RESEARCH TOXICOLOGY CENTRE - ROMA

NAFOL 2022

DELAYED DERMAL SENSITISATION STUDY IN THE GUINEA PIG (MAGNUSSON AND KLIGMAN TEST)

FINAL REPORT

RTC Study Number: 7719
RTC Report Number: 7719/T/148/2000

Sponsor:
CONDEA CHEMIE GmbH
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RTC Report Number: 7719/T/148/2000

COMPLIANCE STATEMENT

We, the undersigned, hereby declare that the following report constitutes a true and faithful account of the procedures adopted, and the results obtained in the performance of this study. The aspects of the study conducted by Research Toxicology Centre S.p.A. were performed in accordance with:

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A *"Good Laboratory Practice Standards"* of the U.S. Environmental Protection Agency, Code of Federal Regulations, 40, Part 792, (7-1-97 Edition) and subsequent revisions.

B Commission Directive 1999/11/EC of 8 March 1999 adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (adoption of the *"OECD principles on Good Laboratory Practice – as revised in 1997"*) and subsequent revisions.

C Decreto Legislativo 27 gennaio 1992, n. 120 published in the Gazzetta Ufficiale della Repubblica Italiana 18 Febbraio 1992 (adoption of the Commission Directive of 18 December 1989 adapting to technical progress the Annex to Council Directive 88/320/EEC on the inspection and verification of Good Laboratory Practice (90/18/EEC)) and subsequent revisions.

C. Longobardi, Biol.D.
(Study Director): Date : 17-07-2000

J. Brightwell, Ph.D.
(Scientific Director): Date : 17.07.2000

RTC Report Number: 7719/T/148/2000

QUALITY ASSURANCE STATEMENT

(Relevant to those aspects of the study conducted by Research Toxicology Centre S.p.A.)

Study phases monitored by RTC's QAU according to current relevant Standard Operating Procedures	Quality Assurance Inspections (Day Month Year)		
	Inspection	Report to Study Director	Report to Company Management
PROTOCOL CHECK	16.03.2000	16.03.2000	16.03.2000
PROCEDURAL-BASED INSPECTION ON THIS TYPE OF STUDY			
Allocation	01.03.2000	-	16.03.2000
Dose preparation	12.04.2000	-	20.04.2000
Body weight	12.05.2000	-	02.06.2000
Dosing (induction dermal)	22.02.2000	-	17.03.2000
Dosing (induction intradermal)	08.05.2000	-	26.05.2000
Dosing (challenge)	07.03.2000	-	16.03.2000
Clinical observations	18.05.2000	-	02.06.2000
Other routine inspections of a procedural nature were carried out on activities not directly related to this type of study. The relevant documentation is kept on file although specific inspection dates are not reported here.			
FINAL REPORT Review of this report by RTC's QAU found the reported methods and procedures to describe those used and the results to constitute an accurate representation of the recorded raw data.		Review completed 17.07.2000	

pp

M. Brunetti, Biol.D.
(Head of Quality Assurance)

17/7/2000
Date

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1. SUMMARY

The potential of the test item, NAFOL 2022, to induce and elicit delayed dermal sensitisation was assessed by a guinea pig model using the maximisation test of Magnusson and Kligman.

The concentrations of the test item used in the main study were determined by the results of preliminary screening tests. The main sensitisation test was undertaken using a test group of 10 animals and a control group of 5 animals. In an attempt to induce sensitisation, test animals were intradermally injected with an emulsion of Freund's complete adjuvant and the test item at 5% concentration in both the selected vehicle and an emulsion of Freund's complete adjuvant. One week later this was boosted by topical application of the test item at 75% concentration over the injection sites. Control group animals were treated in the same manner but the selected vehicle (Corn oil) was used in place of the test item. Two weeks after the second induction stage, all animals were challenged by topical application of both the vehicle (petrolatum) and the test item at 10% concentration.

At challenge no response to the test item was observed in any animal of the test or control groups following topical exposure to the test item at 10% concentration. No reaction to the vehicle alone was observed in any animal of test or control groups.

