

Trade Name: Supposi-Plex V65

1 Identification

1.1 Product identifier

Trade name: Supposi-Plex V65

Product Code: B0061

Application of the substance / the mixture: Pharma Excipient

1.2 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

SpecializedRx Products, LLC

3787 95th Ave NE Suite 100

Circle Pines, MN 55014 USA

www.specializedrx.com

sales@specializedrx.com

Information department:

Tel.: 1-888-512-1209

Fax: 1-612-424-8481

1.3 Emergency telephone number:

Emergency Telephone:

US: 1-888-512-1209

International: 1-888-512-1209

2 Hazard(s) identification

2.1 Classification of the substance or mixture

Material is not classified according to the Globally Harmonized System (GHS).

Material is not classified according to HCS 2012.

Substance is not subject to labelling according to Regulation (EC) 1272/2008.

2.2 Label elements

Hazard pictograms

N/A

Signal word N/A

Precautionary statements (GHS US) : N/A

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

Trade Name: Supposi-Plex V65

3 Composition/information on ingredients

3.1 Chemical Characterization: Substances

Description: Glycerides

3.2 Mixtures

3.2 Description: Nonhazardous mixture

Dangerous components: Void

3.3 Composition:

Chemical Name	CAS Number	% By Weight
Glycerides (plant origin)	67701-26-2	Proprietary
Cetylstearyl alcohol	68439-49-6	Proprietary
Cera alba	8012-89-3	Proprietary

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

Notes: *Proprietary: Ingredients indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as trade secret.

4 First-aid measures

4.1 Description of first aid measures

General information: If symptoms persist, contact physician. Have product container or label handy if medical advice is required.

After inhalation: Remove from exposure and move to fresh air immediately. If symptoms appear, consult physician.

After skin contact: Wash with soap and water. Get medical advice if skin irritation persists.

After eye contact: Rinse opened eye for several minutes under running water.

After swallowing: Rinse mouth with water; spit water out after rinse. Repeat. Consult doctor if symptoms persist.

4.2 Most important symptoms and effects, both acute and delayed

No relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

Perform symptomatic treatment.

5 Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing agents: alcohol-resistant foam, carbon dioxide, water spray, sand. Use fire-fighting measures that suit the environment. **Do not use direct water stream; it may spread fire.**

5.2 Special hazards arising from the substance or mixture

Trade Name: Supposi-Plex V65

Combustion of material will yield carbon monoxide & carbon dioxide; other combustion products of varying composition may also be produced, which may be toxic and/or irritating.

5.3 Advice for firefighters

Protective equipment: In the event of fire, wear self-contained breathing apparatus.

Other information: closed containers exposed to fire may be cooled with water spray. Do not allow run-off from fire-fighting to enter drains or water courses; run-off should be disposed of in accordance with local regulations.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

General measures: spilled material may present a slipping hazard.

Protective equipment: wear personal protective clothing (see chapter 8).

6.2 Environmental precautions:

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Collect into properly-labeled, suitable containers, using mechanical pick-up procedures.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

Protective Action Criteria for Chemicals

No relevant information available.

7 Handling and storage

7.1 Precautions for safe handling: Do not smoke near material. Wear personal protective equipment. Always wash hands after handling. Keep ignition sources away.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: store container tightly sealed, with adequate ventilation.

Information about storage in one common storage facility:

Store away from foodstuffs and feed.

Further information about storage conditions: None.

7.3 Specific end use(s): No further relevant information available.

8 Exposure controls/personal protection

Trade Name: Supposi-Plex V65

Additional information about design of technical systems: No further data; see item 7.

8.1 Control parameters

Components with limit values that require monitoring at the workplace:

There are no materials with critical values requiring monitoring in the workplace present in this product at relevant quantities.

8.2 Exposure controls

Personal protective equipment:

Wear suitable protective clothing in accordance with EN 340 and EN 13034.

General protective and hygienic measures:

Wash hands before breaks and at the end of work and following usual precautionary measures for working with or handling chemicals. Do not eat/drink while working with material.

Breathing equipment: Not required under normal use; if necessary, this is indicative of insufficient ventilation. May only be used to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out.

Eye Protection:

In case of dust production, wear protective goggles that meet requirements of EN 166.

