

SAFETY DATA SHEET (SDS)

Issued: April 22, 2013

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FileNo. 2012-1

1. Chemical Product & Company Identification

CHEMICAL PRODUCT NAME: DURANEX® 531AR ED3002
RECOMMENDED USE: Industrial products
RESTRICTED USE: Contact sales division about medical equipment products.
NAME OF COMPANY: Polyplastics Co., Ltd.
ADDRESS: 2-18-1 Konan, Minato-ku, Tokyo, 108-8280 Japan
SECTION IN CHARGE: Quality Assurance Dept.
TELEPHONE NUMBER: +81-3-6711-8605
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2. Hazards identification

[GHS CLASSIFICATION]

Physical and Chemical Hazards : ·Flammable solids : Classification not possible
·Self-reactive substances and mixtures : Not applicable
·Pyrophoric solids : Not classified
·Self-heating substances and mixtures : Classification not possible
·Substances and mixtures, which in contact with water, emit flammable gases : Not classified
·Oxidizing solids : Not classified
·Corrosive to metal : Not classified

Health Hazards : ·Carcinogenicity : Suspected of causing cancer
·Specific target organ/systemic toxicity (Repeated exposure) : No hazard

Environmental Hazards : Classification not possible

[SYMBOL]

: None

[SIGNAL WORD]

: None

[HAZARD STATEMENT]

: None

[PRECAUTIONARY STATEMENTS]

Prevention : ·Wash hands thoroughly after handling.
·Wear protective gloves.

Response : -

Storage : Avoid direct sunlight and store in a well-ventilated place.

Disposal : ·Dispose of contents/container in accordance with local and national regulations.

[REMARKS]

: Category 2 carcinogen ingredient (Carbon black/CAS: 1333-86-4) is present in the mixture at a concentration between 0.1% and 1%.

3. Composition/information on ingredients

SUBSTANCE/MIXTURES : Mixtures
COMMON CHEMICAL NAME : Modified Polybutyleneterephthalate
SYNONYMS : Modified Polybutyleneterephthalate(PBT)
INGREDIENTS AND COMPOSITION : Modified PBT $\geq 51.5\%$, Glass fiber 30%, Silica $< 1\%$, Carbon black $\leq 0.5\%$, Other polymer, etc. $\leq 17\%$
CHEMICAL FORMULA : Not open
CAS No. : Not open
INGREDIENTS CONTRIBUTING TO THE HAZARD : Cadmium, lead, hexavalent chromium and mercury are not used in this grade.

The specific chemical identities and percentages of composition are withheld as trade secrets.

4. First-aid measures

INHALATION : When a gas generated from the molten polymer has been inhaled,

		move to area of fresh air without delay and wait until the victim is recovered. If sick feeling continues, ask a physician for advice.
SKIN CONTACT	:	Cool the contacted skin with clean water without delay, if a contact with the polymer in a molten form. Do not force to remove the solid resin on the skin. If any burns are observed on the skin, ask a physician for advice.
EYE CONTACT	:	Cool and rinse the eye with clean water for at least 15 minutes when the eyes had contact with molten polymer. In case of wearing contact lenses, remove the lenses as soon as possible, and ask a physician for advice. When the eye had contact with the polymer in an ordinary solid form, rinse the eye with clean water without delay. If the discomfort persists, ask a physician for advice.
INGESTION	:	Help to vomit as much as possible. If sick feeling continues, ask a physician for advice.
MOST IMPORTANT SYMPTOMS	:	Suspected of causing cancer.
IMMEDIATE MEDICAL ATTENTION	:	If exposed or concerned: Get medical advice/attention.
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5. Fire-fighting measures		
EXTINGUISHING MEDIA	:	Water, foam fire-extinguishing agent, powder fire-extinguishing agent, and carbon dioxide gas.
SPECIFIC METHODS	:	Extinguish the fire with water. A method of extinguishing an ordinary fire may be applied. Do not apply water directly to processing machines.
SPECIFIC HAZARDS	:	Incomplete combustion leads to generation of toxic gases such as carbon monoxide or tetrahydrofuran, in addition to carbonic acid gas and water.
SPECIAL PROTECTIVE EQUIPMENT FOR FIREFIGHTERS	:	In case the fire gained force, use a gas mask or other protective equipment.
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6. Accidental release measures		
PERSONAL PRECAUTIONS	:	When pellets were spilled on the road or floor, wipe them off with a besom or cleaner not to cause slipping.
METHODS FOR CLEANING UP	:	Handle the spillage in accordance with provisions given in the "Resin pellet spillage preventive manual", in order to prevent intakes by marine animals and birds.
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7. Handling and storage		
HANDLING	:	Polybutyleneterephthalate resin in a pellet form will neither ignite nor explode at room temperatures. Keep it away from the igniting sources, as it quickly gains force once it is ignited.
HANDLING 2	:	This pellets spilled on the floor are likely to cause slipping. Remove such spillage at any times.
HANDLING 3	:	For molding work, effective means for local exhaust are required to discharge gases generated by melt processing.
HANDLING 4	:	Avoid inhaling of gases generated in molding work. Do not directly touch resin of high temperature.
HANDLING 5	:	Avoid retaining hot resin in the processing machines for many hours.
HANDLING 6	:	Glass fibers are not generally exposed in a single substance under normal processing and handling conditions as they are compounded in pellets. However, the following measures will be necessary to minimize the exposure to glass fibers or dusts containing glass fibers, when pellets or molded parts containing glass fibers are cut, ground or burnt, depending on environmental and operational conditions. ·Those who are sensitive in skin to glass fiber should wear suitable(protective) clothes to minimize the exposure of their

skin.