Group	Treatment	Incidence of response (%) at challenge:-	
		24 Hours	48 Hours
Control	Test item	0%	0%
	Vehicle	0%	0%
Test	Test item	0%	0%
	Vehicle	0%	0%

These results indicate that the test item, NAFOL 2022, does not elicit a sensitisation response in the guinea pig, there being no reaction observed at challenge that could not be clearly attributed to irritation. European Directives concerning the classification, packaging and labelling of dangerous substances would indicate the following:-

Classification : Not required
Symbol : None indicated
R Phrase : None indicated

2. INTRODUCTION

The purpose of the study was to assess the ability of the test item to cause delayed dermal sensitisation by use of a guinea pig model.

The procedures used were those of the maximisation test for skin sensitisation described by Magnusson and Kligman. These methods meet the requirements of OECD guideline Number 406, adopted on 17th July 1992. Methods were in agreement with those of B.6 detailed in Commission Directive 96/54/EEC. The species and route of administration were those stated in the regulations, giving a valid model for the assessment of sensitisation.

The study was carried out at:	Research Toxicology Centre S.p.A. Via Tito Speri, 12 00040 Pomezia (Roma) Italy
On behalf of:	CONDEA CHEMIE GmbH Uberseering 40 D-22297 Hamburg Germany

The study started on 24th February 2000 with signing of the protocol by the Study Director. The experimental work described in this report started on 15th March 2000 with allocation of animals to treatment and ended on 12th May 2000 with termination of the study. The study was completed on the date shown against the Study Director signature at the front of this report.

3. TEST ITEM

Details of the test item received at RTC were as follows:

Name	: NAFOL 2022
Lot or Batch Number	: A58125
Expiry date	: -
Received from	: CONDEA CHEMIE GmbH
Date received	: 29th February 2000
Amount received	: 100 grams
Description	: Small white scales
Container	: White plastic bottle
Storage at RTC	: Ambient conditions
RTC reference number	: 4210

Detailed characterisation of the test item was not undertaken at the testing facility. The determination of the identity, strength, purity, composition, stability and method of synthesis and/or derivation of the test item was the responsibility of the Sponsor. A certificate of analysis, supplied by the Sponsor, can be found in Appendix 1 of this report. An aliquot of the test item was taken and will be retained within the RTC archives for a period of 10 years.

The test item was prepared for dosing by mixing with the selected vehicle. A range of concentrations in corn oil was selected for the preliminary tolerance phase of the study. The results of this indicated that the test item at 5% concentration would be suitable for use in the intradermal injection phase of the induction procedure, being judged to be reasonably tolerated by the test system. Suitable concentrations for topical application were investigated in a screening study and a concentration of 75% in corn oil was selected for use in the second induction phase of the study. A lower concentration of 10% in petrolatum was prepared for use at challenge, being judged non-irritant.

Freund's complete adjuvant (FCA), a mixture of paraffin oil, an emulsifier and killed mycobacteria, was used to enhance the potential of the substance to cause a delayed contact hypersensitivity reaction. It was used as a 50% v/v emulsion of FCA in sterile water.

During handling of the substance and its formulations, precautions were taken to reduce possible operator exposure. This included, but was not limited to, use of a face mask, eye protection and the wearing of gloves.

4. METHODS

Any deviations from the protocol are detailed within the text of the report. No deviations occurred which were considered to have compromised the purpose or conduct of the study.

Dated and signed records were made of all activities relating to the day by day conduct and maintenance of the study.

4.1 Animal management

4.1.1 Animal supply

Young adult female guinea pigs of the Dunkin-Hartley strain were ordered from Harlan Nossan S.r.l., Correzzana (MI), Italy. Animals were ordered nulliparous and non-pregnant, within the weight range of 300 to 350 grams and 4 to 5 weeks of age. They were supplied by Harlan UK LTD, Firgrove Farm Cross-in Hand - Heathfield - Sussex TN21 0QL Great Britain, and appeared to be in an acceptable condition following arrival on 10th March 2000. Animals were identified by temporary markings following arrival and an acclimatisation period of at least 5 days was permitted before undertaking any dosing procedure.

4.1.2 Animal husbandry

Animals were housed, in groups of up to 5 animals, in stainless steel cages, measuring 48 x 63 x 41 cm, with a grid floor. Cages were suspended over metal trays which held an absorbent material. This was inspected daily and changed as necessary. Throughout the study, each cage was identified by a label, colour-coded according to group, recording the study number, animal numbers and details of treatment.

