

**FEE**

**Date:** June 1, 2011

**SUBJECT:** Product Chemistry Review of Chlorothalonil Technical TGAI/MUP

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**DP BARCODE:** 385899

**DECISION No.:** 443314

**Registration No. / File Symbol No.:** 88058-R

**PRODUCT NAME:** Chlorothalonil Technical

**PC Code:** 081901

**REGISTRANT:** Orion ATO, LLC

**USE:** Fungicide

**FOOD USE:** Yes  No

**MRID Numbers:** 483266-01 through 483266-05

**INTRODUCTION:**

The registrant has submitted group A product chemistry data and a CSF (dated 12/10/2010) for a basic formulation of Chlorothalonil Technical (EPA Reg. No. 88058-R). The registrant states that the product is substantially similar to Technical Chlorothalonil Fungicide (EPA Reg. No. 50534-7). The registrant cited Group B data from the cited "me-too" product with an offer to pay.

**SUMMARY OF FINDINGS:**

1. Group A guidelines:

830.1550 (Product identity & composition)

Acceptable data for the identity and composition of the product were provided. The active ingredient is present at a nominal concentration of 98.5%. The product chemistry data submitted corresponding to Guideline 830.1550 satisfy the data requirements of 40CFR§158.320.

830.1600 (Description of materials used to produce the product)

The registrant provided MSDSs for the materials used to produce the product. The product chemistry data submitted corresponding to Guideline 830.1600 satisfy the data requirements of 40CFR§158.325.

830.1620 (Description of production process)

An acceptable description of the production process was provided. The product chemistry data submitted corresponding to Guideline 830.1620 satisfy the data requirements of 40CFR§158.330.

830.1670 (Discussion on the formation of impurities)

An acceptable discussion of the origin and mechanism formation for the impurities in the product was provided. The product chemistry data submitted corresponding to Guideline 830.1760 satisfy the data requirements of 40CFR§158.340.

830.1700 (Preliminary analysis)

Acceptable results of a five-batch preliminary analysis were provided, and the content of a.i. ranged from 98.6% to 98.9%. These values are within the certified limits specified on the CSF. The product chemistry data submitted corresponding to Guideline 830.1700 satisfy the data requirements of 40CFR§158.345.

830.1750 (Certified limits)

Certified limits were provided for the active ingredient, and upper certified limits were provided for the impurities in the product. The product chemistry data submitted corresponding to Guideline 830.1750 satisfy the data requirements of 40CFR§158.350.

830.1800 (Enforcement analytical method)

An acceptable description of the enforcement analytical method and its validation were provided. The product chemistry data submitted corresponding to Guideline 830.1800 satisfy the data requirements of 40CFR§158.355.

2. 830 series group B guidelines (physical-chemical properties)

Group B product chemistry data were not provided.

**CONCLUSIONS:**

The TRB has reviewed the product chemistry data submitted for Chlorothalonil Technical and has concluded that:

1. All product chemistry data submitted for guideline 830 Series group A are acceptable.
2. Product chemistry data corresponding to 830 series group B (physical-chemical properties) were cited with an offer to pay to the me-too registrant. Since this product is manufactured in the

same location as the “me-too” products and the two products are essentially identical the group B data requirement is satisfied.

3. The proposed CSF for the basic formulation (dated 12/10/2010) is acceptable. This product and the “me-too product” alternate CSF dated February 9, 2007 are from an identical manufacturing site in China. Both CSFs claim 98.5% Chlorthalonil and substantially similar impurity profile. Potential toxic impurities were at non-detectable limits.

