

Case No.: 4023
Chemical No(s): 020503
DP Barcode No(s): D185072; D185407
CBRS Nos.: 10940; 10993

CBRS TRANSMITTAL SHEET FOR PHASE 4 REVIEWS

Transmitted to HED on 12/03/92
Case name: Chlorine Dioxide
Chemical name(s): Chlorine Dioxide
Data submitter(s): Bio-Cide International; International Dioxide; Chemical Cealin Co., Inc.
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Branch: CBRS, Reregistration Section II
Reviewed by: Christina B. Swartz Date: 2/1/93 *Christina B. Swartz*

Approvals:
Section Head: William J. Hazel, Ph.D. Date: 2/2/93 *W. J. Hazel*
Branch Chief: Edward Zager Date: 2/2/93 *E. Zager*
Division Approval: P. Q. Fenner-Crisp, Ph.D. Date: 2/2/93 *P. Q. Fenner-Crisp*

cc: CBSwartz; List D Reregistration File; RF; SF; Circulation; Betsy Grim (EFED).

Case No.: 4023

Page 2 of 4

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Issues/flags:

Other: Use information gathered from LUIS reports dated 10/26/92 and REFS. Chlorine dioxide is used as a disinfectant, sanitizer, bacteriostat, fungicide/fungistat; and microbicide/microbiostat on food/meat/poultry/dairy/cheese/fish/seafood processing premises and equipment, in eating establishments, in industrial/commercial/institutional water systems, premises and equipment, in hospitals, in empty mushroom houses, and in household dwellings. Dilute solutions of chlorine dioxide may come into contact with food (fruits and vegetables) during food processing. In addition, chlorine dioxide is used in the purification of water in municipal drinking water, as well as in industrial and food processing water. The use in drinking water systems involves the addition of chlorine dioxide gas, dissolved in water, directly into water purification systems. The chlorine dioxide gas solution is either generated on site using a chlorine dioxide generator, or purchased as a solution.

The acceptability of the database to support the use of chlorine dioxide as a sanitizer in food processing plants (premises and equipment) and during food processing is under the purview of FDA.

CBRS defers to the EPA Office of Water regarding the adequacy of the database to support the use of chlorine dioxide in municipal water systems [Guideline No. 171-4(f), Magnitude of the Residue in Potable Water]. Conclusions reached during the Phase 4 process regarding this Guideline Requirement render moot the CBRS recommendation to SRRD in the 9/23/92 memo (CBSwartz; CBRS No. 10221; DP Barcode No. D180659).

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Response, by Guideline

Guideline #: <u>171-4(a)</u>	Description: <u>Nature of residue - plants</u>
Guideline #: <u>171-4(c)</u>	Description: <u>Res. analyt. method - plant</u>
Guideline #: <u>171-4(g)</u>	Description: <u>Magnitude residue - fish</u>
Guideline #: <u>171-4(h)</u>	Description: <u>Mag. res. - irrigated crop</u>
Guideline #: <u>171-4(i)</u>	Description: <u>Mag. res. - food handling</u>
Guideline #: <u>171-4(k/l)</u>	Description: <u>Crop field trials/process</u>

Is requirement applicable? (Y/N): N

Data Gap: None.

Guideline #: <u>171-4(b)</u>	Description: <u>Nature of residue - animals</u>
Guideline #: <u>171-4(d)</u>	Description: <u>Res. anal. method - animals</u>
Guideline #: <u>171-4(e)</u>	Description: <u>Storage stability</u>
Guideline #: <u>171-4(j)</u>	Description: <u>Mag. meat/milk/poultry/eggs</u>

Is requirement applicable? (Y/N): Y

Discussion: The only source of chlorine dioxide which could result in residues of interest in the edible tissue of livestock, milk, and eggs would come from potable water treated with chlorine dioxide. While water treated in this manner is a potential water source for livestock used in the production of meat, milk and eggs, CBRS assumes that most livestock used for these purposes are maintained in rural settings where municipally treated water is not available and where an alternate/less costly water source is normally used. Furthermore, in the event that treated water containing chlorine dioxide residues is available/consumed by some livestock used to produce meat, milk and eggs, CBRS has determined that although it is not possible to establish with certainty whether finite residues will be incurred in meat, milk and eggs, there is no reasonable expectation of finite residues or residues significantly above the naturally occurring background levels. Therefore, animal metabolism, analytical methodology, storage stability, and magnitude data are not required.

Data Gap: None.

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Page 4 of 4

Guideline #: 171-4(f) Description: Mag. res. - potable water

Is requirement applicable? (Y/N): Y

Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A

Data Waiver() Time Extension() Other ()

Data Waiver/Time Extension (If applicable) Granted? (Y/N):

Discussion: The LUIS reports indicate that chlorine dioxide is used in water treatment facilities to prepare drinking water for public consumption. Finite residues of chlorine dioxide are anticipated in drinking water as a result of this use. Since chlorine dioxide is used as an integral part of the preparation of a safe water supply for public consumption, CBRS assumes that, by virtue of their expertise and the availability of submitted/published data, the EPA Office of Water should have jurisdiction over this unique use. Therefore, CBRS defers to the EPA Office of Water for the determination of the nature and magnitude of the residue of chlorine dioxide in potable water resulting from its use in water treated in municipal facilities.