Controls for the animal room were set to maintain temperature within the range of 20 to 24°C and relative humidity within the range of 45 to 65%. Actual conditions achieved were recorded daily. The room was lit by fluorescent light to give an artificial cycle of 12 hours light/12 hours dark.

4.1.3 Water and diet

Animals were offered drinking water supplied to each cage via a water bottle and a commercially available laboratory diet (Altromin MSK, A. Rieper S.p.A., Bolzano, Italy) ad libitum throughout the study.

There was no information to indicate that any component was present in either diet or drinking water at a level likely to interfere with the purpose or conduct of the study.

4.2 Experimental Design

The study was divided into 2 distinct phases. The first of these was a dose-ranging screen which was used to determine suitable dose levels for use in the second phase. This second phase formed the main study, a determination of the sensitisation potential of the test item.

4.2.1 Allocation to groups

Animals were selected from available stock and randomly allocated to treatment groups prior to each phase of the study. Animals were then identified by tattoo in the ear with an individual number.

4.2.2 Intradermal injection tolerance test

Two animals were selected from those available and the hair over the scapulae was removed using an electric clipper with suitable blade. Six sites were selected on each animal and these injected intradermally with 0.1 ml of the test item. Each site was injected with a single concentration of the test item. The 2 animals were treated with the substance at concentrations of 10%, 5%, 1%, 0.5%, 0.1% and 0.05% in corn oil

The treated sites of the animals were examined 6 days later for any signs of reaction to treatment. Observed irritation was recorded using the Draize scoring scale (below) and any response not covered by the scoring scale was separately described.

Erythema and eschar formation	Value
No response	0
Very slight erythema	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema to slight eschar formation	4

4.2.3 Topical application tolerance test

Five animals were selected from those available and the hair over the scapulae was removed using an electric clipper with suitable blade. Each animal was then injected intradermally at the prepared site with two injections, each of 0.1 ml, of emulsified Freund's complete adjuvant.

Eight days later, the flanks of each animal were clipped free of hair. Each animal was dosed with 2 concentrations of the test item, 1 on either flank. A gauze patch measuring at least 20 x 20 mm was soaked with 0.2 ml of the selected concentration of the test item. This was then placed onto the selected treatment site. When both sites of the animal had been treated, they were covered with a strip of aluminium foil to act as an occlusive barrier and the trunk of the animal was wrapped with an elastic adhesive bandage to maintain the test item in contact with the skin.

All animals were treated in this manner such that a total of 5 concentrations (75%, 50%, 20%, 10% and 5% in corn oil) of the test item were each dosed in duplicate. The adhesive dressings and gauze patches were removed after 24 hours contact with the skin.

Twenty four and 48 hours after removal of the dressings, the treated sites were examined for signs of reaction to treatment. Each site was assessed and scored on the following scale:-

Reaction observed	Value
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

4.2.4 Main study - Induction - Intradermal injection

Animals were allocated to treatment to give a test group of 10 animals and a control group of 5 animals. On the day of dosing (Day 1) the hair was clipped from the scapular region of each animal over an area approximately 20 x 40 mm. Three pairs of intradermal injections were made at the prepared skin site of each animal. All injections were made at the edge of the prepared site and the anterior and median injections were positioned close together and distant from the posterior injections. A volume of 0.1 ml was injected at each point.

Animals of the test group were treated as follows:-

Injection site	Treatment
Anterior	Emulsified Freund's complete adjuvant
Median	5% in corn oil
Posterior	5% test item in emulsified Freund's complete adjuvant

Animals of the control group were treated in the same manner except that the test item was replaced by the vehicle alone. The treatment plan was:-

Injection site	Treatment
Anterior	Emulsified Freund's complete adjuvant
Median	Vehicle (corn oil)
Posterior	Vehicle mixed with emulsified Freund's complete adjuvant

Skin reaction at the injection sites was assessed approximately 24 hours after injection.

4.2.5 Main study - Induction - Topical application

Six days after injection (Day 7 of the study) the area surrounding the injection sites on each animal was clipped free of hair. A 0.5 ml aliquot of sodium lauryl sulphate at 10% concentration was spread evenly over the skin surrounding the injection sites. The next day (Day 8) animals of the test group were treated with the test item at 75% concentration by a gauze patch which was covered with 0.4 ml of the substance and then placed over the injection sites. This was covered with a strip of aluminium foil to serve as an occlusive barrier and the animal was then wrapped with a length of elastic adhesive bandage to maintain the gauze patch in contact with the skin. All animals of the test group were treated in this manner. Animals of the control group were similarly treated with the vehicle alone (corn oil). After a contact period of 48 hours the dressings were removed and the treated sites gently cleaned by washing with warm water.