4. As stated in 3, above this product and the cited “me-too” product are “substantially similar”.

830.1550. Product identity & composition: (483226-01 )

Common Name: Chlorothalonil

Chemical name (CAS): 2,4,5,6-Tetrachloro-1,3-benzenedicarbonitrile

(IUPAC): Tetrachloroisophthalonitrile

CAS No.: 1897-45-6

PC Code No.: 081901

Empirical Formula:  $C_8Cl_4N_2$

Molecular Weight: 265.9

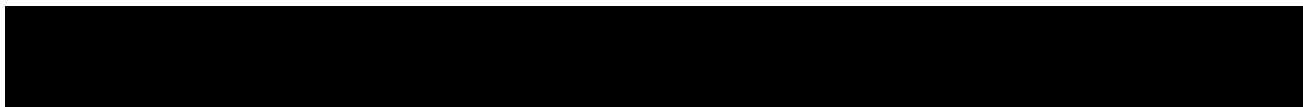
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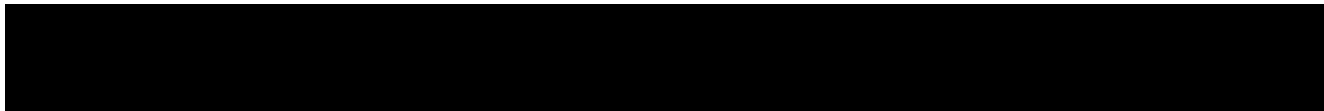
Table 1. Manufacturing and Impurity Data for Chlorothalonil Technical TGAI				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	483266-01	A	The nominal concentration of a.i. (98.5%) is supported by the five-batch analysis and agrees with the label. The impurities are listed on the CSF.
830.1600	Description of materials used to produce the product	483266-01	A	The description and composition of the starting materials are provided.
830.1620	Description of production process	483266-01	A	Chlorothalonil Technical is produced using an integrated process. A description of the process is provided.
830.1670	Discussion of formation of impurities	483266-01	A	The impurities were identified and their origins are provided.
830.1700	Preliminary analysis	483266-02	A	Satisfactory results of a five-batch analysis are provided.
830.1750	Certified limits	CSF	A	The certified limits for the a.i. are supported by the five-batch analysis. Upper certified limits are provided for the impurities.
830.1800	Enforcement analytical method	483266-05	A	The a.i. content is determined using GC/FID with an internal standard.
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ; U = Up-grade (additional information required);				



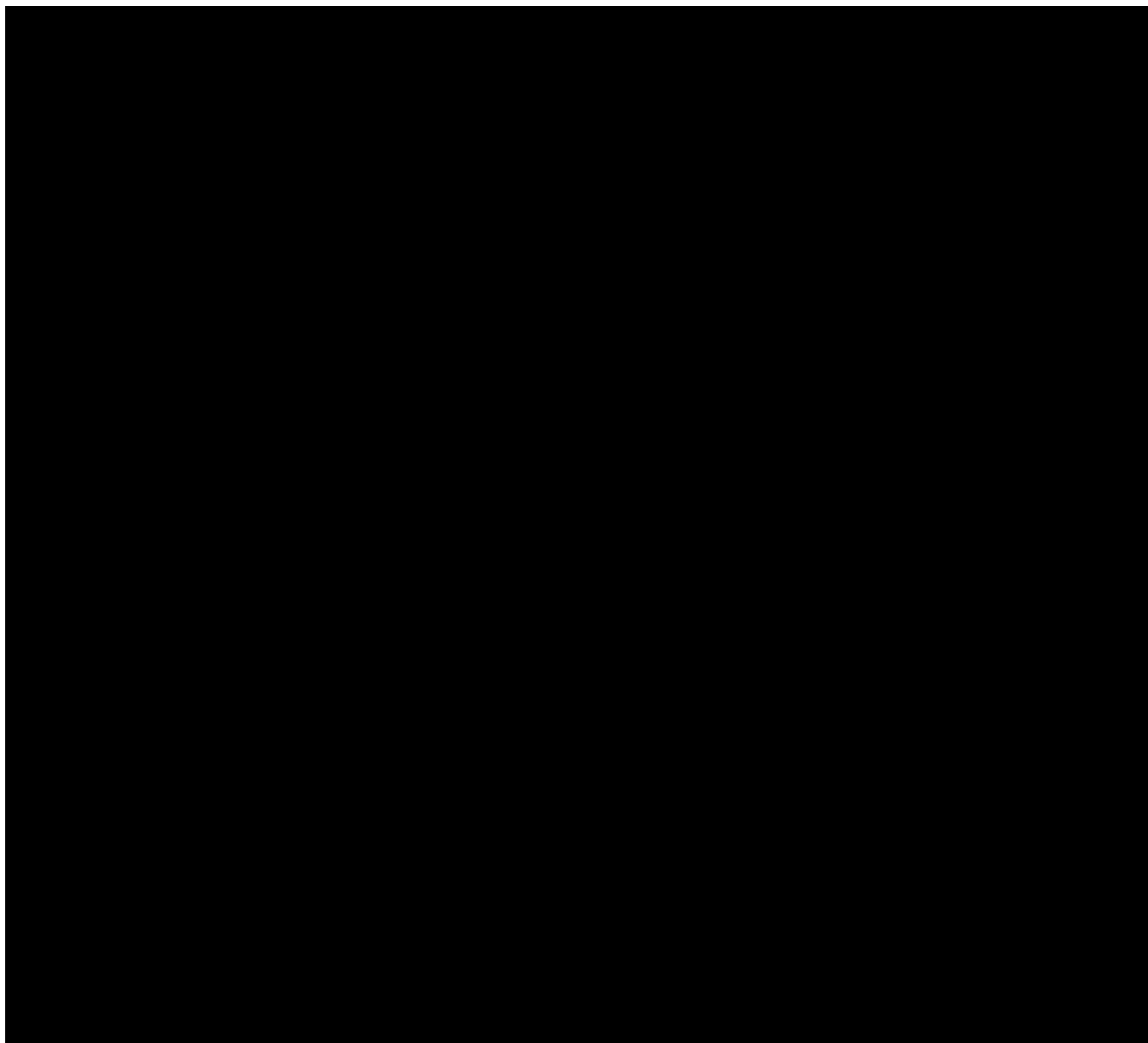
830.1600 (Description of materials used to produce the product)



