

Section 1. IDENTIFICATION of SUBSTANCE/MIXTURE and the COMPANY/UNDERTAKING

1.1 Product Identifier

Product form: Article
Product Name: Vispore
Product Code(s): X-6150
Product Description: Nonwoven

1.2 Relevant Identified Uses and Restrictions

Intended Use: Cheese wrap
Restrictions: Medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

1.3 Company Details

Manufacturer: Fitesa Terre Haute
3400 Fort Harrison Rd,
Terre Haute, IN 47804,
United States

Contact Person: Dr. Nora Xin
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Section 2. HAZARDS IDENTIFICATION

2.1 Classification

Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200

Not classified

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

2.2 Label Requirements

Label Elements/Pictograms: Not required

Signal Word: Not required

Hazard Statement: Not required

2.3 Other Hazards

Physical Hazards: Not classified

Health Hazards:

Acute Toxicity:	Not classified
Skin corrosion/irritation:	Not classified
Serious eye damage/ eye irritation:	Not classified
Respiratory Sensitization:	Not classified
Germ cell mutagenicity:	Not classified
Carcinogenicity:	Not classified
Reproductive toxicity:	Not classified
Specific target organ toxicity, single exposure:	Not classified
Specific target organ toxicity, repeated exposure:	Not classified
Skin Sensitization	Not classified
Aspiration hazard:	Not classified

OSHA Defined Hazards: Not classified.

Precautionary Statement:

Prevention:	Not required.
Response:	Not required.
Storage:	Not required.
Disposal:	Not required.

Hazards not Otherwise Classified: Processing of this material may generate fine dust. Fine dust dispersed in air in sufficient concentration can cause mechanical irritation of the eyes, skin, nose, and throat and in the presence of an ignition source is a potential dust explosion hazard. Irritating fumes may be produced by combustion. Molten polymer may cause thermal burns.

Section 3. COMPOSITION / INFORMATION ON HAZARDOUS INGREDIENTS

This material is an “article” as defined by the United States Department of Labor, Occupational Safety and Health Administration (OSHA) and is a “manufactured article” as defined by the Canadian hazardous Products Act (R.S.C., 1985, c. H-3) and as such is exempt from the requirement for creation of an SDS. This document is created as a courtesy.

Article: The composition of this article is proprietary information. Composition may be provided in a separate document with completion of a signed confidentiality agreement. In the event of a medical emergency, compositional information will be provided to a physician or nurse. This product is not considered hazardous.

This product does not contain any substances to be mentioned according to REACH annex II.

Section 4. FIRST AID MEASURES

4.1 Description of First Aid Measures

Inhalation: Inhalation exposure unlikely due to form. Like other inert materials, dust can be mechanically irritating. In case of accidental inhalation of nuisance dust or fumes

from overheating or combustion, move to fresh air. Seek medical attention if cough or other symptoms develop.

Skin Contact: Skin absorption unlikely given this product is an inert solid. Wash with soap & water. For skin contact with molten material, cool with water. Seek medical attention.

Eye Contact: Like other inert particles, nuisance dust generated during cutting operations may be mechanically irritating to the eyes. Flush eyes with plenty of water. Remove contact lenses if easily possible. If eye irritation persists, seek medical attention.

Ingestion: Not likely to be ingested in present form. In the unlikely event that the film is ingested, do not induce vomiting without medical advice.

4.2 Most Important Symptoms and Effects, both Acute and Delayed

Symptoms/Injuries: Mechanical irritant effects from nuisance dust or inhalation of fumes caused by overheating or combustion may include stinging, tearing, redness, blurred vision or coughing.

4.3 Indication of any Immediate Medical Attention and Special Treatment Needed

Attention/Treatment: Provide general supportive measures. No health conditions aggravated by exposure are identified.

General: Take proper precautions to ensure your own health and safety before attempting rescue and providing first aid.

Section 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media

Suitable Extinguishing media: CO₂, foam, dry chemical, or water spray

Unsuitable Extinguishing media: None

5.2 Special Hazards Arising from the Mixture

Specific Hazards: Upon decomposition, this product may emit carbon monoxide, olefinic & paraffinic compounds and/or form trace amounts of organic acids, ketones, aldehydes and/or alcohols.