Reaction to treatment was assessed approximately 24 hours after removal of the dressings using the following scoring system:-

Reaction observed	Value
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

4.2.6 Main study - Challenge

On Day 22, 3 weeks after preparing the animals for the first induction phase of the main study, all animals were prepared for challenge by clipping the flanks free of hair to expose areas approximately 50 mm x 50 mm on each flank.

Patches of gauze measuring 20 mm x 20 mm were coated with 0.2 ml aliquots of the test item at 10% concentration. These were placed on the right flank of each animal, of both test and control groups, in the centre of the prepared skin site. The left flank of each animal was similarly treated with patches soaked with 0.2 ml of the vehicle alone (petrolatum). The treated sites were covered with a strip of aluminium foil to act as an occlusive barrier and each animal then wrapped with a length of elastic adhesive bandage to keep the test item and vehicle in contact with the skin. After a contact period of 24 hours the dressings and patches were removed.

Approximately 22 hours after removal of the dressings and patches, the treated sites were closely clipped to remove any hair that may have grown. Approximately 2 hours later, 24 hours after removal of the dressings, the treated sites were examined for any signs of reaction to treatment. The times in which the above procedures were carried out were not those indicated in the protocol (21 hours after removal of dressings for clipping and 24 hours for observations).

The following scoring scale was used to describe any observed reaction:-

Reaction observed	Value
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

This examination was repeated 24 hours later, 48 hours after removal of the dressings.

4.2.7 Body weight

Animals used in the main sensitisation assessment were weighed at the start of treatment (Day 1) and on completion of the study (Day 25).

4.2.8 Termination and necropsy

All animals were killed by carbon dioxide narcosis following the end of the experimental procedure. No necropsy examination was undertaken.

4.3 Classification

The results obtained on testing were used to classify the test item according to the requirements of European Directives concerning the classification, packaging and labelling of dangerous substances.

The test would be considered positive if 30% or more of animals in the test group exhibited erythema or dermal swelling following challenge with a non-irritant concentration of the test item. The non-irritant nature of the test item at the concentration used at challenge would be demonstrated by the lack of dermal responses in the control group.

Should the test have been considered positive, the test item would require labelling with the risk phrase (R 43) "May cause sensitisation by skin contact" and symbol "Xi".

4.4 Archives

The raw data and documentation generated during the course of this study will be retained at RTC for 5 years after which the Sponsor will be contacted regarding despatch or disposal of the material.

5. RESULTS

5.1 **Preliminary tolerance tests** (Table 1)

The preliminary tolerance test to establish a suitable concentration for injection in the main sensitisation test indicated that the test item at 5% concentration should be reasonably tolerated by the test system. The topical application test indicated that the test item at 75% concentration should be tolerated by the test system. A lower concentration of 10% was selected for use at challenge, being judged non-irritant.

5.2 **Induction** (Tables 2 and 3)

Moderate reaction was apparent at the sites of intradermal injection following administration of Freund's complete adjuvant (test and control groups) or the vehicle mixed with Freund's complete adjuvant (control group). Slight to well defined reaction was observed at sites treated with the test item mixed with the vehicle (test group). Necrosis was observed at the sited treated with the test item mixed with Freund's complete adjuvant (test group), with the exception of two animals which showed a well defined erythema. No reaction was observed at those sites treated with the vehicle alone (control group).

A significant reaction (discrete erythema) was observed around the injection sites of animals following 48 hours topical exposure to the test item (test group). A minor response was observed to the vehicle alone (control group).

5.3 **Challenge** (Table 4)

At challenge no response was observed in any animals of both test and control groups following 24 hours topical exposure to the test item at 10% concentration.

No reaction to the vehicle alone was observed in any animal of test or control groups.

Group	Treatment	Incidence of response (%) at challenge:-	
		24 Hours	48 Hours
Control	Test item	0%	0%
	Vehicle	0%	0%
Test	Test item	0%	0%
	Vehicle	0%	0%

5.4 **Body weight** (Table 5)

Changes in body weight of animals during the period of the study were generally similar in animals from both test and control groups.

