Version



Date of last issue: 2020/10/10

Pancrelipase Formulation

Revision Date:

| 3.0 | 2021/04/09 | | 2037-00004 | Date of first issue: 2019/11/22 |
|-----------------|---|------------|-----------------------------------|--|
| 1. PRODU | JCT AND COMPANY ID | ENT | IFICATION | |
| Chen | nical product name | : | Pancrelipase F | ormulation |
| | blier's company name, a pany name of supplier | | ess and phone Organon & Co. | |
| Addro | ess | : | 30 Hudson Stro Jersey City, Ne | eet, 33nd floor ew Jersey, U.S.A 07302 |
| Telep | phone | : | 551-430-6000 | |
| E-ma | ail address | : | EHSSTEWARI | D@organon.com |
| Emei | rgency telephone numbe | r : | 215-631-6999 | |
| | ommended use of the clommended use | - | ical and restric Pharmaceutica | |
| 2. HAZAR | RDS IDENTIFICATION | | | |
| | classification of chemi corrosion/irritation | cal : | broduct Category 2 | |
| Serio tatior | bus eye damage/eye irri- N | : | Category 2A | |
| Resp | iratory sensitisation | : | Category 1 | |
| Shor haza | t-term (acute) aquatic rd | : | Category 2 | |
| | label elements Ird pictograms | : | | |
| Signa | al word | : | Danger | |
| Haza | rd statements | : | | serious eye irritation. se allergy or asthma symptoms or breathing naled. |
| Preca | autionary statements | : | P264 Wash sk P273 Avoid rel | eathing dust/ fume/ gas/ mist/ vapours/ spray. in thoroughly after handling. ease to the environment. itective gloves/ eye protection/ face protection. |

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| | | P284 Wear res | spiratory protection. | |
| | | | F ON SKIN: Wash with plenty of water. F INHALED: Remove person to fresh air and | |
| | | keep comfortable for breathing. P305 + P351 + P338 IF IN EYES: Rinse cautiously with v for several minutes. Remove contact lenses, if present ar easy to do. Continue rinsing. P332 + P313 If skin irritation occurs: Get medical advice/ tion. P337 + P313 If eye irritation persists: Get medical advice tention. | | |
| | | | | |
| | | POISON CEN | f experiencing respiratory symptoms: Call a TER/ doctor. Fake off contaminated clothing and wash it before | |
| | | Disposal: P501 Dispose disposal plant. | of contents/ container to an approved waste | |

Other hazards which do not result in classification

Important symptoms and out- : May form combustible dust concentrations in air. lines of the emergency assumed

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

: Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) | ENCS No. |
|-------------------|------------|-----------------------|----------|
| Pancrelipase | 53608-75-6 | >= 50 - < 60 | |
| Starch | 9005-25-8 | >= 30 - < 40 | 8-98 |
| Calcium carbonate | 471-34-1 | >= 1 - < 10 | 1-122 |

4. FIRST AID MEASURES

| General advice | : | In the case of accident or if you feel unwell, seek medical ad- vice 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. |



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| In case of eye contact | | : | Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. 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. | | | | |
| If swallowed | | | Get medical atten | NOT induce vomiting. tion if symptoms occur. | | | |
| | nportant symptoms fects, both acute and d | : | ties if inhaled. Excessive exposu other respiratory of | tion. | | | |
| | tion of first-aiders | : | First Aid responde and use the recon when the potentia | ers should pay attention to self-protection, nmended personal protective equipment I for exposure exists (see section 8). | | | |
| | to physician | : | Treat symptomation | cally and supportively. | | | |
| 5. FIREFIG | HTING MEASURES | | | | | | |
| | le extinguishing media able extinguishing | : | Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical High volume wate | 202) | | | |
| media Specifi fightino | ic hazards during fire- 9 | : | concentrations, ar potential dust exp Do not use a solic fire. | dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. I water stream as it may scatter and spread pustion products may be a hazard to health. | | | |
| Hazaro ucts | dous combustion prod- | : | Carbon oxides Nitrogen oxides (I Sulphur oxides Metal oxides | NOx) | | | |
| ods | ic extinguishing meth- | : | cumstances and t Use water spray t Remove undamag so. Evacuate area. | measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do | | | |
| for fire | Il protective equipment fighters NTAL RELEASE MEA | | Use personal prot | e, wear self-contained breathing apparatus. ective equipment. | | | |