5.3 Advise for Firefighters

Firefighting Instructions: Cool with extinguishing media, remove heat source.

Flammability Classification: Not applicable. Polymer will burn but does not easily ignite.

Protection during Firefighting: Do not enter fire area without proper protective equipment. Wear positive pressure, self-contained breathing apparatus (SCBA) when fighting a fire in any closed space.

Section 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Non-emergency Personnel: Evacuate unnecessary personnel

Emergency Responders: Wear the appropriate personal protective equipment for the task.
Ventilate the area.

6.2 Environmental Precautions

Environmental Precautions: Not applicable

6.3 Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: Clean up promptly by sweeping or vacuum. Place in clean, dry container and cover loosely. Store in waste container and recycle, incinerate or landfill in conformance with local disposal regulations.

Section 7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling

Safe Handling: Minimize dust generation and accumulation during processing. Use routine housekeeping practice to ensure dusts do not accumulate. Heat only in areas with appropriate ventilation. Avoid exposure to heat, sparks or open flames.

7.2 Conditions for Safe Storage, including any Incompatibilities

Safe Storage Conditions: Store in accordance with local regulations at ambient temperatures <math><40^{\circ}</math> C in clean, dry warehouse. Eliminate all ignition sources. Separate from oxidizing material. Product should remain stretch wrapped or in the original package until conversion. Do not stack too high.

Incompatible Materials: Protect from excessive moisture or water. Do not expose to UV radiation (sunlight). Store away from immediate or dangerous sources of ignition. Avoid exposure to corrosive substances. Limit exposure to petroleum powered engine exhaust.

Section 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1 Control Parameters

Occupational Exposure Limits: Not established. Product is not considered to present a health hazard under reasonably anticipated conditions of use.

For dusty conditions, OSHA recommends for particulates not otherwise regulated an 8-hour TWA of 15 mg/m³ (total dust), 5 mg/m³ (respirable fraction).

Biological Limit Values: Not established. Product is not considered to present a biological hazard under reasonably anticipated conditions of use

Exposure Guidelines: Occupational exposure to nuisance dust (total and respirable) should be monitored and controlled.

8.2 Exposure Controls

Appropriate Engineering Controls: Normal room ventilation is usually adequate. Ventilation rates should be matched to conditions. Maintain airborne levels to an acceptable level.

Individual Protection Measures, such as Personal Protective Equipment:

Eye/Face Protection: None usually required under conditions of normal use. Wear eye/face protection appropriate for the specific hazard.

Skin Protection:	None usually required under conditions of normal use.
Hand protection:	None usually required under conditions of normal use. Use protective gloves if handling hot plastic.
Respiratory Protection:	None usually required under conditions of normal use.
Thermal Hazards:	None usually required under conditions of normal use. Wear appropriate thermal apparel for handling hot or molten product
General Use Statement:	Follow individual plant safety rules. Practice good personal hygiene measures and good housekeeping.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties

Physical State:	Solid
Appearance:	Sheet on roll
Color:	White
Odor:	Negligible; faint, mild hydrocarbon odor
Odor Threshold:	No data available
pH:	No data available
Relative evaporation rate (butylacetate=1):	No data available
Melting Point Ranges:	104 to 120°C (LL & LDPE)
Freezing Point:	No data available
Boiling Point/Boiling Range:	Not applicable
Flash Point:	No data available
Decomposition temperature:	Not data available
Flammability:	Not Classified. Polymer will burn but does not easily ignite
Auto-ignition Temperature	No data available
Vapor Pressure:	NIL
Vapor Density:	Not applicable
Relative Densities:	0.88 – 0.99 (PE/PP) / (water = 1)
Solubility (H₂O):	Insoluble
Partition Coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity:	No data available
Explosive Properties	No data available
Percent Volatiles:	NIL

Section 10. STABILITY AND REACTIVITY INFORMATION

Reactivity:	This product is stable and non-reactive under normal conditions of use.
Chemical Stability:	Material is stable under normal conditions of use and storage
Possibility of Hazardous Reactions:	No dangerous reaction known under conditions of normal use.
Conditions to avoid:	Heat, moisture, sunlight. Material will burn if exposed to open flame.
Incompatible Materials:	Strong oxidizing agents, fluorine
Hazardous Decomposition:	Oxides of nitrogen and carbon, aldehydes, alcohols and other toxic gases. Not expected to decompose under normal condition.