6. CONCLUSION

The results obtained in this study indicate that the test item, NAFOL 2022, does not elicit a sensitisation response in the guinea pig, there being no reaction observed at challenge.

European Directives concerning the classification, packaging and labelling of dangerous substances would indicate the following:-

Classification : Not required
Symbol : None indicated
R Phrase : None indicated

DELAYED DERMAL SENSITISATION STUDY IN THE GUINEA PIG
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TABLE 1 - PRELIMINARY SCREENS - INDIVIDUAL RESULTS

This table details the results of examination of injection sites 6 days after injection of a range of concentrations of the test item (NAFOL 2022) in the selected vehicle (corn oil).

Animal number	Test item concentration	Erythema	Additional comments
21	10%	0	Difficulty in dosing
	5%	0	Difficulty in dosing
	1%	0	Difficulty in dosing
	0.5%	0	-
	0.1%	0	-
	0.05%	0	-
23	10%	0	Difficulty in dosing
	5%	0	Difficulty in dosing
	1%	0	Difficulty in dosing
	0.5%	0	-
	0.1%	0	-
	0.05%	0	-

KEY: 0 = No response
1 = Very slight erythema
2 = Well defined erythema
3 = Moderate to severe erythema
4 = Severe erythema to slight eschar formation

This table details the results of examination of treated sites following topical application of a range of concentrations of the test item (NAFOL 2022) in the selected vehicle (corn oil).

Animal Number	Observation time	Test item concentration				
		75%	50%	20%	10%	5%
25	24 hours	0	0			
	48 hours	0	0			
27	24 hours		0	0		
	48 hours		0	0		
29	24 hours			0	0	
	48 hours			0	0	
31	24 hours				0	0
	48 hours				0	0
33	24 hours	0				0
	48 hours	0				0

KEY: 0 = No visible change
1 = Discrete or patchy erythema
2 = Moderate and confluent erythema
3 = Intense erythema and swelling

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TABLE 2 - MAIN STUDY - INDUCTION INJECTION - INDIVIDUAL RESULTS

This table details the responses observed 24 hours after injection of animals with the vehicle alone (corn oil) in the initial phase of induction.

Group Function	Animal number	Dermal response					
		Anterior site (FCA emulsion)		Median site (Vehicle)		Posterior site (Vehicle/FCA)	
		Left	Right	Left	Right	Left	Right
CONTROL	469	2	2	0	0	2	2
	471	2	2	0	0	2	2
	473	2	2	0	0	2	2
	475	2	2	0	0	2	2
	477	2	2	0	0	2	2

This table details the responses observed 24 hours after injection of animals with the test item (NAFOL 2022) at 5% concentration in the initial phase of induction.

Group Function	Animal Number	Dermal response					
		Anterior site (FCA emulsion)		Median site (Test item)		Posterior site (Test item/FCA)	
		Left	Right	Left	Right	Left	Right
TEST	479	2	2	1	1	N	N
	481	2	2	1	1	N	N
	483	2	2	1	1	N	N
	485	2	2	1	1	N	N
	487	2	2	1	1	N	N
	489	2	2	2	2	2	2
	491	2	2	2	2	N	N
	493	2	2	2	2	2	2
	495	2	2	2	2	N	N
	497	2	2	2	2	N	N

KEY: 0 = No response
1 = Very slight erythema
2 = Well defined erythema
3 = Moderate to severe erythema
4 = Severe erythema to slight eschar formation
N = Necrosis

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TABLE 3 - MAIN STUDY - TOPICAL INDUCTION - INDIVIDUAL RESULTS

This table details the findings at the injection sites of each animal 24 hours following 48 hours topical exposure to either the test item (NAFOL 2022) at 75% concentration or the vehicle alone (corn oil) during the second stage of the induction procedure.

Group function	Animal number	Dermal response
CONTROL	469	1
	471	1
	473	1
	475	1
	477	1
TEST	479	2
	481	2
	483	2
	485	2
	487	2
	489	2
	491	2
	493	2
	495	2
	497	2

KEY: 0 = No visible change
1 = Discrete or patchy erythema
2 = Moderate and confluent erythema
3 = Intense erythema and swelling

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TABLE 4 - MAIN STUDY - CHALLENGE - INDIVIDUAL RESULTS

This table details the responses observed 24 and 48 hours following the first challenge by 24 hours topical exposure to the test item (NAFOL 2022) at 10% concentration and the vehicle alone (petrolatum).

