

| Revision Date: 10/10/2020 | - | | Date of last issue: 03/23/2020 Date of first issue: 11/22/2019 | | | |
|------------------------------|--|--|---|--|--|--|
| 1. IDENTIFICATION | | | | | | |
| ct name | : | Pancrelipase (H | ligh / Low Lipase) Formulation | | | |
| facturer or supplier's | deta | ails | | | | |
| | : | 30 Hudson Stre | Organon & Co. 30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302 | | | |
| gency telephone | : | : 551-430-6000 : 215-631-6999 : EHSSTEWARD@organon.com | | | | |
| mmended use of the | chen | nical and restric | tions on use | | | |
| nmended use | : | Pharmaceutical | | | | |
| 2. HAZARDS IDENTIF | | ΓΙΟΝ | | | | |
| 1200) | rdan | ce with the OSH | A Hazard Communication Standard (29 CFF | | | |
| rritation | : | Category 2 | | | | |
| ritation | : | Category 2A | | | | |
| ratory sensitization | : | : Category 1 | | | | |
| label elements | | | | | | |
| d pictograms | : | | | | | |
| l Word | : | Danger | | | | |
| d Statements | : | H315 Causes s H319 Causes s H334 May caus | erious eye irritation. e allergy or asthma symptoms or breathing | | | |
| utionary Statements | : | P264 Wash skir P280 Wear prot tion. | athing dust, fume, gas, mist, vapors or spray. In thoroughly after handling. Sective gloves, eye protection and face protec- inadequate ventilation wear respiratory protec | | | |
| | 10/10/2020 1. IDENTIFICATION Intername facturer or supplier's any name of supplier any name of supplier iss hone gency telephone I address mmended use of the mmended use 2. HAZARDS IDENTIF | 10/10/2020 53 1. IDENTIFICATION | 10/10/2020 5322088-00003 1. IDENTIFICATION ict name : Pancrelipase (H facturer or supplier's details iany name of supplier : Organon & Co. iss : : Organon & Co. iss : : Organon & Co. iss : : : inny name of supplier : Organon & Co. iss : : : inny name of supplier : : : iss : : : iss : : : : iss : : : : inderess : : : : inderess : Pharmaceutical : 2. HAZARDS IDENTIFICATION : : Category 2 citation : : Category 2 iritation : : Category 1 iabel elements : : Category 1 iabel elements : Danger : | | | |



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|----------------|------------------------------|---|---|
| | | for several minu to do. Continue P332 + P313 If P337 + P313 If P342 + P311 If tor. | P338 IF IN EYES: Rinse cautiously with water utes. Remove contact lenses, if present and easy rinsing. skin irritation occurs: Get medical attention. eye irritation persists: Get medical attention. experiencing respiratory symptoms: Call a doc- ake off contaminated clothing and wash it before |
| | | Disposal: P501 Dispose o disposal plant. | of contents and container to an approved waste |
| •• | r hazards known. | | |
| SECTION | 3. COMPOSITION/I | NFORMATION ON ING | REDIENTS |
| Subs | tance / Mixture | : Mixture | |
| Com | ponents | | |

| Chemical name | CAS-No. | Concentration (% w/w) |
|-------------------|------------|-----------------------|
| Pancrelipase | 53608-75-6 | 72 |
| Talc | 14807-96-6 | 8.6 |
| Starch | 9005-25-8 | 2.9 |
| Sucrose | 57-50-1 | 2.9 |
| Diethyl phthalate | 84-66-2 | 2.1 |

SECTION 4. FIRST AID MEASURES

| General advice : | In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice. |
|---------------------------|--|
| If inhaled : | If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention. |
| In case of skin contact : | In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. |
| In case of eye contact : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention. |
| If swallowed : | If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water. |
| Most important symptoms : | Causes skin irritation. |



