US EPA ARCHIVE DOCUMENT

Sub, file

Case No.:4022
Chemical No(s).:020501
DP Barcode No.:D182547 and D183313
CBRS No.:10576 and 10701

CBRS TRANSMITTAL SHEET FOR PHASE 4 REVIEWS

Transmitted to HED on 09/15/92
Case name: Chlorine
Chemical name(s): Chlorine
Data submitter(s): Chlorine Reregistration Task Group (CRTG)

CRM: Barbara Briscoe/Betty Crompton Phone #: 308-8067

Branch: CBII, Reregistration Section II
Reviewed by: Bonnie Cropp-Kohlligian Date: 11/30/92

Approvals:
Section Head: William J. Hazel, Ph.D. Date: 11/30/92
Branch Chief: Edward Zager Date: 12/1/92
Division Approval: Penelope Fenner-Crisp, Ph.D. Date: 12/2/92

cc: BLCKohlligian, List D Reregistration File, RF, SF, Circ., Betsy Grim (EFED).

1

Case No.:4022
Chemical No(s).:020501
DP Barcode No.:D182547 and D183313
CBRS No.:10576 and 10701

Issues/flags:

This action contains a request for a DATA WAIVER ( )
TIME EXTENSION ( )
ALTERED/DELETED USE ( )

Other: Use information gathered from LUIS report dated 8/20/92 and REFS. Chlorine gas is used as a disinfectant, sanitizer, bacteriostat, microbicide/microbiostat, and algicide, on a variety of fruit/vegetable/seed crops to prevent decay and in food processing water systems (EPA Reg. No. 37982-2 only), pasteurizer/warmer/cannery cooling water systems, pulp/paper mill water systems, swimming pool water systems, human drinking water systems, commercial/industrial water cooling systems, ornamental ponds/aquaria, sewage systems, lakes/ponds/reservoirs (without human and wildlife use) and in/on food/meat/poultry processing plant premises and equipment.

Chlorine gas is exempt from the requirement of a tolerance when used preharvest or postharvest in solution on all raw agricultural commodities [40 CFR 180.1095]. No tolerance/exemption currently exists for the use of chlorine gas in potable water.

NOTE TO CRM: CBRS suspects that RD/RSB has conducted a duplicate review of the product chemistry package. If this is the case, please don't hesitate to set up a meeting at which SRRD, RD, and CBRS will resolve any differences.

Response, by Guideline

Guideline #: 171-4(a) Description: Nature of residue - plants
Is requirement applicable? (Y/N): Y

Guideline #: 171-4(b) Description: Nature of residue - animals
Is requirement applicable? (Y/N): Y

Guideline #: 171-4(c) Description: Res. analyt. method - plant
Is requirement applicable? (Y/N): Y

Guideline #: 171-4(d) Description: Res. anal. method - animals
Is requirement applicable? (Y/N): Y

Guideline #: 171-4(e) Description: Storage stability
Is requirement applicable? (Y/N): Y

Guideline #: 171-4(j) Description: Mag. meat/milk/poultry/eggs
Is requirement applicable? (Y/N): Y

Guideline #: 171-4(k/l) Description: Crop field trials/process
Is requirement applicable? (Y/N): Y

Discussion: In their Phase 2 response, the registrant indicated that these data requirements did not apply to their chemical. No residue chemistry data have been submitted during Phase 2 or Phase 3 in support of reregistration of chlorine gas.

Currently, chlorine gas is exempt from the requirement of a tolerance when used preharvest or postharvest in solution on all raw agricultural commodities [40 CFR 180.1095]. Assuming that TOX upholds this exemption, plant metabolism, storage stability, and magnitude data are not required.

Since an exemption exists for chlorine residues in/on all RACs, the only remaining source of chlorine which

could result in residues of interest in the edible tissues of livestock, milk and eggs would come from chlorinated potable water. While chlorinated water 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 (chlorinated) water is not available and where an alternate/less costly water source is normally used. Furthermore, in the event that chlorinated water 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 [40 CFR 180.69(c)] or residues significantly above the naturally occurring background levels. Therefore, animal metabolism, storage stability, and magnitude data are not required.

Data gap: None.

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?: ___
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion: In their Phase 2 response, the registrant indicated that these data requirements did not apply to their chemical. No residue chemistry data have been submitted during Phase 2 or Phase 3 in support of reregistration of chlorine gas.