·Wash working clothes apart from other laundry, so that the latter will not cause contamination with glass fibers.

·Provide the workshop with partitions to prevent diffusion of glass fiber dusts.

·Pay precautions not to rub face, neck, arms or hands. Wash them with water and gargle after working.

·Keep dust sources totally enclosed.

·Provide local air exhausters and implement periodical inspections and adjustments at least once a year.

·Reduce cutting and grinding processes to the possible minimum, and devise working procedures to minimize dust generation.

·Provide dust-preventive masks, protective glasses and gloves for personal hygiene.

·Determine the operational environment at indoor working places and confirm the effects of environmental improvement.

Note) Glass fibers are, like road dusts, told to be least hazardous to human bodies, but proper measures are required to avoid useless inhaling.

STORAGE : Keep the substance away from any fire or heat sources for the sake of safe storage.

STORAGE 2 : This polymer is an inflammable synthetic resin and should be handled in accordance with municipal rules and regulations (concerning fire-fighting equipment, indoor storage, for instance).

RECOMMENDED PACKAGING MATERIALS : No information.

8. Exposure controls/ personal protection

CONTROL CONCENTRATION : None at present

PERMISSIBLE CONCENTRATION : OSHA PEL

Max. permissible concentration of inactive powder 15mg/m³

- ditto - (Aspiration) 5 mg/m³

ACGIH TLV

Exposure limit of the powder TWA 10 mg/m³

ENGINEERING MEASURE : ·When handling dust: Use totally enclosed containers resisting dust explosion.

·When heat melted in molding: Effective local ventilation must be provided.

PERSONAL PROTECTIVE EQUIPMENT

RESPIRATORY PROTECTION : Wear a dust-proof mask.

HAND PROTECTION : Wear heat-resisting gloves against burns, when handling molten polymer.

EYE PROTECTION : Wear protective glasses or goggles.

SKIN & BODY PROTECTION : Wear long sleeve clothes against burns, when handling molten polymer.

9. Physical and chemical properties

APPEARANCE etc. : Pellet

ODOR : No data available

ODOR THRESHOLD : No data available

PH : No data available

MELTING POINT : 221°C

BOILING POINT : Not applicable

FLASH POINT : 300°C or higher

EVAPORATION RATE : No data available

FLAMMABILITY : Flammable

EXPLOSIVE LIMITS	: Upper explosion limit : Not applicable. Lower explosion limit : 35g/m3
VAPOR PRESSURE	: Not applicable
VAPOR DENSITY	: No data available
RELATIVE DENSITY	: 1.50
SOLUBILITY	: Insoluble in water
PARTITION COEFFICIENT (n-octanol/water)	: No data available
AUTO-IGNITION TEMPERATURE	: 300°C or higher
DECOMPOSITION TEMPERATURE	: No data available
VISCOSITY	: No data available

10. Stability and reactivity

STABILITY AND REACTIVITY	: Stable for normal storage or handling.
POSSIBILITY OF HAZARDOUS REACTIONS	: No data available
CONDITIONS TO AVOID	: Keep the substance away from any fire or heat sources for the sake of safe storage.
INCOMPATIBLE MATERIALS	: No data available
HAZARDOUS DECOMPOSITION PRODUCTS	: Incomplete combustion leads to generation of toxic gases such as carbon monoxide or tetrahydrofuran, in addition to carbonic acid gas and water

11. Toxicological information

SKIN CORROSION/IRRITATION	: No finding.
SERIOUS EYE DAMAGE/IRRITATION	: Gas generated in drying or melting is irritating eyes and skins.
RESPIRATORY OR SKIN SENSITISATION	: No finding
ACUTE TOXICITY(INCLUDING LD50)	: No finding.
SUBACUTE TOXICITY	: No finding.
CHRONIC TOXICITY	: The product contains the substance that causes damage to lung and respiratory through prolonged or repeated exposure.(CB)
CARCINOGENICITY	: This product contains the substance of carcinogenic category 2 in the GHS classification.(CB)
MUTAGENICITY(Micro organisms, chromosomal aberration)	: No finding.
REPRODUCTIVE TOXICITY	: No finding.
TERATOGENICITY	: No finding.
OTHERS(Including generation of hazardous gases by reaction with water, for example)	: No finding in this report means that there will be no hazard in general, but no proving data available at the time of reporting.
OTHER CAUTIONS	: With regard to dust, the maximum permissible concentration and limits are fixed by OSHA and ACGIH.
OTHER CAUTIONS 2	: Information on hazards of glass fibers as filler.

