SAFETY DATA SHEET

SDS Identifier: Clobetasol Propionate Cream USP, 0.05% (Emollient)

SECTION 1 - IDENTIFICATION	
Product Name	Clobetasol Propionate Cream USP, 0.05% (Emollient)
Company Identification	**Teligent Pharma, Inc.**
	105 Lincoln Avenue
	Buena, New Jersey 08310
	Emergency: Call Poison Control Center: 1 – 800 – 222 – 1222
	SDS prepared August 2017
SECTION 2 – HAZARD(S) IDENTIFICATION	
Emergency overview: This mixture is a product regulated by the FDA. Within the meaning of the OSHA Hazard Communications Standard [29 CFR 1910.1200]: this product is not considered a hazard material when used in a manner which is consistent with the labeled directions.	
Eyes	Will cause irritation to the eyes
Skin	May cause skin irritation or redness
Inhalation	Unlikely due to viscosity of the product.
Ingestion	May be harmful
SECTION 3 – COMPOSITION AND INGREDIENTS	
Active Ingredient	Clobetasol Propionate 0.05%, CAS # 25122-46-7, LD50: 3000 mg/kg
Other Ingredients	Cetomacrogol 1000, Cetostearyl Alcohol, Citric Acid, Dimethicone 350, Imidurea, Isopropyl Myristate, Polyoxyl-20-cetostearyl Ether, Propylene Glycol, Purified Water and Sodium Citrate.
The product does not contain ingredients considered hazardous as defined by OSHA, 29 CFR 1910.1200 and/or WHMIS under the HPA.	
SECTION 4 – FIRST AID MEASURES	
After Eye Contact	Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
After Skin Contact	Remove contaminated clothing immediately. For accidental and non-therapeutic exposures, immediately flush skin with large amounts of water. If irritation (redness, rash, blistering) develops, get medical attention. If skin irritation occurs get medical advice/ attention.
After Inhalation	Remove from source of exposure. Move individual(s) to fresh air. No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention or call Poison Control Center immediately.
After Ingestion	Wash out mouth with water if conscious. Do not induce vomiting unless directed to do so by medical personnel. If large quantities of material are swallowed, obtain medical attention.
SECTION 5 – FIRE FIGHTING MEASURES	
Fire Fighting Instructions	Wear approved breathing apparatus and full protective turn out gear. Wear full protective clothing and use positive pressure self-contained breathing apparatus (SCBA).
Explosion Hazards	No data available.
Extinguishing Media	Use water fog or spray, carbon dioxide, dry chemical or alcohol-resistant foam.
Flash Point	No data available.

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SECTION 6 – ACCIDENTAL RELEASE MEASURES	
Personal Safeguards	Wear appropriate protective clothing and equipment as described in Section 8.
Environmental Precautions	Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil
Spill Clean-up Procedures	Stop spill at the source if it is safe to do so. Use double gloves for spill response. Absorb with an inert material. Collect into a suitable container for disposal. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Dispose of in accordance with Section 13. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.
SECTION 7 – HANDLING AND STORAGE	
Handling procedures	All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. Appropriate personal protective equipment must be worn (see Section 8, Engineering Controls and Personal Protection). Avoid generation of aerosols. Use only with adequate ventilation. Wash thoroughly after handling. Keep containers closed when not in use.
Storage	Store at room temperature 15-30ºC (59-86ºF), to maintain product integrity. Protect containers from physical damage. Keep containers tightly closed when not in use. This product should not be refrigerated.
Other Precautions	Avoid direct sunlight. Read label and package insert carefully.
SECTION 8 – EXPOSURE CONTROLS, PERSONAL PROTECTION	
Personal Protection Equipment:	
Ventilation	Use with adequate general or local exhaust ventilation to minimize exposures levels.
Eye Protection	Chemical safety goggles recommended if contact with the drug product is possible.
Skin Protection	Impervious gloves recommended if contact with the drug product is possible
Hand Protection	Not normally needed during normal use. Wear protective gloves when handling bulk product. Chemically compatible gloves are recommended. Use handling practices that minimize direct hand contact.
Respiratory Protection	None needed under normal use conditions
SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES	
Description	White to off-white cream
Specific Gravity	Approximately 0.9 (water = 1)
pH	4.5 – 7.0
Boiling Point:	No data available
Freezing Point	No data available
Vapor Density	No data available
Vapor Pressure	No data available

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Evaporation Rate	Not available
Solubility in Water	Dispersible
SECTION 10 – STABILITY AND REACTIVITY	
Stable	Not reactive under normal conditions of use.
Hazardous Polymerization	Stable under normal temperature and pressure.
Conditions to Avoid	No data available
Incompatibility	Acids, strong oxidizers, water reactive materials, and other chemicals that could affect its performance should be avoided.
Hazardous Decomposition	If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon and nitrogen oxides, formaldehyde, ethylene glycol, formic acid, glyoxal, dioxalane, hydrogen chloride and hydrogen fluoride).
SECTION 11 – TOXICOLOGICAL INFORMATION	
Individuals who have had allergic reactions to products containing any component of this product may experience allergic reactions to this product. This product may be mildly to moderately irritating. Hazardous Scale [**0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe]	

Health (blue)	2
Fire Hazard (Red)	1
Reactivity (Yellow)	0
Personal Protection	See section 8

Acute and Chronic Toxicity	
Genotoxicity study	No data available
General Toxicity	No data available
Skin Sensitivity	***Chronic:*** Repeated skin contact may cause dermatitis (dry, red skin).
Eye Sensitivity	Eye contact will cause irritation.
Sensitization	No data available
Carcinogenicity	The following information is available for the active ingredient. Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids or the active ingredient, Clobetasol Propionate. The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.
Mutagenicity/ Embryo / Reproductive Toxicity / Teratogenicity	There are no adequate and well-controlled studies of this product in pregnant women; however, this product may cause fetal harm when administered to a pregnant woman. In the workplace, the risk to the fetus should be communicated and the appropriate action should be taken to prevent exposure in accordance with company policy and regulatory requirements. This product is rated by the FDA for therapeutic risk as Pregnancy Risk Category C (Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks). ***Mutagenicity:*** Clobetasol Propionate was negative in the in vitro mammalian chromosomal aberration test and in the in vivo mammalian erythrocyte micronucleus test. **Embryotoxicity/Teratogenicity:**

	Human Data: As a group, corticosteroids have not been associated with congenital malformations in humans. *Animal Data*: Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application to laboratory animals. Clobetasol Propionate is absorbed percutaneously, and when administered subcutaneously it was a significant teratogen in both the rabbit and the mouse. Clobetasol propionate has greater teratogenic potential than steroids that are less potent. The effect of Clobetasol Propionate on pregnancy outcome and development of offspring was studied in the rat. Clobetasol propionate was administered subcutaneously to female rats twice daily (0, 12.5, 25, and 50 µg/kg/day) from day 7 of presumed gestation through day 25 of lactation or day 24 presumed gestation for those rats that did not deliver a litter. The maternal NOEL for Clobetasol Propionate was less than 12.5 µg/kg/day due to reduced body weight gain and feed consumption during the gestation period. The reproductive NOEL in the dams was 25 µg/kg/day (ratio of animal dose to proposed human dose of 0.07 on a mg/m2/day basis) based on prolonged delivery at a higher dose level. The no-observed-adverse-effect-level (NOAEL) for viability and growth in the offspring was 12.5 µg/kg/day (ratio of animal dose to proposed human dose of 0.03 on a mg/m2/day basis) based on incidence of stillbirths, reductions in pup body weights on days 1 and 7 of lactation, increased pup mortality, increases in the incidence of umbilical hernia, and increases in the incidence of pups with cysts on the kidney at higher dose levels during the pre-weaning period. The weights of the epididymides and testes were significantly reduced at higher dosages. Despite these changes, there were no effects on the mating and fertility of the offspring. ***Reproductive Toxicity:*** The effect of subcutaneously administered Clobetasol Propionate on fertility and general reproductive toxicity was studied in rats at doses of 0, 12.5, 25, and 50 µg/kg/day. Males were treated beginning 70 days before mating and females beginning 15 days before mating through day 7 of gestation. A dosage level of less than 12.5 µg/kg/day Clobetasol Propionate was considered to be the no-observed-effect-level (NOEL) for paternal and maternal general toxicity based on decreased weight gain and for male reproductive toxicity based on increased weights of the seminal vesicles with fluid. The female reproductive NOEL was 12.5 µg/kg/day (ratio of animal dose to proposed human dose of 0.03 on a mg/m2/day basis) based on reduction in the numbers of estrous cycles during the pre-cohabitation period and an increase in the number of nonviable embryos at higher doses. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. ***Non-Teratogenic Effects:*** Hypoadrenalism may occur in infants born of mothers receiving corticosteroids during pregnancy.

SECTION 12 – ECOLOGICAL INFORMATION

The environmental characteristics of this product have not been fully evaluated. Releases to the environment in pure form should be avoided.

MOBILITY: This product has not been tested for soil absorption or mobility. The following information is available for the components of this product:

CETOSTEARYL ALCOHOL**:** The Koc is estimated as 25,000, using a water solubility of 4.122X10-2 and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests that this material is expected to be immobile in soil.

PROPYLENE GLYCOL**:** The Koc is estimated as 8, using a log Kow of -0.92 and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests that this compound is expected to have very high mobility in soil.

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PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. The following information is available for the components of this product:

CETOSTEARYL ALCOHOL**:** If released to air, a vapor pressure of 6X10-6 mm Hg at 25°C indicates this material will exist in both the vapor and particulate phases in the atmosphere. Vapor-phase material will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 16 hours. Particulate-phase material will be removed from the atmosphere by wet or dry deposition. If released to soil, this compound is expected to have no mobility based upon an estimated Koc of 25,000. Volatilization from moist soil surfaces is expected to be an important fate process based upon an estimated Henry's Law constant of 4.6X10-2 atm-cu m/mole. However, adsorption to soil is expected to attenuate volatilization. Various biological screening studies have demonstrated that this compound biodegrades both aerobically and anaerobically. If released into water, this material is expected to adsorb to suspended solids and sediment based upon the estimated Koc. Volatilization from water surfaces is expected to be an important fate process based upon this compound's estimated Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 23 hours and 12 days, respectively. However, volatilization from water surfaces is expected to be attenuated by adsorption to suspended solids and sediment in the water column. The estimated volatilization half-life from a model pond is 1.8 years if adsorption is considered. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions.

PROPYLENE GLYCOL**:** Based on a classification scheme, an estimated Koc value of 8, determined from a log Kow of -0.92 and a regression-derived equation, indicates that this material is expected to have very high mobility in soil. Volatilization of this compound from moist soil surfaces is not expected to be an important fate process given an estimated Henry's Law constant of 1.3X10-8 atm-cu m/mole, derived from its vapor pressure, 0.13 mmHg, and water solubility, 1X10+6 mg/liter. This compound is not expected to volatilize from dry soil surfaces based upon its vapor pressure. Laboratory experiments using agricultural soils from South Carolina conducted at 22°C and a fortification of 1,000 ppm this compound, yielded 73-78% mineralization during a 51 day incubation period, suggesting that biodegradation will be an important fate process in soils. Based on a classification scheme, an estimated Koc value of 8, determined from a log Kow of -0.92 and a regression-derived equation, indicates that this compound is not expected to adsorb to suspended solids and sediment. Volatilization from water surfaces is not expected based upon an estimated Henry's Law constant of 1.3X10-8 atm-cu m/mole, derived from its vapor pressure, 0.13 mmHg, and water solubility, 1X10+6 mg/L. Numerous screening studies using wastewater or sewage inoculum as seed, suggests that this material will be degraded readily under aqueous environments. According to a model of gas/particle partitioning of semi-volatile organic compounds in the atmosphere, Propylene Glycol, which has a vapor pressure of 0.13 mmHg at 25°C, is expected to exist solely as a vapor in the ambient atmosphere. Vapor-phase material is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 32 hours, calculated from its rate constant of 1.2X10-11 cu cm/molecule-sec at 25°C.

BIOACCUMULATION: This product has not been tested for bioconcentration. The following information is available for the components of this product:

CETOSTEARYL ALCOHOL**:** In a 3-day static exposure study using golden orfe fish (Leuciscus idus melanotus), a bioconcentration factor (BCF) of 56 was observed. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is moderate, provided the compound is not metabolized by the organism. A 24-hr BCF of 17000 was observed in algae (*Chlorella fusca*).

PROPYLENE GLYCOL**:** An estimated BCF of 3 was calculated, using a log Kow of -0.92 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is low.

ECOTOXICITY: No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated terrestrial and aquatic plant and animal life, especially in large quantities. The following are aquatic toxicity data currently available for some components of this product.

CLOBETASOL PROPIONATE:

EC50 (*Oncorhynchus mykiss* rainbow trout) 96 hours = > 0.75 mg/L
EC50 (*Daphnia magna* Water flea) 48 hours = > 1.4 mg/L
IC50 (Selenastrum algae) 72 hours = > 4.2 mg/L
IC50 (Other Microorganisms) 3 hours = > 100 mg/L
NOEC (*Selenastrum* algae) 72 hours =1.3 mg/L
NOEC (*Daphnia magna* Water flea) 48 hours = 1.4 mg/L

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CETOSTEARYL ALCOHOL:
EC50 (*Scenedesmus subspicatus* Algae) 72 hours = 676 mg/L; Effect: cell multiplication inhibition test
PROPYLENE GLYCOL:
EC50 (*Photobacterium phosphoreum*, bacteria) 30 minutes = 26,800 mg/L
EC50 (*Daphnia magna*, crustacean) 48 hours = 34,400 mg/L
EC50 (*Daphnia magna*, crustacean) 24 hours = > 10,000 mg/L
EC50 (*Nitocra spinipes*, crustacean) 96 hours = > 10,000 mg/L
LC50 (*Carassius auratus*) 24 hours = > 5,000 mg/L
LC50 (*Lebistes reticulatus*, guppy) 48 hours > 10,000 mg/L
LC50 (*Salmo gairdneri*) 24 hours = 50,000 mg/L
LC50 (*Pimephales promelas*) 96 hr = 54,900 mg/L
LC50 (Artemia salina) 24 hours = >10,000 mg/L
LC100 (*Pimephales promelas*) 96 hr = 65,610 mg/L

SECTION 13 – DISPOSAL INFORMATION

Product Disposal	Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator. Permeable cardboard containers are not appropriate and should not be used.
Packaging	Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

SECTION 14 – TRANSPORTATION INFORMATION

Not regulated for transport under USDOT (transportation by land), IATA (transportation by sea) or IMDG (transportation by air) regulations.

SECTION 15 – REGULATORY INFORMATION

The product described in this SDS are regulated under the Federal Food, Drug and Cosmetics Act and are safe to use as per directions on container, box or accompanying literature (where applicable). This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

SECTION 16 – OTHER INFORMATION

The information contained in this Safety Data Sheet has been compiled from information believed to be accurate and from experience. While we believe that the data presented is factual, Teligent Pharma Inc. and its affiliates make no warranty or representation, nor assumes any responsibility in conjunction with the use of this information.