Section 11. TOXICOLOGICAL INFORMATION

11.1 Information on Likely Routes of Exposure

Ingestion:	Not likely to be ingested in its current form. Single dose oral toxicity is considered to be extremely low.
Inhalation:	Not likely to be inhaled in its current form. Single exposure to dust is not likely to be hazardous.
Skin Contact:	Essentially non-irritating to skin. Skin absorption unlikely due to physical form.
Eye Contact:	Like other inert particles, dust may be mechanically irritating to the eyes.

11.2 Information on Toxicological Effects

Acute Toxicity:	Not classified
Skin corrosion/irritation:	Not classified
Serious eye damage/eye irritation:	Not classified
Respiratory sensitization:	Not classified
Skin sensitization:	Not classified
Germ cell mutagenicity:	Not considered to be a mutagenic
Carcinogenicity:	Not listed by IARC, NTP, OSHA or EPA
Reproductive toxicity:	Not believed to be a reproductive hazard
Specific target organ toxicity/single exposure:	Not classified
Specific target organ toxicity/repeated exposure:	Not classified
Aspiration Hazard:	Due to physical form, not expected to be an aspiration hazard
Chronic effects:	Not classified
Symptoms related to the Physical, Chemical and toxicological Characteristics: Mechanical irritant effects may include stinging, tearing, redness, blurred vision or coughing.	

11.3 Other Toxicological Information



Specific Toxicity Testing: Specific toxicity testing has not been performed on this product. Hazard evaluation is based on information from similar products, raw material data and technical literature.

Section 12. ECOLOGICAL INFORMATION

Eco toxicity: No indication this material is a risk to the environment. The chemicals are bound in the polymer matrix and not readily available.

Persistence and Degradability: No data is available on the degradability of this product

Bio accumulative Potential: This material is not expected to bio-accumulate.

Mobility in Soil: Not available.

Results of PBT and vPvB Assessment: Not available

Other Adverse Effects: No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this product.

Section 13. DISPOSAL CONSIDERATIONS

US EPA Waste Number & Descriptions: No EPA Waste Numbers are applicable for this product's components.

Disposal Instructions: This product can be recycled and this is preferred to landfill disposal or incineration. If the ability to recycle is not available, dispose of unused material in accordance with federal, state, and local requirements.

Hazardous Waste Code: The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues/unused products: Dispose of unused material in accordance with federal, state, and local requirements.

Contaminated Packaging: Packaging can be recycled and this is preferred to landfill disposal or incineration. If the ability to recycle is not available, dispose of unused packaging in accordance with federal, state, and local requirements.

General Comments: Processing, use or contamination of this product may change the waste management options.

Section 14. TRANSPORT INFORMATION

14.1 In Accordance with ADR / RID / IMDG / IATA / ADN

This product is not regulated for transportation.

DOT: Not regulated for transport.

TDG (Canada): Not regulated for transport.

IMDG/IMO: Not regulated for transport.

ADR/RID: Not regulated for transport.

ICAO: Not regulated for transport.



Transport in Bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

14.2 Other

UN Number: Not regulated for transport.

UN Proper Shipping Name: Not applicable.

Transport Hazard Class(es): Not applicable

Packing Group: Not applicable

Environmental Hazards: No supplementary information available

14.3 Special Precautions for User

Overland Transport: No additional information available

Transport by Sea: No additional information available

Air Transport: No additional Available

Section 15. REGULATORY INFORMATION

15.1 US Regulations

US Federal Regulations: This product is classified as non-hazardous per 29 CFR 1910.1200 based on its components.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D): Not regulated

US OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050): Not listed

CERCLA Hazardous Substance List (40 CFR 302.4): Not listed

Superfund Amendments and Reauthorization Act of 1986 (SARA):

Hazard Categories Immediate Hazard – No
Delayed Hazard – No
Fire Hazard – No
Pressure Hazard – No
Reactivity Hazard - No

SARA 302/304 Not regulated. This product contains no known chemicals regulated under SARA 302/304

SARA 311/312 Not regulated. Based upon available information, this material is not classified as a health and/or physical hazard according to Section 311 & 312

SARA 313 (TRI reporting) Not regulated.