6. ACCIDENTAL RELEASE MEASURES

| Personal precautions, protec- : | Use personal protective equipment. |
|---------------------------------|---|
| tive equipment and emer- | Follow safe handling advice (see section 7) and personal pro- |



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| g | ency p | procedures | | tective equipment | recommendations (see section 8). |
| E | Inviron | nmental precautions | : | Retain and dispos | akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages |
| | Methods and materials for containment and cleaning up | | : | tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the att Local or national posal of this mate employed in the c mine which regula Sections 13 and 1 | dust in the air (i.e., clearing dust surfaces |
| 7. HAI | NDLIN | IG AND STORAGE | | | |
| н | landlii | ng | | | |

| панинну | | |
|-------------------------|---|--|
| Technical measures | : | Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
| Local/Total ventilation | : | |
| | : | Do not get on skin or clothing. |
| Advice on safe handling | • | Avoid breathing dust, fume, gas, mist, vapours or spray. Do not swallow. |
| | | Do not get in eyes. |
| | | Wash skin thoroughly after handling. |
| | | Handle in accordance with good industrial hygiene and safety |
| | | practice, based on the results of the workplace exposure as- |
| | | Keep container tightly closed. |
| | | Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers. Minimize dust generation and accumulation. |
| | | Keep container closed when not in use. |
| | | Keep away from heat and sources of ignition. |
| | | Take precautionary measures against static discharges. |
| | | Take care to prevent spills, waste and minimize release to the environment. |
| Avoidance of contact | : | Oxidizing agents |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. |
| | | When using do not eat, drink or smoke. |
| | | Wash contaminated clothing before re-use. |
| | | The effective operation of a facility should include review of |
| | | |



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| | | appropriate c industrial hyg | controls, proper personal protective equipment, legowning and decontamination procedures, iene monitoring, medical surveillance and the istrative controls. |
| Stora | ge | | |
| Condi | itions for safe storage | Keep tightly o | erly labelled containers. closed. rdance with the particular national regulations. |
| Mater | ials to avoid | | with the following product types: |
| Packa | aging material | : Unsuitable m | aterial: None known. |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis | | |
|-------------------|----------------|-------------------------------------|--|----------------|--|--|
| Pancrelipase | 53608-75-6 | TWA | OEB 3 (>= 10 < 100 μg/m3) | Internal | | |
| Starch | 9005-25-8 | TWA | 10 mg/m3 | ACGIH | | |
| Calcium carbonate | 471-34-1 | OEL-M (Respirable dust) | 2 mg/m3 | JP OEL JSOH | | |
| | Further inform | Further information: Class 3 Dust | | | | |
| | | OEL-M (Total dust) | 8 mg/m3 | JP OEL JSOH | | |
| | Further inform | ation: Class 3 D | ust | | | |

| 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 con- tainment devices). Minimize open handling. |
|--------------------------------|-----|--|
| Personal protective equipme | ent | |
| Respiratory protection | : | If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. |
| Filter type Hand protection | : | Particulates type |
| | | |
| 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 ar | nd body protection | : | potential for direct aerosols. Work uniform or la Additional body ga task being perform posable suits) to a | arments should be used based upon the ned (e.g., sleevelets, apron, gauntlets, dis- avoid exposed skin surfaces. legowning techniques to remove potentially | | | | | |
| 9. P | 9. PHYSICAL AND CHEMICAL PROPERTIES | | | | | | | | | |
| | Physica | al state | : | solid | | | | | | |
| | Colour | | : | No data available | 9 | | | | | |
| | Odour | | : | No data available | 9 | | | | | |
| | Odour | Threshold | : | No data available | 9 | | | | | |
| | Melting | point/freezing point | : | No data available | 9 | | | | | |
| | | point, initial boiling nd boiling range | : | No data available | 9 | | | | | |
| | Flamm | ability (solid, gas) | : | May form combu | stible dust concentrations in air. | | | | | |
| | Flamm | ability (liquids) | : | Not applicable | | | | | | |
| | Upper | explosion limit and upp explosion limit / Upper ability limit | | | | | | | | |
| | | explosion limit / Lower ability limit | : | No data available | | | | | | |
| | Flash p | point | : | Not applicable | | | | | | |
| | Decom | position temperature | : | No data available | 9 | | | | | |
| | рН | | : | No data available | 9 | | | | | |
| | Evapor | ation rate | : | Not applicable | | | | | | |
| | Auto-ig | nition temperature | : | No data available | 2 | | | | | |
| | Viscosi Visc | ity cosity, kinematic | : | Not applicable | | | | | | |
| | Solubil Wat | ity(ies) ter solubility | : | No data available | | | | | | |
| | Partitio octano | n coefficient: n- I/water | : | Not applicable | | | | | | |