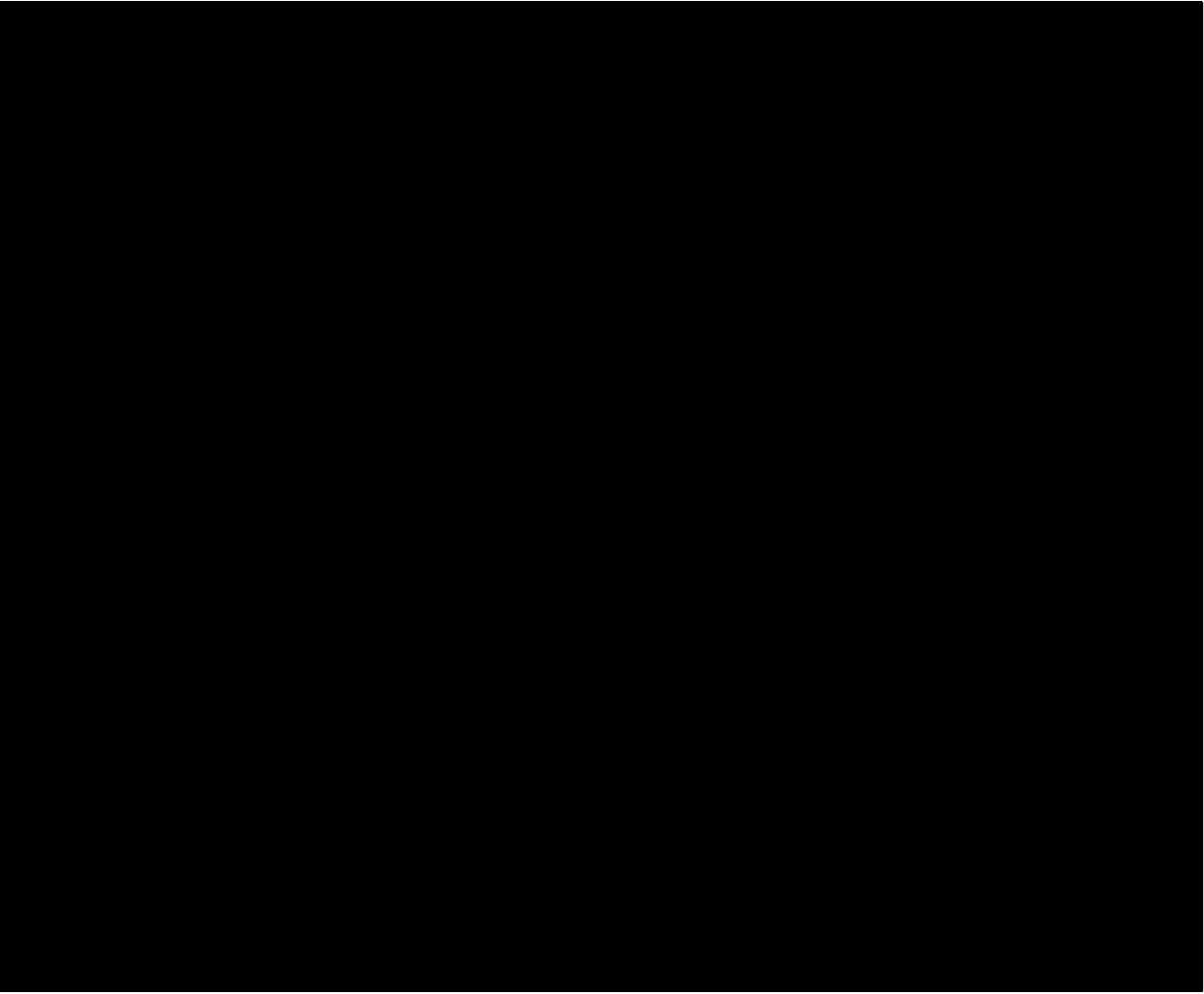
830.1620 (Description of production process)