The LUIS report indicates that chlorine gas is used in water treatment facilities to prepare drinking water for public consumption. The goal of treating water

with chlorine gas is to provide enough hypochlorous acid to oxidize organic matter in the treated water and finally to establish and maintain an effective residual of hypochlorous acid in the system to suppress the growth of microorganisms in the water. According to the LUIS report, a typical treatment is to feed 5 to 6 ppm available chlorine into the system in order to achieve a 0.2 ppm residual chlorine level (American Water Works Association). The loose term "chlorine" is generally used by the industry to mean "available chlorine" and "residual chlorine" to refer to hypochlorous acid.

Since chlorine gas is actually used in water treatment facilities 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 residues of chlorine gas in potable water resulting from the maximum uses of chlorine gas in water treatment facilities.

Guideline #: 171-4(g) Description: Magnitude residue - fish
Is requirement applicable? (Y/N): N

Guideline #: 171-4(h) Description: Mag. res. - irrigated crop
Is requirement applicable? (Y/N): N

Discussion: The registered uses of chlorine gas are not expected to result in any residues in/on fish/aquatic organisms or irrigated crops; therefore, these data are not required.

Data gap: None.

Guideline #: 171-4(i) Description: Mag. res. - food handling
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: ___
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___

Discussion: In their Phase 2 response, the registrant indicated that these data requirements did not apply to their chemical. No residue chemistry data have been submitted in support of reregistration of chlorine gas. However, applications are permitted on food/meat/poultry processing premises and equipment (LUIS specifies EPA Reg. No. 37982-2 only; registered by All Pure Chemical Company which is not listed as a member of the CRTG).

The label specifies ppm of available chlorine for food/meat/poultry processing premises. A chlorine level of 4 to 5 ppm is recommended under normal operating conditions and 10 to 25 ppm chlorine is recommended for cleaning operations. The label further specifies available chlorine levels for food/meat/poultry processing equipment at 50 to 100 ppm available chlorine for sanitizing large equipment and 200 ppm available chlorine for a spraying application to large equipment. The label recommends 15 ppm for porous food contact surfaces and 200 ppm for non-porous food contact surfaces.

Although chlorine gas is not specified under 21 CFR 178.1010 as a sanitizer which may be safely used on food processing equipment and utensils, and on other food contact articles, Section 178.1010(b)(1) does specify sodium hypochlorite. In solution, chlorine gas and sodium hypochlorite produce the same active ingredient, hypochlorous acid. Therefore, CBRS assumes that chlorine gas used in solution as a food contact surface sanitizer in/on food processing premises/equipment is under FDA purview as well.

6

PRODUCT CHEMISTRY

Case No.: 4022 Case Name: Chlorine
Chemical No(s).: 020501
Chemical Name(s): Chlorine
Registrant: Chlorine Reregistration Task Group (CRTG)

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	Y	N	Y[c]	
61-2(a)	Y	Y	N	41767301
61-2(b)	Y	N	Y[d]	
62-1	Y	N	Y[e]	
62-2	Y	N	Y[f]	
62-3	Y	Y	N	41767302
63-2	Y	Y	N	41767303
63-3	Y	Y	N	41767303
63-4	Y	N	N	41767303
63-5	N	N/A	N	
63-6	N	N/A	N	
63-7	Y	Y	N	41767303
63-8	Y	Y	N	41767303
63-9	Y	Y	N	41767303
63-10	N	N/A	N	
63-11	N	N/A	N	
63-12	Y	N	Y[g]	
63-13	Y	N	Y[h]	

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]A superscript in this column indicates any necessary footnotes, including responses to new data waiver/time extension requests.

[c]Members of the CRTG which hold MP registrations must submit up-to-date CSFs.

[d]A discussion of the formation of impurities must be provided for each manufacturing process.

[e]Preliminary analysis of five samples from each of the manufacturing processes is required.

[f]Certified limits are required for all MPs.

[g]pH determinations are required for substances which can be diluted or dispersed with water.

[h]Information must be provided which include a discussion of the sensitivity of the active ingredient to metal ions and metal and the stability of the active ingredient at normal and elevated temperatures.

Note to the PM:

The following product chemistry submissions were sent to CBRS but were not reviewed:

Company Name	MRID No.	Comments
Chemland, Inc	42084301	Chemland, Inc. is not a member of CRTG and the submission concerned an Iodine Complex.
Saskatoon Chemicals Ltd.	42058501	Duplicate of MRID 41767301.
	42058502	Duplicate of MRID 41767302.
	42058503	Duplicate of MRID 41767303.