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|-------------|---|--|----------|---|--|
| | Vapour | pressure | : | Not applicable | |
| | Density and / or relative densi Relative density | | ity : | No data available | 9 |
| | Density | , | : | No data available | 9 |
| | Relative | e vapour density | : | Not applicable | |
| | Explosi | ve properties | : | Not explosive | |
| | Oxidizir | ng properties | : | The substance o | r mixture is not classified as oxidizing. |
| | Molecu | lar weight | : | No data available | e |
| | Particle Particle | e characteristics e size | : | No data available | 9 |
| 10. 9 | STABIL | ITY AND REACTIVITY | Y | | |
| | | rity cal stability lity of hazardous reac- | : | Stable under nor May form combu | a reactivity hazard. mal conditions. stible dust concentrations in air. rrong oxidizing agents. |
| | Conditi | ons to avoid | : | Heat, flames and | |
| | | atible materials ous decomposition ts | : | Avoid dust forma Oxidizing agents No hazardous de | |
| 11. | тохісо | LOGICAL INFORMA | TION | l | |
| | Informa exposu | ation on likely routes of re | f: | Inhalation Skin contact Ingestion Eye contact | |
| | | t oxicity ssified based on availa | able i | nformation. | |
| | Compo | onents: | | | |
| I | _ | lipase: pral toxicity | : | LD50 (Rat): > 10, | 000 mg/kg |
| ı I | Starch Acute c | : oral toxicity | : | LD50 (Rat): > 5,0 | 00 mg/kg |
| | | dermal toxicity | : | LD50 (Rabbit): > 2 | |
| 1 | II Calcium carbonate: | | | | |



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| Acute | Acute oral toxicity Acute inhalation toxicity | | | 00 mg/kg est Guideline 420 substance or mixture has no acute oral tox- |
| Acute | | | | h |
| Acute | e dermal toxicity | : | | 00 mg/kg est Guideline 402 substance or mixture has no acute dermal |
| Skin | corrosion/irritation | | | |
| Caus | es skin irritation. | | | |
| Com | ponents: | | | |
| Panc | relipase: | | | |
| Spec | ies | : | Rabbit | |
| Meth | | : | OECD Test Guide | eline 404 |
| Resu Rema | | : | Skin irritation Based on data fro | om similar materials |
| Calai | um carbonate: | | | |
| | | | Rabbit | |
| Spec Meth | | : | OECD Test Guide | eline 404 |
| Resu | | : | No skin irritation | |
| Serio | ous eye damage/eye irr | itati | ion | |
| | es serious eye irritation. | | | |
| Com | ponents: | | | |
| Panc | relipase: | | | |
| Resu | • | | Irritation to eves | reversing within 21 days |
| Rema | | : | | om similar materials |
| Starc | :h: | | | |
| Spec | | : | Rabbit | |
| Resu | | : | No eye irritation | |
| Calci | um carbonate: | | | |
| Spec | ies | : | Rabbit | |
| Resu | lt | : | No eye irritation | |
| Metho | od | : | OECD Test Guid | eline 405 |
| | | | | |



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|--|--|---|--|--|--|--|--|
| Respi | iratory or skin sensit | isation | | | | | |
| - | Skin sensitisation Not classified based on available information. | | | | | | |
| - | Respiratory sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled. | | | | | | |
| Comp | oonents: | | | | | | |
| Panci | relipase: | | | | | | |
| Expos Speci Resul Rema | t | : Inhalation : Humans : positive : Based on data | from similar materials | | | | |
| | | | | | | | |
| Asses | ssment | : May cause sen | sitisation by inhalation. | | | | |
| Starc | h: | | | | | | |
| Test T Expos Speci Resul | sure routes es | : Maximisation T : Skin contact : Guinea pig : negative | est | | | | |
| Calci | um carbonate: | | | | | | |
| Test T Expos Speci Metho Resul | es es | Local lymph no Skin contact Mouse OECD Test Gu negative | de assay (LLNA) ideline 429 | | | | |
| | cell mutagenicity assified based on ava | ilable information. | | | | | |
| Comp | oonents: | | | | | | |
| Panci | relipase: | | | | | | |
| | toxicity in vitro | Method: OECD Result: negativ | terial reverse mutation assay (AMES) Test Guideline 471 e ed on data from similar materials | | | | |
| | | Method: OECD Result: negativ | itro mammalian cell gene mutation test Test Guideline 476 e ed on data from similar materials | | | | |
| | | Method: OECD Result: negativ | omosome aberration test in vitro Test Guideline 473 e ed on data from similar materials | | | | |
| | h. | Nomaino. Dast | | | | | |