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| | and effects, both acute and delayed | | ties if inhaled. Excessive exposition other respiratory | y or asthma symptoms or breathing difficul- ure may aggravate preexisting asthma and disorders (e.g. emphysema, bronchitis, reac- | |
| Prote | ection of first-aiders | : | tive airways dysfunction syndrome). First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). | | |
| Note | s to physician | : | | cally and supportively. | |
| SECTION | 5. FIRE-FIGHTING ME | ASU | IRES | | |
| Suita | ble extinguishing media | : | Water spray Alcohol-resistant Carbon dioxide (C Dry chemical | | |
| Unsu medi | itable extinguishing a | : | High volume water jet | | |
| Spec fightii | ific hazards during fire ng | : | Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is potential dust explosion hazard. Do not use a solid water stream as it may scatter and sprea fire. Exposure to combustion products may be a hazard to healt | | |
| Haza ucts | rdous combustion prod- | : | : Carbon oxides Nitrogen oxides (NOx) Sulfur oxides | | |
| Spec ods | ific extinguishing meth- | : | Use extinguishing measures that are appropriate to local cir cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to so. Evacuate area. | | |
| | ial protective equipment e-fighters | | | | |

| Personal precautions, protec- tive equipment and emer- gency procedures | : | Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
|---|---|--|
| Environmental precautions | : | Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. |
| Methods and materials for containment and cleaning up | : | Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). |



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| | | Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. | | |
| SECTIO | N 7. HANDLING AND ST | ORAGE | | |
| Teo | chnical measures | causing an ex Provide adeq | ity may accumulate and ignite suspended dust plosion. uate precautions, such as electrical grounding or inert atmospheres. | |
| | al/Total ventilation vice on safe handling | Use only with Do not get on Avoid breathi Do not swallo Do not get in Wash skin the Handle in according practice, base assessment Keep contain Already sension regarding wo Minimize dus Keep contain Keep away fr Take precaut Take care to | adequate ventilation. skin or clothing. ng dust, fume, gas, mist, vapors or spray. w. | |
| | nditions for safe storage terials to avoid | Keep tightly of Store in acco | rdance with the particular national regulations. | |
| IVIA | | : Do not store Strong oxidiz | with the following product types: ing agents | |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

| <u> </u> | • | | | |
|--------------|------------|------------|---------------------|-----------|
| Components | CAS-No. | Value type | Control parame- | Basis |
| | | (Form of | ters / Permissible | |
| | | exposure) | concentration | |
| Pancrelipase | 53608-75-6 | TWA | OEB 3 (>= 10 < | Internal |
| | | | 100 µg/m3) | |
| Talc | 14807-96-6 | TWA (Dust) | 20 Million | OSHA Z-3 |
| | | | particles per cubic | |
| | | | foot | |
| | | TWA (Res- | 2 mg/m ³ | NIOSH REL |

Ingredients with workplace control parameters



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| | | pirable) | | |
|-------------------|-----------|-----------------------|----------------------|-----------|
| | | TWA (Res- | 2 mg/m ³ | ACGIH |
| | | pirable par- | | |
| | | ticulate mat- | | |
| | | ter) | | |
| Starch | 9005-25-8 | TWA | 10 mg/m ³ | ACGIH |
| | | TWA (Res- pirable) | 5 mg/m³ | NIOSH REL |
| | | TWA (total) | 10 mg/m ³ | NIOSH REL |
| | | TWA (total | 15 mg/m ³ | OSHA Z-1 |
| | | dust) | | |
| | | TWA (respir- | 5 mg/m³ | OSHA Z-1 |
| | | able fraction) | | |
| Sucrose | 57-50-1 | TWA | 10 mg/m ³ | ACGIH |
| | | TWA (Res- | 5 mg/m³ | NIOSH REL |
| | | pirable) | | |
| | | TWA (total) | 10 mg/m ³ | NIOSH REL |
| | | TWA (total | 15 mg/m³ | OSHA Z-1 |
| | | dust) | | |
| | | TWA (respir- | 5 mg/m³ | OSHA Z-1 |
| | | able fraction) | | |
| Diethyl phthalate | 84-66-2 | TWA | 5 mg/m ³ | ACGIH |
| | | TWA | 5 mg/m ³ | NIOSH REL |