**3.2 Manufacturing Process**



\*Manufacturing process information may be entitled to confidential treatment\*

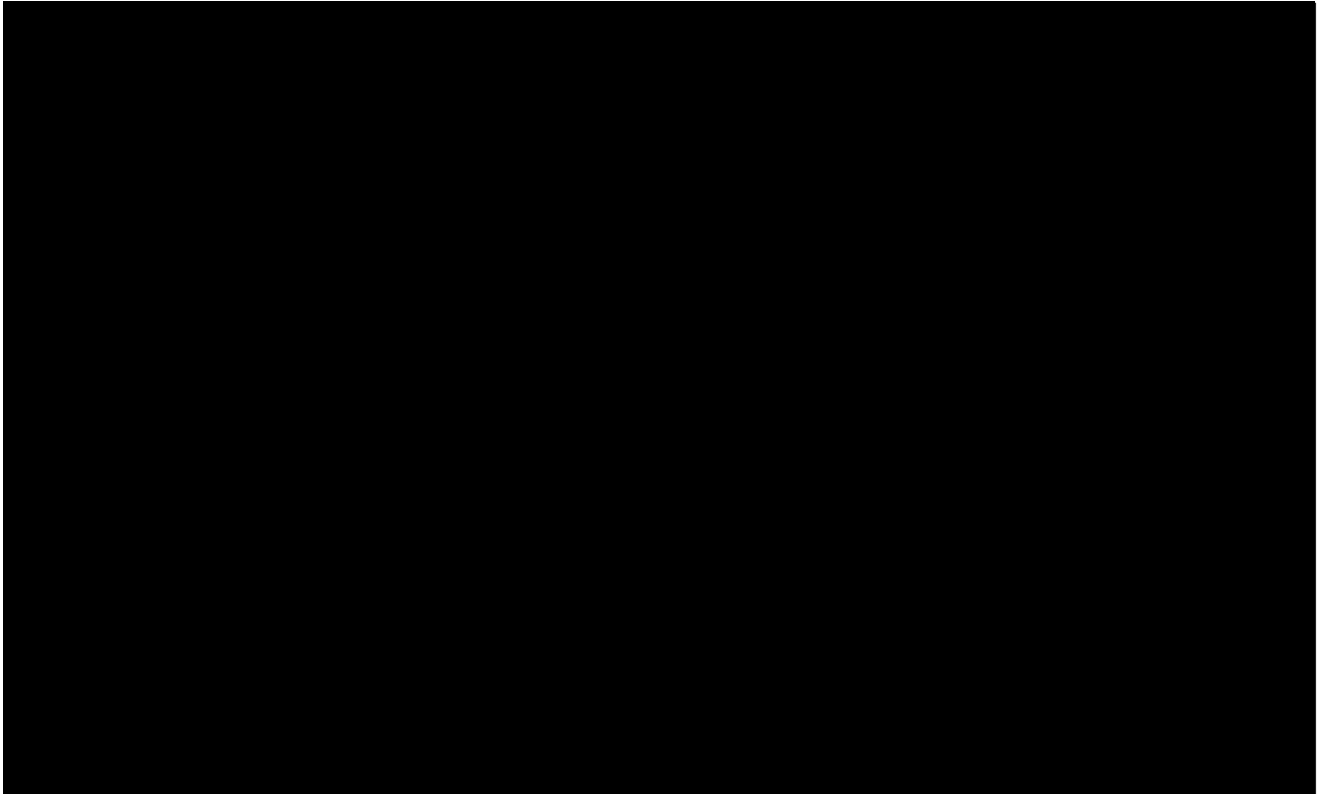


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830.1670 (Discussion on the formation of impurities)

The registrant described the formation of impurities as follows:

**The following impurities were identified in chlorothalonil technical:**



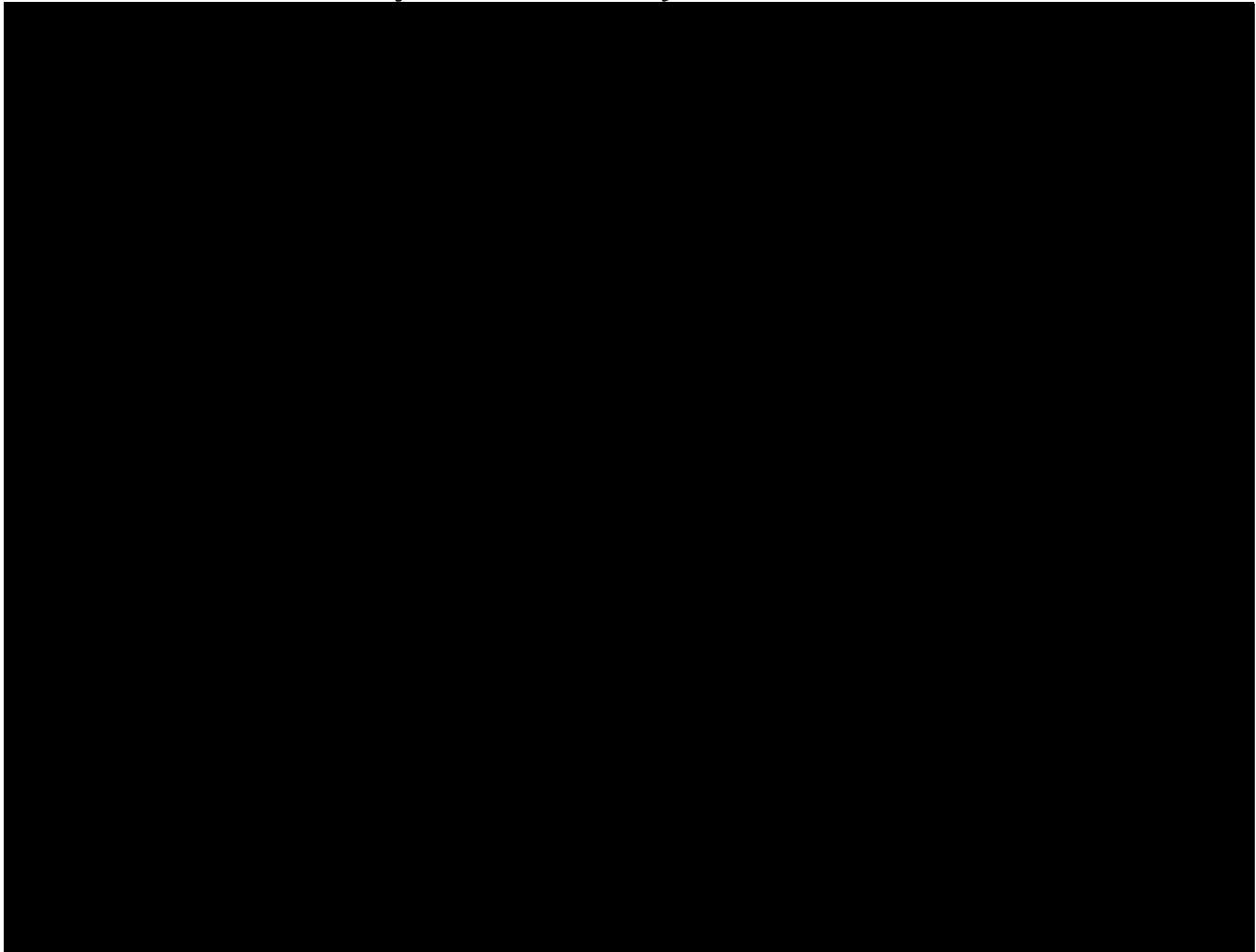
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830.1700 (Preliminary analysis)

Results of the preliminary analysis for Chlorothalonil Technical were as follows:

**TABLE 1 Summary table of the analysis results**



830.1750 (Certified limits)

Acceptable certified limits are included on the CSF for Chlorothalonil Technical (dated 12/10/2010). Upper certified limits for the impurities were also included.

\*Manufacturing process information may be entitled to confidential treatment\*

DATA EVALUATION RECORD

CHLOROTHALONIL  
(Chlorothalonil Technical)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)  
Description of Materials Used to Produce the Product (OPPTS 830.1600)  
Description of the Formulation Process (OPPTS 830.1650)  
Discussion of Formation of Impurities (OPPTS 830.1670)  
Preliminary Analysis (OPPTS 830.1700)  
Certified Limits (OPPTS 830.1750)  
Enforcement Analytical Method (OPPTS 830.1800)

MRIDs 483266-01 through 483366-05

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Disclaimer

This review may have been altered subsequent to the contractor's signatures above.