<Effects on Human Bodies>

(1) Effects on skin

Stimulation to the skin with glass fibers may be caused when glass fibers diameter is larger than 4.5~5 μm. They give mechanical stimulation followed by itchiness to the skin, but further continuous exposure reportedly results in extinction of stimulation. It may sometimes leads to irritable dermatitis complicated with urticaria or eczema-like reaction. It is, however reported that such dermatitis is not so serious in general and does not last too long. Therefore, skin stimulation can be prevented by proper use of glass fibers.

(2) Effects on Tumor

Investigations made on glass fibers till today reveal that there is neither increase in mortality of glass fiber production workers due to lung cancer or mesothelioma nor such cases reported.

<Animal Test Report>

It is suggested that carcinogenicity of mineral fibers is dependent on their shapes rather than on their constituents. According to a report on experiments using 17 kinds of artificial mineral fibers in various sizes prepared by Dr. Stanton of National Cancer Institute, in USA, statistical studies on correlations between the diameter and length of fibers and the coincidence of mesothelioma have revealed that mineral fibers having a diameter smaller than $0.25 \mu\text{m}$ and a length larger than $8 \mu\text{m}$ are closely related to the coincidence of cancers. Since these experiments were performed by artificially dosing the subject animals with a large quantity of glass fibers and consequently they are quite different from the actual exposures to human bodies, it is told to be problematic to make a conclusion that mineral fibers are hazardous to human health, basing on the results obtained from these experiments. Up to the present time, there is no result obtainable to demonstrate a mechanism of glass fibers causing lung cancers in spite of experiment by long exposure to glass fibers with high concentration.

OTHER CAUTIONS 3

: Toxicological information of Carbon black which is an ingredient is shown below. Toxicity of the ingredient does not appear as product for pellet. When dust is generated by cutting and sanding, toxicity appears. Avoid breathing dust and avoid generating dust.

[Carbon black]

Acute toxicity

Oral: Rat LD50 15,400mg/kg GHS Not classified

Dermal: No information

Inhalation: No information

Skin Corrosion/Irritation: No information

Eye Damage/Irritation: No information

Sensitization-Skin: No information

Germ Cell Mutagenicity: No information

Carcinogenicity: IARC 2B; Possible carcinogenic to humans.

Toxicity to Reproduction: No information

Specific Target Organ Toxicity(Single Exposure)

No information

Specific Target Organ Toxicity(Repeated Exposure)

Category 1 based on the influence on lungs (the hyperplasia of the epithelium, pulmonary fiber symptom) in pneumoconiosis of human and a rat inhalational examination in the range of guidance level

Category 1

Aspiration Hazard: No information

REMARKS

: Hazards information and so on result from the national classification of carbon black.

12. Ecological information

BIODEGRADABILITY : No finding.

BIOACCUMULATION : No finding.

FISH TOXICITY : No finding.

HAZARDS TO OZONE LAYER	: None
13. Disposal considerations	
WASTE FROM RESIDUES	: This is designated as waste plastics among industrial wastes by the Wastes Disposal Law. Disposal waste pellets through licensed wastes handlers or local autonomous bodies if they are handling wastes disposal.
WASTE FROM RESIDUES 2	: When disposed by incineration, use the well controlled incinerators in accordance with the Wastes Disposal Law, Air Pollution Control Law and Water Pollution Prevention Law.
14. Transport information	
UN CLASSIFICATION NUMBER	: Not restricted for ICAO/IATA.
OTHER CAUTIONS	: Handle with care so as not to give damages to containers or not to be subjected to wetting.
OTHER CAUTIONS 2	: Secure the containers firmly so as not to cause collapsing.
15. Regulatory information	
TSCA INVENTORY	: All ingredients are listed on the TSCA inventory.
CA PROPOSITION 65	: None are listed.* *This product contains carbon black bound within the PBT. The CA PROPOSITION 65 listing only applies to carbon black in unbound, airborne particles of respirable size, which is not relevant for this product.
16. Other information	
HANDLING OF THE DETAILS GIVEN ABOVE	: Details given above are based on references, information and data available at this moment, but no warranty can be made on exactness of these details. They are also prepared on the assumption that the product will be handled in a normal way. For special handling, adequate safety and environmental measures should be taken in respect to its applications. Our products are not specifically intended for implants for medical and dental applications, and therefore they are not recommended for such applications. "No finding" in this report means that there will be no hazard in general, but no proving data is available at the time of reporting.
WHERE TO CALL FOR FURTHER INFORMATION	: Polyplastics Co., Ltd. Quality Assurance Dept. Tel. No +81-3-6711-8605
DATE OF PREPARATION	: May 17, 2019

*DURANEX® is a registered trademark of Polyplastics Co., Ltd. in Japan and other countries.