known.

Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Not an explosive

Reactivity: Hazardous reactions will not occur under normal conditions.

Advice for Firefighters

Precautionary Measures Fire: Standard procedures fighting any chemical fires.

Firefighting Instructions: Use water spray or fog; do not use straight stream.

Protection of Firefighters: Wear self-contained breathing apparatus and full firefighting turnout gear.

Other information: Refer to section 9 for flammability properties.

SECTION 6: ACCIDENT RELEASE MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Personal Precautions, Protective Equipment and Emergency Procedures

Personal Precautions: Avoid contact with skin, eyes or clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Use personal protective equipment (PPE) as required.

For Non-emergency Personnel

Personal Protective Equipment: Use personal protection equipment as required.

Emergency Procedures: Evacuate personnel to safe areas.

For Emergency Responders

Personal Protection Equipment: Use personal protection equipment as required.

Emergency Procedures: Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources, if safe to do so.

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Environmental Precautions Do not flush into surface water or sanitary sewer system. Should not be released into the environment.

See section 12 for additional Ecological Information.

Methods and Material for Containment and Cleaning Up

For Containment: Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up: Use appropriate personal protective equipment. Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.

Prevention of Secondary Hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to Other Sections: See Section 8 for more information. See Section 13 for more information.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Keep container closed in a dry, cool and well-ventilated place. Keep away from heat. Protect from light.

Specific End Use(s) Pharmaceutical - use only as directed. Refer to product label for usage instructions and product information.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Exposure limits: No information available

Exposure controls

Appropriate engineering controls: Site-specific risk assessment should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

Eye/face protection: Safety glasses with side shield are recommended for medical or industrial exposures.

Skin and body protection: Wear suitable protective clothing.

Respiratory protection: No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required. If exposure limits are exceeded or irritation is experienced, NIOSH/MS approved respiratory protection should be worn.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: Yellow Tablets
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

Other Information No additional information available

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SECTION 10: STABILITY AND REACTIVITY

Reactivity: Hazardous reactions will not occur under normal conditions.

Chemical Stability: Stable under normal conditions.

Possibility of Hazardous Reactions: None of normal processing.

Conditions to Avoid: Extremes of temperatures and direct sunlight.

Incompatible Materials: Strong oxidizing agents, strong acids, and strong bases.

Hazardous Decomposition Products: None known.

SECTION 11: TOXICOLOGICAL INFORMATION

Information On Toxicological Effects

Information on likely routes of exposure

Inhalation: Not an expected route of exposure.

Ingestion: May be harmful if swallowed in amounts above the therapeutic dose.

Eye contact: Not an expected route of exposure.

Skin contact: Not an expected route of exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitization: NA

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT - single exposure: Based on available data, the classification criteria are not met.

STOT - repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Numerical measures of toxicity

Acute toxicity: No information available.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity

No information available.

Persistence and degradability

No information available.

Bioaccumulation

No information available.

Mobility

No information available.

Other adverse effects

No information available.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

SECTION 14: TRANSPORT INFORMATION

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

In accordance with DOT / ICAO / IATA / TDG

UN Number

Not regulated

UN proper shipping name

Not regulated

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Transport hazard class(es)

Hazard Class: Not regulated

Packing group

Not regulated

Environmental hazards

No

Special precautions for user

No information available

Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

SECTION 15: REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

International Regulations

Ozone-depleting substances (ODS): Not applicable

Persistent Organic Pollutants: Not applicable

The Rotterdam Convention: Not applicable

US Federal Regulations

SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Right-to-Know Regulations

US State Regulations: This product does not contain any substances regulated by state right-to-know regulations

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 11/08/2023

Other Information : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

Key or Legend to abbreviations and acronyms used

Party responsible for the preparation of this document Vespyr Brands phone number 1-732-839-9400

This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product.

Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution.

Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

VBI SDS NA GHS SDS 2023