Clean air Act (CAA) section 112 Hazardous Air Pollutants (HAPs) List: Not regulated.

Clean air Act (CAA) section 112(r) Accidental Release Prevention (40 CFR 68.130): Not regulated

Safe Drinking Water act: Not regulated

Food & Drug Administration: Not regulated.

US STATE Reporting Not regulated.



This product is manufactured with one or more raw materials that contain Titanium Dioxide (CAS 13463-67-7), and other additives encapsulated in a polymer matrix. Under normal conditions and use, the encapsulated additives are not expected to pose any health hazard. Only unbound particles are required to be labeled for California Proposition 65 or listed for State Right to Know regulations.

15.2 EU Regulations

EU Regulations: Contains no substances with Annex XVII restrictions.

This product is manufactured with one or more raw materials that contain Titanium Dioxide (CAS 13463-67-7), which is classified H351 - suspected of causing cancer when in powder form containing 1% or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$. Under normal conditions and use, the encapsulated additives are not expected to pose any health hazard. Only unbound particles are required to be labeled.

15.3 National Regulations

Regulatory Status:

All components are acceptable for use under:

Country	Inventory
Australia	AICS
Canada	DSL
China	IECS
European Union	EINECS
Japan	ENCS
Korea	ECL
Philippines	PICCS
United States	TSCA

Section 16. OTHER INFORMATION including DATE of PREPARATION or LAST REVISION

16.1 Date of Preparation and Last Revision

Issue Date: 30 June 2021

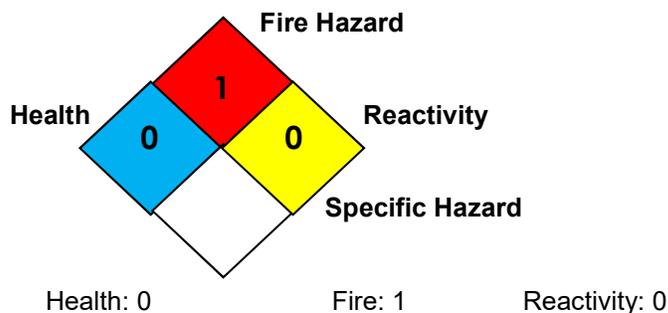
Version: 1

Review Date:

Revision Date:

Reason for Change:

16.2 HMIS Ratings



HMIS Ratings:

Health	0
Fire Hazard	1
Reactivity	0
Personal Protection	

Health: 0 Fire: 1 Reactivity: 0

16.3 Caution

Medical Application Caution: Do not use this material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

Do not use this material in medical applications involving brief or temporary implantation in the human body or permanent contact with internal body fluids or tissues.

16.4 Other Information

This Product is considered an article and does not require a safety data sheet (SDS). Classification of chemical components based on GHS (Globally Harmonized System of Classification and Labeling of Chemicals).

Disclaimer: The information contained in this SDS is provided by the suppliers of our raw materials. While Fitesa believes the information contained herein is accurate, Fitesa makes no warranty, express or implied, with respect to this information and expressly disclaims all liability for reliance thereon. This data is provided only as guidance for safe handling, use, storage, transportation, disposal, and release and is not considered a warranty or quality specification. This shall not constitute a guarantee for any specific product features. No toxicity data are available on this specific formulation; this health hazard assessment is based on information that is available for its components. Fitesa makes no warranties, express or implied, with respect to the product, including (without limitation) warranties of merchantability or fitness for a particular purpose. The customer or other user of the product assumes all risk and liability arising out of the use of the product, whether used alone or in combination with other materials. Fitesa’s liability, if any, for breach of contract, breach of warranty, negligence (including that of Fitesa) or other tort, strict liability, or any other claim shall not exceed in amount the purchase price of Fitesa products with respect to which such cause arose. In no event shall Fitesa be liable for consequential, special, or incidental damages.

Reviewed by: Dr. Nora Xin