Group function	Animal number	Dermal response			
		Vehicle		Test item	
		24 hours	48 hours	24 hours	48 hours
CONTROL	469	0	0	0	0
	471	0	0	0	0
	473	0	0	0	0
	475	0	0	0	0
	477	0	0	0	0
TEST	479	0	0	0	0
	481	0	0	0	0
	483	0	0	0	0
	485	0	0	0	0
	487	0	0	0	0
	489	0	0	0	0
	491	0	0	0	0
	493	0	0	0	0
	495	0	0	0	0
	497	0	0	0	0

KEY: 0 = No visible change
1 = Discrete or patchy erythema
2 = Moderate and confluent erythema
3 = Intense erythema and swelling

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TABLE 5 - MAIN STUDY - BODY WEIGHT - INDIVIDUAL VALUES

This table details the body weights of animals used in the study.

Group function	Animal Number	Body weight (g) on Day:-		Change in body weight (g) Day 1 to Day 25
		1	25	
CONTROL	469	670	730	60
	471	683	742	59
	473	730	850	120
	475	710	810	100
	477	570	603	33
	Mean	672.6	747.0	74.4
	S. Dev.	61.9	94.4	35.0
TEST	479	676	741	65
	481	633	712	79
	483	593	631	38
	485	648	710	62
	487	729	803	74
	489	539	659	120
	491	629	701	72
	493	580	654	74
	495	550	672	122
	497	692	702	10
	Mean	626.9	698.5	71.6
	S. Dev.	62.0	49.3	33.3

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TABLE 6 - RELIABILITY CHECK - SUMMARY

This table summarises the results obtained in the most recent reliability check.

RTC STUDY NUMBER:	5246-010		
REFERENCE SUBSTANCE:	Mercaptobenzothiazole		
CONCENTRATION:	INDUCTION	(INJECTION) -	1% in PEG 400
		(TOPICAL) -	50% in acetone
	CHALLENGE	-	25% in acetone
CRITICAL DATES:	INDUCTION	(INJECTION) -	13th September 1999
		(TOPICAL) -	20th September1999
	CHALLENGE	-	4th October 1999
RESULTS:	100% response in test group and 0% response in control group at challenge		
INTERPRETATION:	Incidence at challenge acceptable Test system regarded as valid		

DELAYED DERMAL SENSITISATION STUDY IN THE GUINEA PIG (MAGNUSSON AND KLIGMAN TEST)

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APPENDIX 1 – CERTIFICATE OF ANALYSIS FOR THE TEST ITEM

· **CONDEA Chemie GmbH**
Überseering 40
22297 Hamburg

CONDEA

Brunsbüttel, 22/02/2000

CONDEA Chemie GmbH
Herr Meier,

.
45764 Marl
Deutschland
FAX: 02365/496360

A N A L Y S E N Z E R T I F I K A T
**** ABNAHMEPRUEFZEUGNIS B DIN 50049-3.1 B -- EN 10204-3.1 B ****

Produkt: N A F O L 2022 (2022003)
Versandanzeige für: 480.0 Kg
Lotnummer: 58125
Versandart:
Bestell-/Freigabenr.: per Telefon
Lieferschein-Nr.: 2012472 vom 6/12/1999
Herstellungsdatum: 18/06/1999

Test	Einheit	Ergebnis
Gehalt an C 16-OH	[Gew.%]	0.3
Gehalt an C 18-OH	[Gew.%]	4.7
Gehalt an C 20-OH	[Gew.%]	60.7
Gehalt an C 22-OH	[Gew.%]	34.0
Gehalt an C 24-OH	[Gew.%]	0.4
Farbzahl	[Hazen]	5.
Esterzahl	[mg KOH/g]	0.14
Saeurezahl	[mg KOH/g]	0.02
Wasser	[%]	0.03
Jodzahl	[mg I/100mg]	0.93

CONDEA Chemie GmbH handelnd im Namen und für Rechnung der
RWE-DEA AG für Mineraloel und Chemie.
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Tel: 04852/392-0 Fax: 04852/3285

Mit freundlichem Gruß
Werkssachverständiger
D. Petersen

Dieses Zertifikat wurde maschinell erstellt und hat ohne Unterschrift Gueltigkeit.