Starch:



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| Genotoxicity in vitro | | : Test Type: Bacterial reverse mutation assay (AMES) Result: negative | |
| Calci | um carbonate: | | |
| Geno | toxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative | |
| | | Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative | |
| | | Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative | |
| II Carci | nogenicity | | |
| | lassified based on avai | able information. | |
| - | oductive toxicity lassified based on avai | able information. | |
| Com | oonents: | | |
| Panc | relipase: | | |
| | ts on fertility | Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials | |
| Effect ment | ts on foetal develop- | : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials | |
| 11 | | | |
| | um carbonate: ts on fertility | : Test Type: Combined repeated dose toxicity study with t reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative | he |
| Effect ment | ts on foetal develop- | : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative | |
| II STOT | - single exposure | | |

STOT - single exposure

Not classified based on available information.



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| | r - repeated exposure | | | | | | | |
| Not c | Not classified based on available information. | | | | | | | |
| Repe | Repeated dose toxicity | | | | | | | |
| Com | Components: | | | | | | | |
| Panc | relipase: | | | | | | | |
| | EL cation Route sure time od | : Rat : > 100 mg/kg : Ingestion : 13 Weeks : OECD Test Gui : Based on data f | deline 408 rom similar materials | | | | | |
| Starc | h: | | | | | | | |
| | EL cation Route sure time | : Rat : >= 2,000 mg/kg : Skin contact : 28 Days : OECD Test Gui | deline 410 | | | | | |
| Calci | um carbonate: | | | | | | | |
| | EL cation Route sure time | : Rat : > 1,000 mg/kg : Ingestion : 28 Days : OECD Test Gui | deline 422 | | | | | |
| - | Aspiration toxicity Not classified based on available information. | | | | | | | |
| 12. ECOL | OGICAL INFORMATIC | DN . | | | | | | |
| Ecoto | oxicity | | | | | | | |
| Com | ponents: | | | | | | | |
| Panc | relipase: | | | | | | | |
| Toxic | ity to fish | : LC50 (Oncorhyr | nchus mykiss (rainbow trout)): > 100 mg/l | | | | | |

| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 10 - 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | | ErC50 (Pseudokirchneriella subcapitata (green algae)): > 1 - 10 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |



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| | | NOEC (Desm Exposure tim Method: OEC | sed on data from similar materials nodesmus subspicatus (green algae)): > 1 mg/l e: 72 h D Test Guideline 201 sed on data from similar materials |
| II Calciu | um carbonate: | | |
| | ty to fish | Exposure tim Test substand | aynchus mykiss (rainbow trout)): > 100 mg/l e: 96 h ce: Water Accommodated Fraction D Test Guideline 203 |
| | ty to daphnia and other c invertebrates | Exposure tim Test substand | ia magna (Water flea)): > 100 mg/l e: 48 h ce: Water Accommodated Fraction D Test Guideline 202 |
| Toxici plants | ty to algae/aquatic | mg/l Exposure tim Test substand | udokirchneriella subcapitata (green algae)): 50 e: 72 h ce: Water Accommodated Fraction D Test Guideline 201 |
| | | mg/l Exposure tim Test substand | okirchneriella subcapitata (green algae)): > 100 e: 72 h ce: Water Accommodated Fraction D Test Guideline 201 |
| Toxici | ty to microorganisms | : NOEC: 1,000 Exposure tim Method: OEC | |
| | | EC50: > 1,00 Exposure tim Method: OEC | 5 |
| Persis | stence and degradabil | ity | |
| Comp | onents: | | |
| | elipase: gradability | : Result: Read | ly biodegradable. |
| Bioac | cumulative potential | | |
| <u>Comp</u> | onents: | | |
| Partitio | elipase: on coefficient: n- ol/water | : log Pow: < 4 | |



