DATE: 20/AUG/2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF TGAI/MP[X] EP []
DP BARCODE No.:D291417 REG. No.: 10308-10
PRODUCT NAME:Gokilaht Manufacturing use product
COMPANY: Sumitomo Chemical Company
PCC: 129013 ; Decision #:290067

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INTRODUCTION

The product chemistry for Gokilaht submitted previously were reviewed under D279274 (PCR dated 01-09-02). The registrant was informed that product chemistry data for guidelines 830.1700 (Preliminary analysis) and 830.1800 (Enforcement analytical method) are required to support the CSF and the registration of the manufacturing use product. The registrant responded on June 09,2003 and submitted the required data and the corrected CSF for basic formulation dated 04-01-02.The data have been provided under MRID Nos. 460040-01 and 460040-02. The TRB has been asked to review the CSF and other product chemistry data.

SUMMARY OF FINDINGS

1. The MUP contains (RS)-α-cyano-3-phenoxybenzyl (1RS)-cis/trans-chrysanthemate as the active ingredient with the product label claim of 94.0%.

2. The CSF for basic formulation (dated 04-01-02) is filled out correctly and completely. The nominal concentration of the active ingredient concurs with the product label claim nominal concentration. The CSF is in compliance with PR Notice 91-2. However, the CSF is not supported by 5 batch analysis. The amounts of the impurities as determined by the 5 batch analysis do not agree with those provided on the CSF. For more details please refer to Confidential Appendix.

The registrant has included the Blocks # 7, 8, 9 in the CSF for density (9.162), pH (NA), and Flash point (130^{0}C) respectively.

The data submitted corresponding to guideline reference 830.1550 and 830.1750 do not satisfy the product chemistry data requirements of 40CFR§158.155 and 158.175 respectively.

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3. With the submission of the additional data on 5 batch analysis (MRID No. 460040-01) and in combination with the previously submitted data (MRID No. 455001-01, D279274), the product chemistry data corresponding to guideline reference 830.1670 (Discussion on the formation of impurities) and 830.1700 (Preliminary analysis) satisfy the data requirements of 40CFR§158.167 and 158.170 respectively.

4. The data submitted corresponding to guideline reference 830.1800 (Enforcement analytical method) satisfy the data requirements of 40CFR§158.180.

CONCLUSION:

The TRB has evaluated the product chemistry data submitted for Gokilaht Manufacturing-use-product and has concluded that:

1. The data submitted corresponding to guideline reference 830.1700 (Preliminary analysis) is acceptable.

2. The data submitted corresponding to guideline reference 830.1670 (Discussion on the formation of impurities) is acceptable.

3. The data submitted corresponding to guideline reference 830.1800 (Enforcement analytical method) is acceptable. The registrant should be reminded that the enforcement analytical method for the determination of the AI is non-confidential document.

4. The CSF for basic formulation (dated 04-01-02) is not acceptable, since the amounts of the impurities listed in the CSF do not concur with those described during five batch analysis. For more details, please refer to Confidential Appendix.

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830.1800. Enforcement analytical method: (MRID No. 460040-02)

The registrant has applied the same analytical method for the determination of Gokilaht content as described in the preliminary analysis (MRID No. 460040-01). The method was validated for the precision, accuracy and linearity.

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830.1670. Discussion on the formation of impurities:
[MRID No. 460040-01 & (Previous submission MRID No. 455001-01)]

The discussion of the formation of the impurities have been reported in the previous report. The impurities reported in 5 batch analysis are the same as reported in the CSF. The five batch analysis provided support the discussion on the formation of impurities provided under MRID No. 455001-01.

Confidential Statement of formula: The CSF (dated 04-01-02) is not acceptable for the reason that the results provided in the 5 batch analysis do not concur with those provided in the 5 batch analysis. The amounts of the impurities reported in the CSF do not concur with the corresponding amounts listed in column # 13b of the CSF.

The registrant has reported and quantitated the following impurities in Gokilaht MUP:

components	Mean % reported in 5 batch analysis	Reported in the CSF (dated 04-01-02) (%)
Gokilaht (AI)	94.7	94.0
[redacted]		

Manufacturing process information is not included

It must be noted that the product label claim is 94% for the AI which is also the minimum amount of the AI determined during the 5 batch analysis of the product. According to the definition, the nominal concentration of the AI can not be minimum amount of the AI present at the time of its production.

The registrant should revise the amounts of the impurities in the CSF based on the 5 batch analysis study provided under MRID No. 460040-01.

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830.1700. Preliminary analysis: (MRID No. 460040-01)

Equipment: GC: Shimadzu Models GC-14A and GC-2010 equipped with hydrogen flame-ionization detector (FID).