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment

| Respiratory protection | : | General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection. |
|---------------------------|---|--|
| | | |
| Material | : | Chemical-resistant gloves |
| Remarks Eye protection | : | Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. |



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| Skin a | and body protection | Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, o aerosols. Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potent contaminated clothing. | | | |
| Hygie | ene measures | : If exposure to cl eye flushing sys working place. When using do Wash contamina The effective op engineering con appropriate deg | nemical is likely during typical use, provide tems and safety showers close to the not eat, drink or smoke. ated clothing before re-use. teration of a facility should include review of trols, proper personal protective equipment, owning and decontamination procedures, ne monitoring, medical surveillance and the | | |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| Appearance | : | solid |
|---|---|--|
| Color | : | No data available |
| Odor | : | No data available |
| Odor Threshold | : | No data available |
| рН | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | Not applicable |
| Evaporation rate | : | Not applicable |
| Flammability (solid, gas) | : | May form combustible dust concentrations in air. |
| Flammability (liquids) | : | Not applicable |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapor pressure | : | Not applicable |
| Relative vapor density | : | Not applicable |



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| F | Relative | e density | : | No data available | 9 |
| C | Density | , | : | No data available | 9 |
| S | Solubili Wat | ty(ies) er solubility | : | No data available | 9 |
| - | Partition | n coefficient: n- | : | Not applicable | |
| | | ition temperature | : | No data available | 9 |
| C | Decom | position temperature | : | No data available | 9 |
| V | √iscosi Visc | ty osity, kinematic | : | Not applicable | |
| E | Explosi | ve properties | : | Not explosive | |
| C | Oxidizir | ng properties | : | The substance o | r mixture is not classified as oxidizing. |
| Ν | Molecu | lar weight | : | No data available | 9 |
| F | Particle | size | : | No data available | 9 |
| | | | | | |

SECTION 10. STABILITY AND REACTIVITY

| Reactivity Chemical stability Possibility of hazardous reac- tions | : | Stable under normal conditions. |
|---|---|---|
| Conditions to avoid | : | Heat, flames and sparks. Avoid dust formation. |
| Incompatible materials Hazardous decomposition | : | |
| products | • | |

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure Inhalation

Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Pancrelipase:

Acute oral toxicity

: LD50 (Rat): > 10,000 mg/kg



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| | Talc: Acute | oral toxicity | : | LD50 (Rat): > 5,0 Remarks: Based |)00 mg/kg on data from similar materials |
| | Starch Acute | n: oral toxicity | : | LD50 (Rat): > 5,0 |)00 mg/kg |
| | Acute | dermal toxicity | : | LD50 (Rabbit): > | 2,000 mg/kg |
| | Sucro Acute | se: oral toxicity | : | LD50 (Rat): 29,7 | 00 mg/kg |
| | - | /l phthalate: oral toxicity | : | LD50 (Rat): > 5,0 | 000 mg/kg |
| | Acute | inhalation toxicity | : | LC50 (Rat): > 4.6 Exposure time: 6 Test atmosphere | h |
| | Acute | dermal toxicity | : | LD50 (Rat): > 11 | ,181 mg/kg |
| | Cause | orrosion/irritation s skin irritation. onents: | | | |
| | - | | | | |
| | Specie Methoo Result Remar | d | : | Rabbit OECD Test Guid Skin irritation Based on data fre | eline 404 om similar materials |
| | Talc: | | | | |
| | Specie Result | | : | Rabbit No skin irritation | |
| | Diethy | l phthalate: | | | |
| | Specie Result | es | : | Rabbit No skin irritation | |
| | | is eye damage/eye irr s serious eye irritation. | | on | |
| | | onents: | | | |
| | Pancr Result Remar | | : | | reversing within 21 days om similar materials |