| No dat Hazaro | ty in soil a available | | | | | | |
|-------------------------|--|-------|--------------------------------------|---|--|--|--|
| Not an | dous to the ozone lay | ver | | | | | |
| Not ap | plicable | | | | | | |
| | adverse effects a available | | | | | | |
| 13. DISPOS | SAL CONSIDERATIO | NS | | | | | |
| Waste | sal methods from residues minated packaging | : | Empty containe dling site for rec | ccordance with local regulations. rs should be taken to an approved waste han- cycling or disposal. specified: Dispose of as unused product. | | | |
| 14. TRANS | PORT INFORMATION | 1 | | | | | |
| Interna | ational Regulations | | | | | | |
| UNRTI | - | s go | od | | | | |
| | IATA-DGR Not regulated as a dangerous good | | | | | | |
| IMDG- Not reç | Code gulated as a dangerou: | s go | od | | | | |
| • | Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable for product as supplied. | | | | | | |
| | National Regulations Refer to section 15 for specific national regulation. | | | | | | |
| 15. REGUL | ATORY INFORMATIC | ON | | | | | |
| Relate | d Regulations | | | | | | |
| | Fire Service Law Not applicable to dangerous materials / designated flammables. | | | | | | |
| Not ap | Chemical Substance Control Law Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance. | | | | | | |
| Indust | rial Safety and Healtl | n La | w | | | | |
| | ul Substances Prohil plicable | oited | I from Manufact | ure | | | |
| | Harmful Substances Required Permission for Manufacture Not applicable | | | | | | |



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|---|--|---|---|--|----------------|--|----------------|
| Substances Prevented From Impairment of Health Not applicable Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Inform on Existing Chemicals having Mutagenicity | | | | | | | |
| | | | | | | | Not applicable |
| | Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Inform on Notified Substances having Mutagenicity | | | | | | |
| Not a | pplicable | | | | | | |
| | tances Subject to be | e Notified Names | | | | | |
| | pplicable | | | | | | |
| | tances Subject to be pplicable | e Indicated Names | | | | | |
| | ance on Prevention | of Hazards Due to Sp | pecified Chemical Substances | | | | |
| | nance on Prevention | of Lead Poisoning | | | | | |
| | ance on Prevention | of Tetraalkyl Lead Po | bisoning | | | | |
| | | of Organic Solvent P | oisoning | | | | |
| Ordinance on Prevention of Organic Solvent Poisoning Not applicable Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dange Substances) | | | | | | | |
| | | | | | Not applicable | | |
| | phous and Deleterio | us Substances Contro | ol Law | | | | |
| Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the vironment and Promotion of Improvements to the Management Thereof | | | | | | | |
| Not a | pplicable | | | | | | |
| High | Pressure Gas Safet | y Act | | | | | |
| Not a | pplicable | | | | | | |
| • | osive Control Law | | | | | | |
| | el Safety Law egulated as a dangero | ous good | | | | | |
| Aviat | ion Law | - | | | | | |
| | | Disaster Prevention | etc I aw | | | | |
| | | | | | | | |
| | ransportation | | as noxious liquid substance | | | | |
| | transportation | | as marine pollutant | | | | |
| | otics and Psychotro otic or Psychotropic R | pics Control Act aw Material (Export / Ir | nport Permission) | | | | |
| | | | | | | | |



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| Specif | Not applicable Specific Narcotic or Psychotropic Raw Material (Export / Import permission) Not applicable | | | | | | |
| | e Disposal and Public rial waste | Cleansing Law | | | | | |
| The c | omponents of this pro | oduct are reported in | the following inventories: | | | | |
| AICS | | : not determined | | | | | |
| DSL | | : not determined | | | | | |
| IECSO | > | : not determined | | | | | |
| | | | | | | | |

16. OTHER INFORMATION

Further information

| Sources of key data used to | : | Internal technical data, data from raw material SDSs, OECD |
|-----------------------------|---|--|
| compile the Safety Data | | eChem Portal search results and European Chemicals Agen- |
| Sheet | | cy, http://echa.europa.eu/ |

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

| Date format | : | yyyy/mm/dd | | | | |
|------------------------------------|---|--|--|--|--|--|
| Full text of other abbreviations | | | | | | |
| ACGIH JP OEL JSOH | | USA. ACGIH Threshold Limit Values (TLV) Japan. The Japan Society for Occupational Health. Recom- mendation of Occupational Exposure Limits | | | | |
| ACGIH / TWA JP OEL JSOH / OEL-M | | 8-hour, time-weighted average Occupational Exposure Limit-Mean | | | | |

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New



| Version | Revision Date: | SDS Number: | Date of last issue: 2020/10/10 |
|---------|----------------|---------------|---------------------------------|
| 3.0 | 2021/04/09 | 5322037-00004 | Date of first issue: 2019/11/22 |

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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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