Column packing for GC: 3% silicone OV-101 on Uniport HP (100-120 mesh), 10% PEG 20M on Chromsorb W AW DMCS (60-8- mesh), 10% PEG 20M on Chromsorb W HP(80-100 mesh) and 20% solicone XE-60 on Chromsorb W AW DMCS (60-80 Mesh).

Capillary Column GC: DB-210 (1 µm, 0.53 mmφ x 30 m)

A. Content of Gokilaht

GC operating conditions:
Detector: FID
Column: A glass column (3 mm id x 1m), packed with 3% silicone OV-101 on Uniport HP (100-120 mesh)
Temperatures: Oven-220°C; Injection port-250°C; Detector-250°C
Carrier gas: Nitrogen
Flow rate: 38 ml/min

The content of Gokilaht was calculated using the following equation:

$$C = \frac{Ws \times Qt \times P}{Wr \times Qs}$$

Where, C: content % of Gokilaht; Ws: amount(mg) of Gokilaht standard; Wr: amount (mg) of the test sample; Qs: ratio fo the peak area of Gokilaht against that of the IS for the standard solution; Qr: ratio of the peak area of Gokilaht against that of the IS for the sample solution; P: purity (%) of Gokilaht standard.

The optical isomer ratio and geometrical (trans-isomer) ratio were also calculated.

[redacted]

Manufacturing process information is not included

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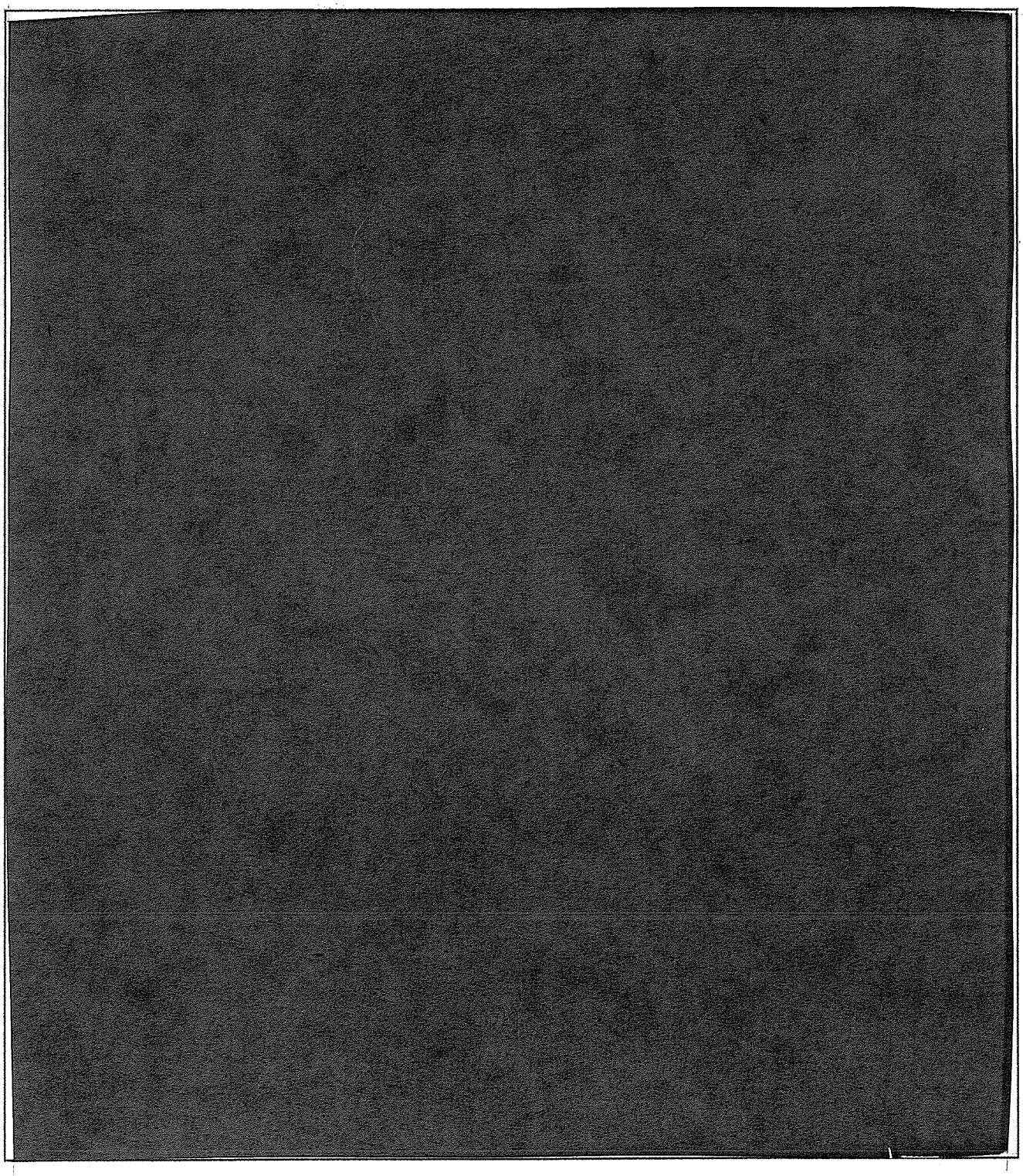