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|-------------------|---|------------------------------|---|
| Talc: | | | |
| Specie | S | : Rabbit | |
| Result | | : No eye irritat | ion |
| | | | |
| Starch | : | | |
| Specie | S | : Rabbit | |
| Result | | : No eye irritat | ion |
| | | | |
| Diethy | l phthalate: | | |
| Species | S | : Rabbit | |
| Result | | : No eye irritat | |
| Remarl | KS | : Based on da | ta from similar materials |
| Respir | atory or skin sensit | ization | |
| - | ensitization | | |
| | | ilable information | |
| | ssified based on ava | liable information. | |
| - | atory sensitization use allergy or asthm | a symptoms or brea | thing difficulties if inhaled. |
| - | onents: | , | 5 |
| Pancre | elipase: | | |
| | of exposure | : Inhalation | |
| Specie | | : Humans | |
| Result | - | : positive | |
| Remarl | ks | | ta from similar materials |
| Assess | ment | : May cause s | ensitization by inhalation. |
| Talc: | | | |
| | of exposure | : Skin contact | |
| Species | | : Humans | |
| Result | | : negative | |
| _ | | | |
| Starch | | . | |
| Test Ty | | : Maximization | n Test |
| Routes Species | of exposure | : Skin contact | |
| Result | 5 | : Guinea pig : negative | |
| Rooult | | . nogativo | |
| Diethy | l phthalate: | | |
| Test Ty | | : Buehler Test | |
| | of exposure | : Skin contact | |
| Species | S | : Guinea pig | |
| Result | | : negative | |
| C a max | cell mutagenicity | | |

Germ cell mutagenicity

Not classified based on available information.



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| Com | ponents: | | |
| Panc | relipase: | | |
| Genc | otoxicity in vitro | Method: OE Result: neg | Bacterial reverse mutation assay (AMES) CD Test Guideline 471 ative ased on data from similar materials |
| | | Method: OE Result: neg | n vitro mammalian cell gene mutation test CD Test Guideline 476 ative ased on data from similar materials |
| | | Method: OE Result: neg | Chromosome aberration test in vitro CD Test Guideline 473 ative ased on data from similar materials |
| Talc: | | | |
| Geno | otoxicity in vitro | | DNA damage and repair, unscheduled DNA syn- mmalian cells (in vitro) ative |
| Genc | otoxicity in vivo | Species: Ra | Route: Ingestion |
| Stard | ch: | | |
| Genc | otoxicity in vitro | : Test Type: I Result: neg | Bacterial reverse mutation assay (AMES) ative |
| Sucr | ose: | | |
| Genc | otoxicity in vitro | : Test Type: I Result: neg | n vitro mammalian cell gene mutation test ative |
| Dieth | yl phthalate: | | |
| Genc | otoxicity in vitro | | Bacterial reverse mutation assay (AMES) CD Test Guideline 471 ative |
| | | | n vitro mammalian cell gene mutation test CD Test Guideline 476 ative |
| | | | Chromosome aberration test in vitro CD Test Guideline 473 ative |

Carcinogenicity

Not classified based on available information.



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| <u>Comp</u> | oonents: | | | |
| | ation Route sure time | : | Mouse inhalation (dust/m 2 Years negative | nist/fume) |
| Dieth | yl phthalate: | | | |
| | ation Route sure time | : | Rat Skin contact 103 weeks negative | |
| IARC | | | | t at levels greater than or equal to 0.1% is onfirmed human carcinogen by IARC. |
| OSHA | | | this product prese regulated carcino | nt at levels greater than or equal to 0.1% is gens. |
| NTP | | | | t at levels greater than or equal to 0.1% is carcinogen by NTP. |
| <u>Comp</u> Pancr | assified based on avail ponents: relipase: s on fertility | : | Test Type: Two-g | eneration reproduction toxicity study |
| Effects | s on fertility | : | Test Type: Two-g Species: Rat Application Route Result: negative | |
| | | | | on data from similar materials |
| Effects | s on fetal development | : | Species: Rat Application Route Result: negative | vo-fetal development e: Ingestion on data from similar materials |
| Talc: Effects | s on fetal development | : | Test Type: Embry Species: Rat Application Route Result: negative | vo-fetal development e: Ingestion |
| - | yl phthalate: s on fertility | : | Species: Rat Application Route | eneration reproduction toxicity study e: Ingestion est Guideline 416 |