PRODUCT CHEMISTRYCase Name/Case No.: Chlorine Dioxide/4023Chemical Name(s)/Chemical No(s): Chlorine Dioxide/020503Registrant: Bio-Cide International

Guideline Number	Is requirement applicable?	Does summary or available information indicate MRID is a candidate for Phase 5 review?	Are additional data required?	MRID Number ^a
61-1	N ^b	N/A	N/A	
61-2(a)	Y	Y	N	42565801
61-2(b)	Y	Y	N	42565801
62-1	Y	Y	N	42442901
62-2	N ^b	N/A	N/A	
62-3	N ^b	N/A	N/A	
63-2	Y	N	N ^c	
63-3	Y	N	N ^c	
63-4	Y	N	N ^c	
63-5	N ^d	N/A	N/A	
63-6	N ^d	N/A	N/A	
63-7	Y	N	N ^c	
63-8	Y	Y	N	42529702
63-9	N	N	N ^c	
63-10	Y	Y	N	42529701
63-11	N ^f	N/A	N/A	
63-12	Y	Y	N ^c	42486401
63-13	Y	N/A	N ^c	

Key: Y=yes; N=no; I=a decision cannot be made at this time; S=fully satisfies requirement;
P=partially; N/A=not applicable; U=unsatisfactory.

^a MRID No. is not listed if study or summary are found to be inadequate.

^b This is a product specific requirement to be dealt with by RD/RSB during Phase 5.

^c The data submitted by the registrant under this guideline were generated with the EP as the test substance; however, no additional data are required since the necessary information for the TGAI can be obtained from the literature.

^d No data are required under this guideline, since the TGAI is a gas at room temperature. The data, however, are easily obtained from the literature.

5

^a Data submitted by the registrant under this guideline pertained to the EP, rather than to the TGAI or PAI. However, no additional data are required, since the TGAI is a gas at room temperature.

^c No data are required under this guideline, since the TGAI is polar.

^a The registrant submitted the pH of the EP, which satisfies the requirement for the TGAI.

^b No data submitted were submitted by the registrant for the TGAI; however, no additional data are required, since this information can be obtained from the literature.

PRODUCT CHEMISTRYCase Name/Case No.: Chlorine Dioxide/4023Chemical Name(s)/Chemical No(s): Chlorine Dioxide/020503Registrant: Chemical Cealin Co.

Guideline Number	Is requirement applicable?	Does summary or available information indicate MRID is a candidate for Phase 5 review?	Are additional data required?	MRID Number ^a
61-1	N ^b	N/A	N/A	
61-2(a)	Y	N/A	Y ^c	
61-2(b)	Y	N/A	Y ^c	
62-1	Y	N/A	Y ^c	
62-2	N ^b	N/A	N/A	
62-3	N ^b	N/A	N/A	
63-2	Y	N/A	N ^d	
63-3	Y	N/A	N ^d	
63-4	Y	N/A	N ^d	
63-5	N ^b	N/A	N/A	
63-6	N ^b	N/A	N/A	
63-7	Y	N/A	N ^e	
63-8	Y	N/A	N ^d	
63-9	N ^f	N/A	N/A	
63-10	Y	N/A	N ^d	
63-11	N ^g	N/A	N/A	
63-12	Y	N/A	Y ^h	
63-13	Y	N/A	N ^d	

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^a MRID No. is not listed if study or summary are found to be inadequate.

^b This is a product specific requirement to be dealt with by RD/RSB during Phase 5.

^c The registrant indicated during Phase 2 that an existing study not previously submitted would be submitted. Correspondence attached to the Phase 3 package indicates that the data have been submitted; however, these data were not included in the CBRS Phase 4 review package, nor were the MRIDs referenced.

^d During Phase 2, the registrant committed to submit an existing study not previously submitted; however, this information can be easily obtained, TGAI/PAI as the test substance, from the literature.

^o No data are required under this guideline, since the TGAI is a gas at room temperature. The data, however, are easily obtained from the literature.

^f No data are required under this guideline, since the TGAI is a gas at room temperature.

^g No data are required under this guideline, since the TGAI is polar.

^h During Phase 2 the registrant committed to submit an existing study not previously submitted. This has not been received. Additional data are required.

8

PRODUCT CHEMISTRYCase Name/Case No.: Chlorine Dioxide/4023Chemical Name(s)/Chemical No(s): Chlorine Dioxide/020503Registrant: International Dioxide

Guideline Number	Is requirement applicable?	Does summary or available information indicate MRID is a candidate for Phase 5 review?	Are additional data required?	MRID Number ^a
61-1	N ^b	N/A	N/A	
61-2(a)	Y	N/A	Y ^c	
61-2(b)	Y	N/A	Y ^c	
62-1	Y	N/A	Y ^c	
62-2	N ^b	N/A	N/A	
62-3	N ^b	N/A	N/A	
63-2	Y	N/A	N ^d	
63-3	Y	N/A	N ^d	
63-4	Y	N/A	N ^d	
63-5	N ^e	N/A	N/A	
63-6	N ^e	N/A	N/A	
63-7	Y	N/A	N ^e	
63-8	Y	N/A	N ^d	
63-9	N ^f	N/A	N/A	
63-10	Y	N/A	N ^d	
63-11	N ^g	N/A	N/A	
63-12	Y	N/A	Y ^h	
63-13	Y	N/A	N ^d	

Key: Y=yes; N=no; I=a decision cannot be made at this time; S=fully satisfies requirement; P=partially; N/A=not applicable; U=unsatisfactory.

^a MRID No. is not listed if study or summary are found to be inadequate.

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^o No data are required under this guideline, since the TGAI is a gas at room temperature. The data, however, are easily obtained from the literature.

^f No data are required under this guideline, since the TGAI is a gas at room temperature.

^s No data are required under this guideline, since the TGAI is polar.

^h During Phase 2 the registrant committed to submit an existing study not previously submitted. This has not been received. Additional data are required.