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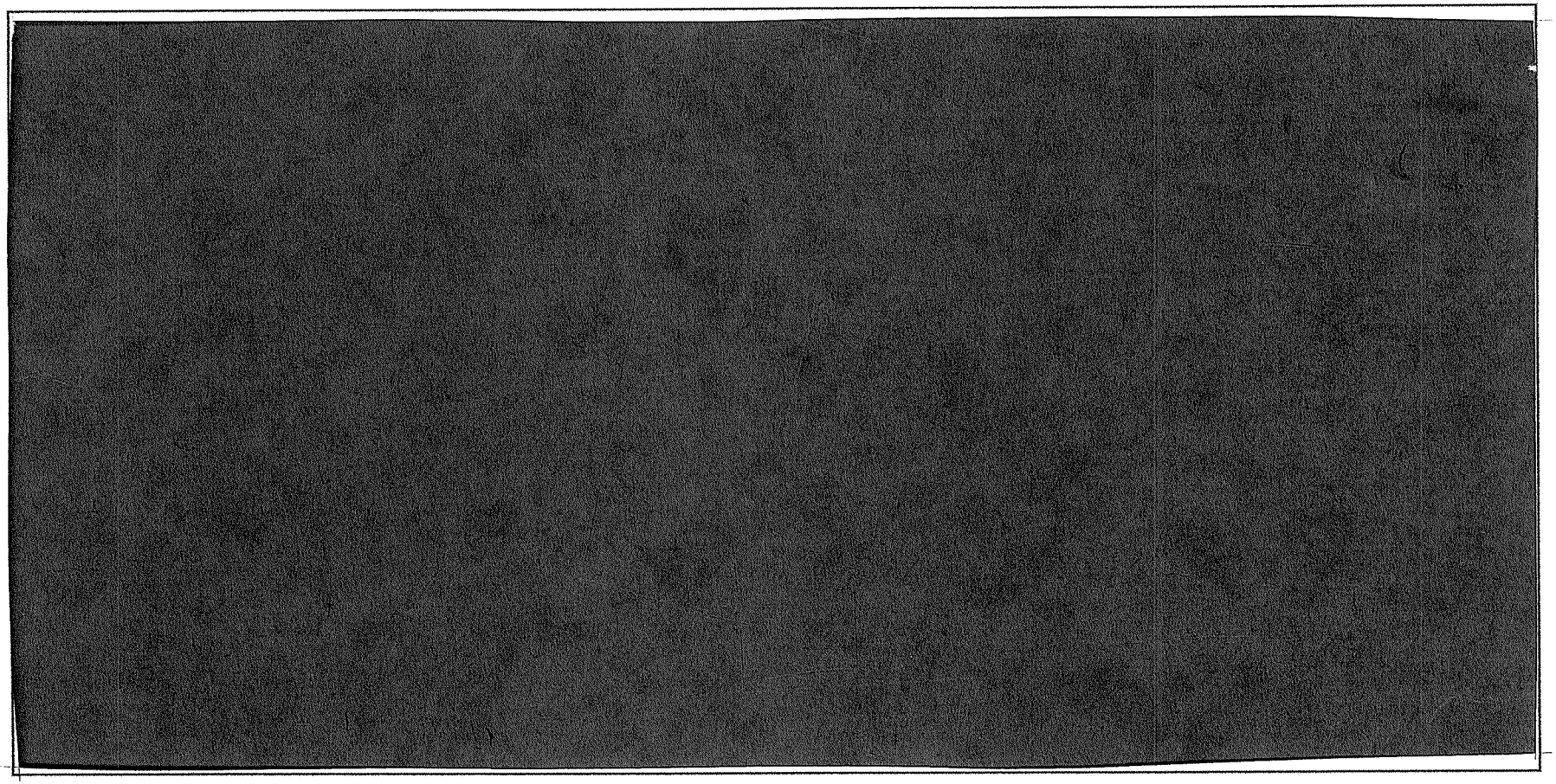

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Component	Lot No.					Mean	SD	RSD
	00604	20314	20316	20319	20320			
Active ingredient	94.0	94.8	94.9	94.9	94.8	94.7	0.38	0.4
[redacted]								

Manufacturing process information is not included