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| | | | Result: negative | |
| Effect | s on fetal development | : | Test Type: Embry Species: Rat Application Route Result: negative | vo-fetal development e: Ingestion |
| | | | Test Type: Embry Species: Rabbit Application Route Result: negative | vo-fetal development e: Skin contact |
| | -single exposure assified based on availa | able | information. | |
| | -repeated exposure assified based on availa | able | information. | |
| Repe | ated dose toxicity | | | |
| Comp | oonents: | | | |
| Panci | elipase: | | | |
| | EL cation Route sure time od | | Rat > 100 mg/kg Ingestion 13 Weeks OECD Test Guide Based on data fro | eline 408 om similar materials |
| Starc | h: | | | |
| | EL cation Route sure time | | Rat >= 2,000 mg/kg Skin contact 28 Days OECD Test Guide | eline 410 |
| Dieth | yl phthalate: | | | |
| | | : | Rat 150 mg/kg Ingestion 16 Weeks | |
| Aspir | ation toxicity | | | |
| Not cl | assified based on availa | able | information. | |

Ecotoxicity

Components:

Pancrelipase:



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| Τοχία | city to fish | : | Exposure time: 96 Method: OECD Te | |
| | city to daphnia and other tic invertebrates | : | Exposure time: 48 Method: OECD Te | |
| Toxic plant | city to algae/aquatic s | : | 10 mg/l Exposure time: 72 Method: OECD Te | |
| | | | Exposure time: 72 Method: OECD Te | |
| Talc | : | | | |
| Τοχία | city to fish | : | LC50 (Brachydan Exposure time: 24 | o rerio (zebrafish)): > 100,000 mg/l h |
| Dietł | hyl phthalate: | | | |
| | city to fish | : | LC50 (Oncorhync Exposure time: 96 | hus mykiss (rainbow trout)): 12 mg/l i h |
| | city to daphnia and other tic invertebrates | : | LC50 (Daphnia m Exposure time: 48 | agna (Water flea)): 90 mg/l h |
| Toxic plant | city to algae/aquatic s | : | ErC50 (Desmodes Exposure time: 72 | smus subspicatus (green algae)): 45 mg/l ! h |
| | | | EC10 (Desmodes Exposure time: 72 | mus subspicatus (green algae)): 9 mg/l ! h |
| Toxic icity) | city to fish (Chronic tox- | : | NOEC (Cyprinus o Exposure time: 28 | carpio (Carp)): 5 mg/l s d |
| aqua | city to daphnia and other tic invertebrates (Chron- kicity) | : | NOEC (Daphnia r Exposure time: 21 | nagna (Water flea)): 25 mg/l d |
| Pers | istence and degradabili | ity | | |
| Com | ponents: | | | |
| | crelipase: | | | |
| | egradability | : | Result: Readily bi | odegradable. |
| Dieth | hyl phthalate: | | | |



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| Biode | egradability | : | Result: Readily b Biodegradation: Exposure time: 2 | 94.6 % |
| Bioa | ccumulative potential | | | |
| Com | ponents: | | | |
| Partit | relipase: ion coefficient: n- ol/water | : | log Pow: < 4 | |
| | ose: ion coefficient: n- ol/water | : | Pow: < 1 | |
| Partit | yl phthalate: ion coefficient: n- ol/water | : | log Pow: 2.2 | |
| | lity in soil ata available | | | |
| •• | r adverse effects ata available | | | |

SECTION 13. DISPOSAL CONSIDERATIONS

| Disposal n | nethods |
|------------|---------|
|------------|---------|

| Waste from residues | : | Dispose of in accordance with local regulations. |
|------------------------|---|---|
| Contaminated packaging | : | Empty containers should be taken to an approved waste |
| | | handling site for recycling or disposal. |
| | | If not otherwise specified: Dispose of as unused product. |

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

49 CFR

| UN/ID/NA number | : | UN 3077 |
|----------------------|---|--|
| Proper shipping name | : | Environmentally hazardous substance, solid, n.o.s. |
| | | (Diethyl phthalate) |
| Class | : | 9 |
| | | |



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| Label ERG | Code e pollutant | SIZES WHER | NFORMATION ONLY APPLIES TO PACKAGE E THE HAZARDOUS SUBSTANCE MEETS ABLE QUANTITY. |

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

| Components | CAS-No. | Component RQ (lbs) | Calculated product RQ (lbs) |
|-------------------|---------|-----------------------|--------------------------------|
| Diethyl phthalate | 84-66-2 | 1000 | 47619 |

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

| SARA 311/312 Hazards | : | Combustible dust Respiratory or skin sensitization Skin corrosion or irritation Serious eye damage or eye irritation |
|----------------------|---|---|
| SARA 313 | : | This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313. |

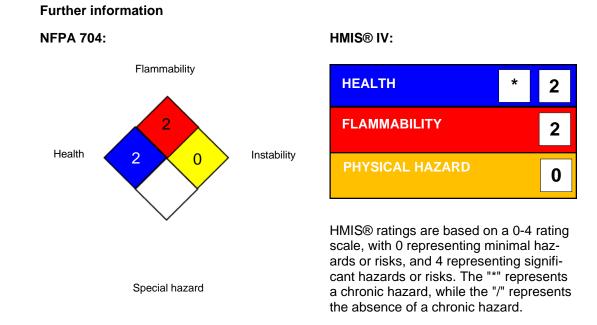
US State Regulations

| Pennsylvania Right To Know | | | | |
|--|------------|--|--|--|
| Pancrelipase | 53608-75-6 | | | |
| Cellacefate | 9004-38-0 | | | |
| Talc | 14807-96-6 | | | |
| Sucrose | 57-50-1 | | | |
| Starch | 9005-25-8 | | | |
| Diethyl phthalate | 84-66-2 | | | |
| California List of Hazardous Substances | | | | |
| Talc | 14807-96-6 | | | |
| Diethyl phthalate | 84-66-2 | | | |
| Polyvinyl pyrrolidone | 9003-39-8 | | | |
| California Permissible Exposure Limits for Chemical Contaminants | | | | |
| Talc | 14807-96-6 | | | |
| Sucrose | 57-50-1 | | | |
| Starch | 9005-25-8 | | | |



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|----------------|------------------------------|------------------|-------------------|---|
| | Diethyl phthalate | | | 84-66-2 |
| | ngredients of this pro | | - | e following inventories: |
| AICS | | | determined | |
| DSL | _ | | determined | |
| IECS | C | : not | determined | |

SECTION 16. OTHER INFORMATION



Full text of other abbreviations

| ACGIH NIOSH REL OSHA Z-1 | : | USA. ACGIH Threshold Limit Values (TLV) USA. NIOSH Recommended Exposure Limits USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim- its for Air Contaminants |
|----------------------------------|---|--|
| OSHA Z-3 | : | USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| NIOSH REL / TWA | : | Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek |
| OSHA Z-1 / TWA OSHA Z-3 / TWA | | 8-hour time weighted average 8-hour time weighted average |

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with



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x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC -International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG -United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

| Sources of key data used to compile the Material Safety Data SheetInternal technical data, data fre eChem Portal search results a cy, http://echa.europa.eu/ | om raw material SDSs, OECD and European Chemicals Agen- |
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Revision Date : 10/10/2020

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