

Trade Name: Excell-RDT SF Unsweetened

1 Identification

1.1 Product identifier

Trade name: Excell-RDT SF™ Unsweetened
Product Code: B0237
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

Classification according to Regulation (EC) No 1272/2008

The product is not classified according to the CLP regulation.
May cause eye irritation
Not a hazardous substance or mixture.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Void
Hazard pictograms



Signal word Warning

Hazard statements H319 - Causes serious eye irritation

Precautionary statements (GHS US) : P264 - Wash exposed skin thoroughly after handling.
P280 - Wear eye protection.

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P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

Dust may form explosive mixture in air.

3 Composition/information on ingredients

3.1 Chemical Characterization: Mixture

Description: Mixture of the substances listed below with nonhazardous additions.

Dangerous components: Void

3.2 Chemical Information:

Chemical Name: Not applicable

Botanical Name: Not applicable

Synonym: Not applicable

Chemical Formula: Not applicable

CAS Number: Not applicable

Alternate CAS Number: Not applicable

Molecular Weight: Not applicable

3.3 Composition:

A proprietary blend of sugar alcohols from natural sources as well as organic/inorganic GRAS compounds for use in hard candy type preparations.

Chemical Name	CAS Number	% By Weight
Isomalt	64519-82-0	*Proprietary
Polyethylene Glycol	25322-68-3	*Proprietary
Sorbitol	50-70-4	*Proprietary
Maltodextrin	9050-36-6	*Proprietary
Colloidal Silicon Dioxide	112945-52-5	*Proprietary
Citric Acid	77-92-9	*Proprietary
Bitter-Bloc™ (Natural Flavor)	1883732-47-5	*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

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4.1 Description of first aid measures

General information: No special measures required.

After inhalation: Remove from exposure and move to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid if cough or other symptoms appear.

After skin contact: Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical aid if irritation develops or persists. Wash clothing before reuse.

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

After swallowing: Never give anything by mouth to an unconscious person. Do NOT induce vomiting. If conscious and alert, rinse mouth and drink 2-4 cupfuls of milk or water. Wash mouth out with water. Get medical aid if irritation or symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing agents: foam, Dry powder, carbon dioxide, water spray, sand. Use fire-fighting measures that suit the environment.

5.2 Special hazards arising from the substance or mixture

Potentially combustible material. Development of hazardous combustion gasses or vapors possible in the event of a fire.

5.3 Advice for firefighters

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

Further information : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures: Avoid breathing dust.

6.2 Environmental precautions:

Dilute with plenty of water.

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

6.3 Methods and material for containment and cleaning up:

Take up dry. Avoid generation of dusts. Clean up with water.

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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

PAC-1: None of the ingredients is listed.

PAC-2: None of the ingredients is listed.

PAC-3: None of the ingredients is listed.

7 Handling and storage

7.1 Precautions for safe handling: Prevent formation of dust.

Information about protection against explosions and fires:

Take precautions against dust explosion. Keep workplaces clean, avoid dust accumulation. Keep away from sources of ignition - No smoking. Observe explosion protection regulations

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: No special requirements.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: Store at room temperature in cool, dry conditions in well sealed receptacles.

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

8 Exposure controls/personal protection

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:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists that were valid during the creation were used as basis.

8.2 Exposure controls

Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

Breathing equipment: Fresh air mask

Protection of hands:

The glove material has to 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

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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. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

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

Eye protection: Goggles recommended during handling.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance: Fine white powder

Form: Powder

Color: White

Odor: Characteristic

pH-value: 3.3 10% solution

Melting point/Melting range: 56°C (132.8°F)

Boiling point/Boiling range: Not determined

Flash point: Not determined.

Flammability (solid, gaseous): Not determined.

Ignition temperature: Not determined.

Decomposition temperature: Not determined.

Auto igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:

Lower: Not determined.

Upper: Not determined.

Vapor pressure: Not determined.

Density: at 60°C approx. 1.23 g/cm³

Relative density: Not determined.

Vapor density: Not determined.

Evaporation rate: Not determined.

Solubility in / Miscibility with Water: Fully miscible.

Partition coefficient (n-octanol/water): Not determined.

Viscosity: Not determined.

Dynamic: Not determined.

Kinematic: Not determined.

Solvent content:

Organic solvents: 0.0 %

Water: 0.0 %

VOC content: 0.0 %

9.2 Other information: No further relevant information available.

10 Stability and reactivity

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10.1 Reactivity: No further relevant information available.

10.2 Chemical stability

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions: No dangerous reactions known.

10.4 Conditions to avoid: No further relevant information available.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

11.1 Information on toxicological effects

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

Primary irritant effect:

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

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

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

Additional toxicological information:

Carcinogenic categories

IARC (International Agency for Research on Cancer): None of the ingredients is listed.

NTP (National Toxicology Program): None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration): None of the ingredients is listed.

12 Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability: No further relevant information available.

12.3 Bioaccumulative potential: No further relevant information available.

12.4 Mobility in soil: No further relevant information available.

Additional ecological information:

General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of 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.

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Quality Assurance

Contact: sales@specializedrx.com

Date of preparation / last revision: 12 Sep 2022

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