Protection of hands:

The glove material must be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation effects of the substance acting on the material.

Material of gloves:

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material

The exact break through time must be found out by the manufacturer of the protective gloves and must be observed.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form: Solid pellet

Color: White to off-white

Odor: Odorless

pH-value: Not applicable

Melting point/Melting range: 33 - 35°C

Boiling point/Boiling range: Not determined

Flash point: > 200°C (DIN ISO 2592)

Flammability (solid, gaseous): Not applicable.

Ignition temperature: Not determined

Decomposition temperature: Not determined.

Auto igniting: Not determined

Danger of explosion: Product is not explosive.

Explosion limits: Product is not explosive.

Lower: Not determined

Trade Name: Supposi-Plex V65

Upper: Not determined
Vapor pressure: Not determined
Density: $\approx 0.96 \text{ g/cm}^3$
Relative density (water = 1): Not determined
Relative Vapor density (air = 1): Not determined
Evaporation rate: Not determined.
Solubility in / Miscibility with Water: Insoluble in water
Slightly soluble in ethanol
Partition coefficient (n-octanol/water): Not determined.
Viscosity:
Dynamic: Not determined
Kinematic: Not determined

9.2 Other information: No further relevant information available.

10 Stability and reactivity

10.1 Reactivity: Stable under normal conditions; no further relevant information available.
10.2 Chemical stability: Stable under normal conditions, no hazardous reactions.
10.3 Possibility of hazardous reactions: Avoid heat and open flame; potential dust explosion hazard from airborne release.
10.4 Conditions to avoid: Do not overheat; avoid all heat sources including direct sunlight in order to avoid thermal decomposition.
10.5 Incompatible materials: No further relevant information.
10.6 Hazardous decomposition products: Hazardous decomposition products should not be produced under normal conditions of storage and use.

11 Toxicological information

11.1 Information on toxicological effects
Acute toxicity: No toxicity data available for the product itself.
Primary irritant effect:
on the skin: No irritating effect
on the eye: No irritating effect
Sensitization: Not a known sensitizer/no known sensitizing effects known.
Additional toxicological information:
Carcinogenic/mutagenic/adverse effects on reproduction:
No carcinogenic/mutagenic/teratogenic effects demonstrated in presently available data.
IARC (International Agency for Research on Cancer): Substance not listed.
NTP (National Toxicology Program): Substance is not listed.
OSHA-Ca (Occupational Safety & Health Administration): Substance is not listed.

12 Ecological information

Trade Name: Supposi-Plex V65

12.1 Toxicity

Aquatic toxicity: No relevant data available.

12.2 Persistence and degradability: No relevant information available.

12.3 Bioaccumulative potential:

Bioaccumulation: No further relevant information available.

12.4 Mobility in soil: No further relevant information available.

Additional ecological information:

General notes:

Do not allow product it to reach ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects: No further relevant information available.

13 Disposal considerations

13.1 Waste treatment methods

Recommendation: Do not dump product directly on ground, into sewers or into any body of water. Dispose in accordance with local authorities.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: No relevant information available.

14 Transport information

14.1 UN-Number

DOT, ADR, ADN, IMDG, IATA

Not regulated for transport

14.2 UN proper shipping name

DOT, ADR, ADN, IMDG, IATA

Not regulated for transport

14.3 Transport hazard class(es)

DOT, ADR, ADN, IMDG, IATA

Class

Not regulated for transport

14.4 Packing group

DOT, ADR, IMDG, IATA

Not regulated for transport

14.5 Environmental hazards:

Not applicable.

14.6 Special precautions for user

Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

Trade Name: Supposi-Plex V65

UN "Model Regulation":

Void

15 Regulatory information

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

- **Sara Section 355 (extremely hazardous substances):** Substance is not listed.
- **Sara Section 313 (Specific toxic chemical listings):** Substance is listed.
- **TSCA (Toxic Substances Control Act):** All components listed or not subject to TSCA requirements.
- **Hazardous Air Pollutants** Substance is not listed.
- **Proposition 65**
- **Chemicals known to cause cancer:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for females:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for males:** Substance is not listed

16 Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

Department issuing SDS:

SpecializedRx Products, LLC

Quality Assurance

Contact: sales@specializedrx.com

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Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit