Appendix XIV

ENVIRONMENTAL ASSESSMENT

1. **Date:** December 23, 1994

2. **Name of Petitioner:** Degussa Corporation

3. **Address:** All communications on this matter are to be sent in care of Counsel for Petitioner, Jerome H. Heckman, Keller and Heckman, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4110.

4. Description of the Proposed Action

The action requested in this Petition is affirmation of the Generally Recognized as Safe (GRAS) status of hydrophobic silicas prepared by the methylation of the surface of particles of fumed or precipitated amorphous silica. More specifically, this Petition deals with the use of hydrophobic silicas as anticaking or free-flow agents in vitamin preparations for animal feed.

As discussed more fully in the main body of the Petition, the typical process by which fumed or precipitated amorphous silica is converted to hydrophobic silica is by the reaction of amorphous or precipitated silicon dioxide with dichlorodimethylsilane. Methylation of the surface silanol (Si-OH) groups renders the particle surface of silicon dioxide hydrophobic and, therefore, promotes miscibility of the parti-

cle, but does not necessarily make it soluble with hydrophobic substances such as the fat soluble vitamins. This increased hydrophobicity of the particle surface allows hydrophobic silicas to act as anticaking and free-flow agents for hydrophobic substrates.

The methylation reaction occurs only at the surface of the silicon dioxide particle leaving 97-99% of the silicon dioxide intact and unmodified. Thus, the hydrophobic silica particle may be viewed as being primarily composed of silicon dioxide but with a surface comprised of a methylated polysilicone. Both of these substances have been widely used for years in the food, pharmaceutical, and dental industries. They have been separately tested and reviewed for safety by several authoritative bodies.[1/] A body of literature supports their safety-in-use; most of the publicly available safety studies were published in the 1950's and 1960's.

Both types of hydrophobic silica, fumed hydrophobic silica (FHS) and precipitated hydrophobic silica (PHS), are registered under the Chemical Abstract Service (CAS) name "Silane, dichlorodimethyl-, reaction products with silica" and

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1/ The authoritative bodies referred to frequently herein are: (1) The Select Committee on GRAS Substances (The Select Committee, or SCOGS), (2) The FAO/WHO Joint Expert Committee on Food Additives (JECFA), and (3) The Scientific Committee for Food (SCF) of the Commission of the European Communities.

are assigned the single CAS Registry Number 68611-44-9. Trade names for FHS are Aerosil® R 972, Aerosil® R 974, and Aerosil® R 976. Sipernat® D 17 is currently the only commercial form of PHS for this use.

The Petitioner intends to produce the hydrophobic silicas at its manufacturing facilities located in Wesseling, Germany (precipitated hydrophobic silica) and in Rheinfelden, Germany (fumed hydrophobic silica). The finished product will be utilized by various companies in the production of vitamin preparations that are added to animal feed.

Unmodified silica has been safely used as a component of vitamin preparations for animal feed for many years. Thus, the use of hydrophobic treated silica in some formulations may be viewed as being in place of conventional untreated silica. In either event, whether silica in unmodified or hydrophobic form is used, the ingredient is expected to pass through the animal following ingestion and to be excreted unchanged. Due to the inertness of these materials, they are expected to remain unchanged in the environment and not to undergo chemical change or degradation. The use of hydrophobic silica in place of silica is not expected to have any effect on the fate and effects of the substance in the environment due to the similarities between the two materials. Consequently, no significant

adverse impact on the environment is anticipated as a result of the use of hydrophobic silica as proposed.

5. Identification of Chemical Substances that are the Subject of the Proposed Action

This Petition proposes affirmation of the GRAS status of hydrophobic silica. The product is also known by the trade names Aerosil® R 972, a fumed hydrophobic silica, and Sipernat® D 17, a precipitated hydrophobic silica. The Chemical Abstract Service (CAS) Registry No. is 68611-44-9, and the corresponding CAS nomenclature is silane, dichlorodimethyl-, reaction products with silica. The substance is also known as synthetic amorphous hydrophobic silica.

The empirical formula for hydrophobic silica is $(SiO_2)_n(CH_3)_x$, with the subscript x varying depending upon the extent of methylation at the surface of the silica particle. Generally, the degree of methylation is less than 1.5% for fumed hydrophobic silicas and less than 3% for precipitated hydrophobic silicas. The products are described more thoroughly in the Degussa Bulletins provided in Appendix I.

The hydrophobic silicas, in their finished form, have the following composition:

Assay: Fumed Hydrophobic Silica: Not less than 99.0% SiO_2 after ignition; Precipitated Hydrophobic Silica: Not less than 98.0% SiO_2 after ignition.

Arsenic (as As): Not more than 3 ppm.

Heavy Metals (as Pb): Not more than 0.003% (30 ppm).

Loss on Drying: Fumed Hydrophobic Silica: Not more than 2.5%; Precipitated Hydrophobic Silica: Not more than 6%.

Soluble Ionizable Salts (as Na_2SO_4): Precipitated Hydrophobic Silica: Not more than 2%.

Insoluble Substances: Not more than 1%.

Dichlorodimethylsilane: Not more than 50 ppm.

6. Introduction of Substances into the Environment

This Petition requests affirmation of the GRAS status of hydrophobic silicas prepared from fumed or precipitated silicon dioxide. The hydrophobic silica will be employed as an anticaking agent in vitamin A formulations added to animal feed.

(a) Substances Expected to be Emitted and Controls.

As shown in the accompanying block diagram (see Item 15, Appendices), beginning at the upper left, the reactants, dichlorodimethylsilane and silicon dioxide, are stored as aqueous slurries in separarate storage bins prior to mixing. The two reactants are blended and, after completion of the reaction, the material is stored as a slurry prior to subsequent workup. The slurry is filtered and washed with water. Typically, 14.3 m^3 of tap water are used per batch.

The filtrate is neutralized with sodium hydroxide (NaOH) to neutralize the HCl. This operation neutralizes the hydrochloric acid (HCl) produced in the silanation reaction. The resulting neutral waste water is combined with waste water from other silica plant operations. The combined waste water is then treated with flocculants to precipitate solids (silicon

dioxide particles). The solids are removed by sedimentation and reused in the manufacture of non-food grade silicon dioxide products.

The final waste water volume amounts to approximately 15.4 m^3 per batch of hydrophobic silica. In accordance with applicable requirements for effluent leaving the plant, the final temperature of the waste water is less than 30°C, has a pH of between 5 and 9, has a content of suspended solids of less than 50 mg/L, and a chemical oxygen demand of less than 20 mg/L. This water is released directly into the Rhine river in compliance with local laws and regulations.

The hydrophobic silica resulting from the filtration step (the filter cake) is moved to a storage hopper and subsequently dried in a drier by direct heating with natural gas. The only emission into the environment from this process is water vapor and the drying air. The air flow through the drier is filtered to remove dust. The dust limitation on air leaving the drying process is less than 50 mg/m^3 as defined by local regulation. The rate of air flow through the drying system is approximately 4,000 m^3 per hour. The dried hydrophobic silica is either stored for future bagging or bagged immediately. Apart from the aqueous and air emissions discussed above, there

are no other releases to the environment at the site of manufacture of the subject hydrophobic silica.

Animals receiving vitamin preparations as part of their feed will ingest hydrophobic silica at a concentration of no greater than 5 ppm in the feed. Data available indicate that, as is the case with unmodified silicon dioxide, hydrophobic silica will not be absorbed by the animal through its gastrointestinal system, but rather will be excreted directly as a component of the feces. Thus, hydrophobic silica used in this manner will ultimately be returned to the soil. Like silicon dioxide, it is extremely stable and is expected to degrade only slowly. Further, hydrophobic silicas are used commercially in the United States for various purposes at an approximate annual rate of approximately 5 million tons. Therefore, the very small amount of hydrophobic silica that enters the environment through the petitioned use (6 million pounds; < 0.1% of the total) will obviously have no significant environmental impact relative to the total amount of hydrophobic silica used commercially.

(b) Statement of Compliance.

The Petitioner has provided letters certifying that its hydrophobic silica production facilities located in Wesseling

and Rheinfelden, Germany are operated in compliance with all applicable federal, state, and local environmental and occupational laws and regulations. These letters are attached hereto under Item 15, Appendices. The applicable laws include the following:

- German Emission Protection Law and Regulations.
- German Water Control Law and Regulations.
- Waste Treatment Law and Regulations.
- Provisions for Trade and Industry.

Because adequate emission control and waste treatment facilities are already in place at the hydrophobic manufacturing sites, and in light of the minimal quantities of waste materials generated, approval of the action requested in this Petition will have no adverse impact on the Petitioner's compliance with the applicable requirements at the manufacturing site.

(c) Annual Volume of Hydrophobic Silica for Intended Use

The Petitioner estimates that the maximum yearly U.S. market volume for its hydrophobic silica for use in vitamin preparations for animal feed will be six (6) million pounds per year.

7. Fate of Emitted Substances in the Environment

(a) Air: The subject hydrophobic silica is a nonvolatile solid and, as such, only minor amounts may be emitted to the air as a dust where it is manufactured or incorporated into vitamin preparations for use in animal feed. Such small amounts of the material would likely be contained by the use of scrubbers or dust collectors and be appropriately disposed of as nonhazardous solid waste. Accidental spills or similar excursions would also be minor sources of release. As the product will be appropriately packaged for shipment, accidental spills from transportation accidents are unlikely to result in anything more than an extremely minor environmental discharge.

(b) Water: Similarly, no significant aqueous releases of hydrophobic silica are expected as a result of its use as described herein. The only foreseeable source of release to water would be as a result of intermittent equipment cleaning at sites where the material is manufactured and/or used to produce vitamin preparations for use in animal feed. Hydrophobic silica is insoluble in water and, consequently, would not be expected to remain or build up in the water once released. Rather, it would be expected to precipitate out into the soil; once present as a component of the soil, the extremely inert material would be expected to behave indistinguishably from unmodified silica.

(c) Terrestrial: The major route of introduction of hydrophobic silica to the environment is expected to be as a component of fecal matter excreted by animals that consume feed containing vitamin preparations made with the use of hydrophobic silica. Due to the low concentration at which hydrophobic silica will be present in the feed (i.e., at 5 ppm or less), it will similarly be present only at extremely low levels in the feces.

Once released to the environment by this means, hydrophobic silica is expected to remain essentially unchanged or, at most, to hydrolyze very slowly over time; this expectation is supported by the stability studies presented in Appendix XV of this Petition which demonstrate a high degree of stability upon exposure to boiling water. To the extent that some degradation does occur, the substance will be slowly converted back to its original state as unmodified silicon dioxide. Thus, whether there is some slow rate of degradation of hydrophobic silica to untreated silica, or whether the material remains entirely inert to such decomposition, its presence at extremely low levels in the environment (annual market volume = 6 million pounds or less) is expected to be indistinguishable in terms of fate and effects from the natural presence in the environment of vastly higher quantities of unmodified silica.

8. Environmental Effects of Released Substances

As discussed above, only extremely small quantities of hydrophobic silica are expected to be released to the environment, either as accidental releases or as a component at low concentrations ($\leq$ 5 ppm) of animal feces. Due to the insolubility and extremely inert nature of the substance, and considering that no more than six (6) million pounds of the material is expected to be released per year nationwide, it is highly unlikely that the anticipated level of release could have any significant adverse environmental effects.

As further indication of the safety of hydrophobic silica, we note that a very large volume of relevant toxicological data are summarized in Section (iv) of this Petition. These data include the results of acute, subchronic, and chronic consumption of the material by animals; an article summarizing the available data is included in Appendix VI. The available data indicate that hydrophobic silica and similar silicates are virtually nontoxic at current levels used in food, and that the lack of toxicity is related to their nonabsorbability. Moreover, the large effective molecular weights and large particle sizes of hydrophobic silicas suggest that their toxicological properties are not significantly different from those of other silica-based products. In other words, the available data indicate that the inherent safety of silicon

dioxide, which is ubiquitous in the environment, is not altered by the minor surface alteration involved in producing hydrophobic silica. Consequently, the use of hydrophobic silica as described herein, and its subsequent release to the environment at the levels indicated, is expected to have no adverse impact on organisms in the environment.

9. Use of Resources and Energy

As is the case with any other component of human or animal feed, the manufacture of the subject hydrophobic silica will require the consumption of resources and energy. The process involves only a minor surface modification to the basic silicon dioxide particle that would otherwise be utilized in animal feed preparation. The slight increase in the energy cost of preparing the hydrophobic-treated silica as opposed to the process for preparing the starting fumed or precipitated silica is offset by the considerable advantages of using the hydrophobic material rather than the unmodified silica in the preparation of vitamin formulas based on hydrophobic components. Thus, the use of hydrophobic silica as proposed is expected to have no adverse impact on the use of resources and energy from this perspective. In addition, no impact is expected upon endangered or threatened species or upon property listed in or eligible for listing in the National Register of Historic places.

10. Mitigation Measures

Measures taken by the Petitioner to treat and dispose of waste streams produced in the manufacture of hydrophobic silica and to minimize the release of waste substances to the environment are discussed in Item 6 above. Considering the lack of any anticipated adverse environmental effects from the use of hydrophobic silica as intended in the production of vitamin formulations for use in animal feed, the Petitioner respectfully submits that no additional mitigation measures are required.

11. Alternatives to the Proposed Action

No potential adverse environmental impacts have been identified for the proposed action. Consequently, alternatives to the proposed action are not presented here.

12. List of Preparers

a. John Lewinson, Ph.D.
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65 Challenger Road
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b. Robert A. Mathews, Ph.D., Staff Scientist,
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c. Holly H. Foley, B.S., Staff Scientist,
Keller and Heckman, 1001 G Street, N.W.,
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13. Certification

The undersigned certifies that the information presented is true, accurate, and complete to the best of his knowledge.

Date: December 22, 1994

Jerome H. Heckman

Counsel for Degussa Corporation

14. References

All data referenced in this Environmental Assessment are contained elsewhere in this Petition.

15. Appendices

A process flow diagram for the manufacture of hydrophobic silica is attached hereto. Also attached are letters from the Petitioner certifying compliance with the pertinent laws and regulations applicable to the manufacture of hydrophobic silica at the Petitioner's production facilities located in Wesseling and Rheinfelden, Germany.

Flow Chart Delineating the

Production of Hydrophobic Silica

Explanation of the Flow Chart

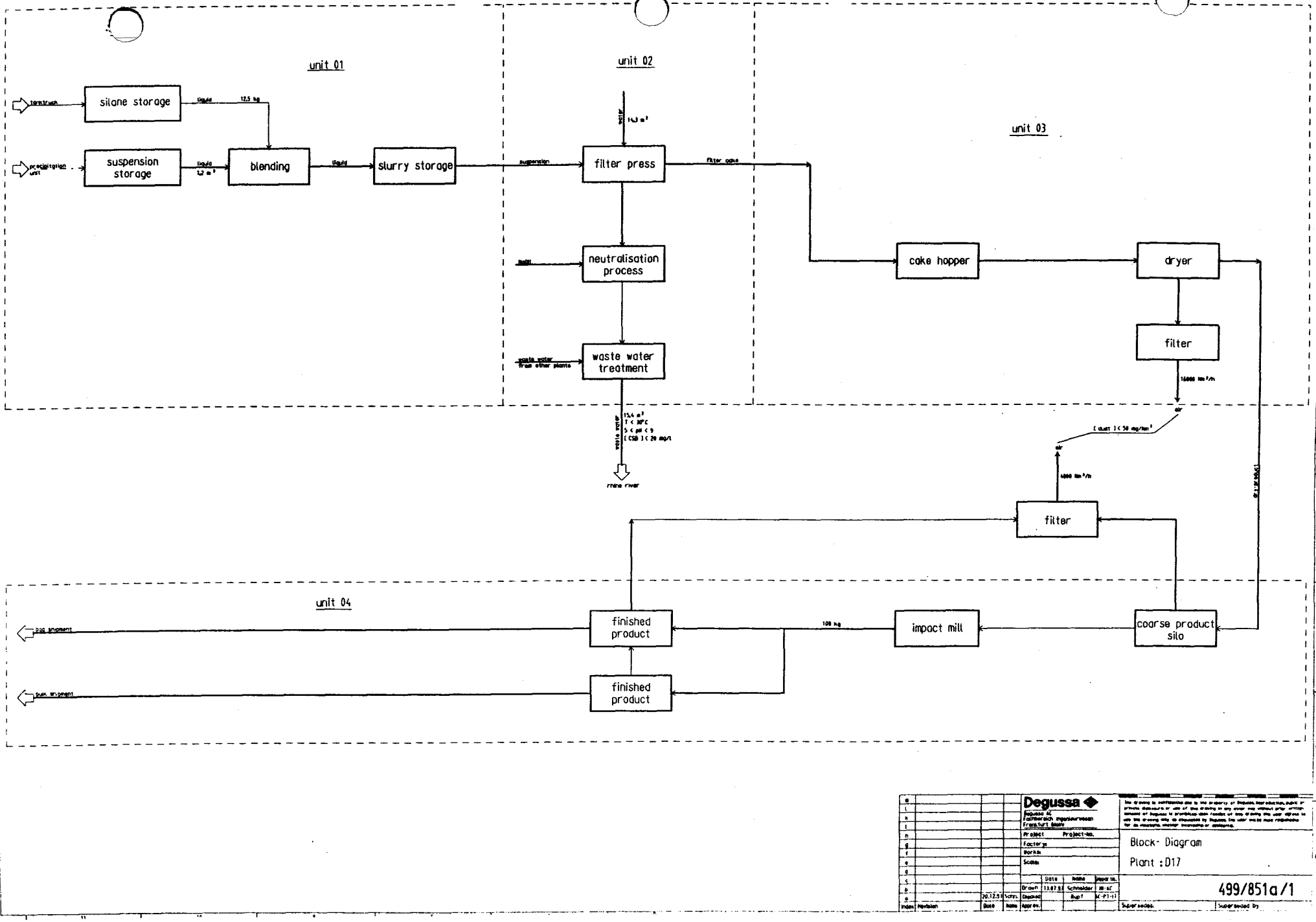
At the upper left of the chart the silane (12.5 kg) and silicon dioxide (1.2 m^3) reactants are prepared as slurries. They are then mixed and blended. The reacted mixture is then stored as a slurry prior to filtering.

The reacted slurry is filtered and the filter cake is washed with approximately 14.3 m^3 tap water per batch. The filter cake is stored in the cake hopper prior to drying.

The filtrate from the filter press is neutralized with sodium hydroxide and mixed with waste water from other silica operations. For each batch of hydrophobic silica produced approximately 15 m^3 neutral filtrate results. The neutralized filtrate has a temperature of 30°C, a pH of 5-9, a suspended solids content of less than 50 mg/L, and a chemical oxygen demand (COD; CBD in the chart) of less than 20 mg/L.

The hydrophobic silica, after storage in the cake hopper, is dried by direct heating with natural gas. The coarse product is stored in a silo. After crushing the dried hydrophobic silica in an impact mill, the product, approximately 100 kg (220 lbs.) per batch, is either bagged for shipment or shipped in bulk form.

Air used in the drying process (approximately 16,000 m^3/hr.) is filtered prior to release into the ambient air. In accordance with local laws and regulations, dust levels are less than 50 mg/m^3 in the released air.


unit 01
unit 02
unit 03
unit 04
silane storage
suspension storage
blending
slurry storage
filter press
neutralisation process
waste water treatment
cake hopper
dryer
filter
filter
finished product
finished product
impact mill
coarse product silo
Degussa
Block- Diagram
Plant : D17
499/851a/1

Degussa

Werk Rheinfelden
17.11.94

Werksleitung
Dr.B/bl

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Production of R 972

We herewith confirm to strictly adhere to governmental regulations presently in force for the production of R 972.

These regulations include:

- German emission protection law including regulations pertaining there to
- German water control law and ist regulations
- Waste treatment law and its regulations
- Provisions for Trade and Industry.

D e g u s s a AG
Rheinfelden Plant

Dr. Buder Dr. Fuchs

Degussa

Werk Rheinfelden
17.11.94

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Produktion von R 972

Hiermit bestätigen wir, daß bei der Herstellung von R 972 alle derzeit geltenden Rechtsvorschriften eingehalten werden.

Zu diesen Rechtsvorschriften gehören:

- Bundes-Immissionsschutzgesetz und seine Verordnungen
- Wasserhaushaltsgesetz und seine Verordnungen
- Abfallgesetz und seine Verordnungen
- Gewerbeordnung und ihre Verordnungen
- Richtlinien, Sicherheitsregeln und
- Unfallverhütungsvorschriften der gewerblichen Berufsgenossenschaften.

D e g u s s a AG
Werk Rheinfelden
i.V.

Dr. Buder Dr. Fuchs

Degussa

TRANSLATION

PRODUCTION OF SIPERNAT D 17

We herewith confirm to strictly adhere to governmental regulations presently in force for the production of Sipernat D 17.

These regulations include:

- German emission protection law including regulations pertaining there to
- German water control law and its regulations
- Waste treatment law and its regulations
- Provisions for Trade and Industry

Degussa

Produktion von Sipernat D 17

Hiermit bestätigen wir, daß bei der Herstellung von Sipernat D 17 alle derzeit geltenden Rechtsvorschriften eingehalten werden.

Zu diesen Rechtsvorschriften gehören:

- Bundes-Immissionsschutzgesetz und seine Verordnungen
- Wasserhaushaltsgesetz und seine Verordnungen
- Abfallgesetz und seine Verordnungen
- Gewerbeordnung und ihre Verordnungen
- Richtlinien, Sicherheitsregeln und
- Unfallverhütungsvorschriften der gewerblichen Berufsgenossenschaften

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- Werk Wesseling -

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Dr. Theissen

Dr. Rodenbach