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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

JAN 24 1995

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT:

Iprodione. Magnitude of the Residue Studies for Caneberries and

Raspberries. Reregistration Case No. 2335. Chemical No. 109801. MRIDs #40244001 and 43262501 DP Barcodes D208276 and D205015

CBRS #14497 and 13955

FROM:

Steven A. Knizner, Chemist

Chemistry Pilot Review Team

Health Effects Division (7509C)

THRU:

Francis B. Suhre, Acting Chief

Chemistry Branch II - Reregistration Support

Health Effects Division (7509C)

TO:

William Wooge, PM Team 52

Special Review and Registration Division (7505C)

The Iprodione Phase 4 Review (C. Olinger, 3/15/92) required the registrant to conduct magnitude of the residue trials for raspberries in CA. The WP formulation was to be used at an application rate of 1.0 lb ai/A, with a total of 4 applications (the first at early bloom and final three applications at appropriate intervals (14 days) and PHI). Applications were to be made using ground equipment.

In response, Rhone-Poulenc has submitted data (MRID #43262501) from three raspberry field trials conducted in 1992 in CA. Rhone-Poulenc had previously submitted data (MRID #40244001) from 10 field trials conducted in 1986 depicting the residues of iprodione, its isomer, and its metabolite in/on the raw agricultural commodity of blackberries grown in OR(4) and raspberries grown in MI(1), OH(1), OR(2), and WA(2). CBRS notes that MRID #40244001 was screened in Phase IV and was determined to be a candidate for Phase V review.

Data from these submissions are described and presented in the attached Data Evaluation Record, which was produced by Dynamac Corp. under contract to the Agency.

In addition to various other tolerances, the following tolerances are established for the combined residues of iprodione, its isomer, and its metabolite [40 CFR §180.399(a)]: 25.0 ppm for caneberries; 15.0 ppm for boysenberries; and 15.0 ppm for raspberries. CBRS notes that residues in/on raspberries and boysenberries are presently covered by two tolerances, caneberries at 25 ppm and individual tolerances at 15 ppm.

In PP#7F3542 the registrant petitioned for a caneberry crop group tolerance. The Petition Review Quick Form (M.Nelson, 7/28/87) noted that "If/when this caneberry tolerance is established, the separate commodity listings for boysenberries and raspberries need to be deleted from 40 CFR 180.399(a)." The July, 1994 CFR does not reflect this recommended change. Issues pertaining to tolerance reassessment with respect to caneberries will be addressed when the reregistration eligibility decisions for iprodione are made.

Recommendations

The available data support the established tolerance of 25 ppm for the combined residues of iprodione, its isomer, and its metabolite in/on caneberries. Tolerances for boysenberries and raspberries should be revoked in conjunction with the iprodione RED.

CBRS notes that the tolerance for caneberries is based upon residue data obtained in 1986 using a 1.25x application rate (5 foliar applications at 1.0 lb ai/application) and backpack sprayer application. Residue values obtained in 1992 using the 1.0x application rate (4 foliar applications at 1.0 lb ai/application) and a boom sprayer were considerably lower (although insufficient data are available to recommend for a lower tolerance level). CBRS considers boom sprayer application to be more representative of actual commercial practices. The registrant attributed the higher residue levels observed in the 1986 trials to the additional application of iprodione and to the use of a backpack sprayer for iprodione application.

NOTE TO CRM:

The registrant may elect to conduct additional field trials using a boom sprayer and the current label application rate (4 foliar applications at 1.0 lb ai/application, with the first application at early bloom, second at full bloom, a 14 day interval for last two applications, and a 0 day PHI). According to the Follow-Up Guidance for Number and Location of Domestic Crop Field Trials, EPA 738-K-94-001, a minimum of 5 trials (and 10 samples) are required (either blackberry or raspberry). Three trials should be conducted in region 12, one trial in regions 1 or 2, and one trial in regions 5 or 6. Side by side studies should be conducted using the various formulations (WP, EC, and FIC) registered for use on caneberries. The study reported in MRID #43262501 (three raspberry field trials conducted in 1992 in CA) would suffice for the 3 trials required for Region 12.

Conclusions

- 1. MRID #40244001 Ten field trials were conducted in 1986 in the test states of MI(1), OH(1), OR(6), and WA(2) depicting the magnitude of iprodione residues of concern in/on blackberries and raspberries. Blackberries and raspberries were harvested 0 days following the last of five foliar applications, with 5- to 40-day retreatment intervals, of the 50% WP formulation at 1.0 lb ai/A/application (1.25x the maximum registered seasonal rate, current labels only permit 4 applications per season) in 50-100 gal water/A using ground equipment (CO₂ backpack sprayer).
- 2. MRID #43262501 Three field trials were conducted in 1992 in CA depicting the magnitude of iprodione residues of concern in/on raspberries. Raspberries were harvested 0 days following the last of four foliar applications, with 14- to 21-day retreatment intervals of the 50% WP formulation (EPA Reg. No. 264-453) at 1.0 lb ai/A/application (1x the maximum registered seasonal rate) in 100 gal water/A using ground equipment (boom sprayer).
- 3. The submitted method validation and concurrent method recovery data indicate that Rhone-Poulenc Method No. 151 and the common moiety method are adequate for residue data collection of iprodione residues of concern in/on caneberries.
- 4. The blackberry data (MRID 40244001) from field trials conducted in 1986 indicate that the combined residues of iprodione, its isomer, and its metabolite will not exceed the established tolerance (25.0 ppm for caneberries) in/on blackberries. The combined residues (corrected for method recoveries) in/on blackberries were 6.11-22.81 ppm.
- 5. The raspberry data (MRIDs 40244001 and 43262501) from separate field trials conducted 1986 and 1992, respectively, indicate that the combined residues will not exceed the established tolerance of 15.0 ppm in/on raspberries. The combined residues in/on raspberries treated with the described treatment regime were <1.28-13.85 ppm in/on samples collected from the 1986 trials and 1.7-5.7 ppm in/on samples collected from the 1992 trials. The registrant attributed the higher residue levels observed in the 1986 trials to the additional application of iprodione and to the use of a backpack sprayer for iprodione application.
- 6. CBRS notes that residues in/on raspberries and boysenberries are presently covered by two tolerances, caneberries at 25 ppm and individual tolerances at 15 ppm. Issues pertaining to tolerance reassessment with respect to caneberries will be addressed when the reregistration eligibility decisions for iprodione are made.

ce: S.F., circ., R.F., List B File, S.Knizzer

RDI: W. Smith, B. Cropp-Kohlligian, L.Edwards, P.Deschamp, C. Olinger, 1/9/95, M.Metzger, 1/19/94, F.Suine 1/20/95
7509C:CBRS:CM#2:305-6903:SAK:sek:birodion\resp:1/9/95

DATA EVALUATION RECORD

DP BARCODE(S):

D205015 and D208276

CBRS NO(S).:

13955 and 14497

STUDY TYPES:

Magnitude of the Residue in/on Caneberries

[Guideline Reference No. 171-4(k)].

STUDY SPONSOR:

Rhone-Poulenc Ag Company (Research Triangle Park, NC).

MRID NOS.:

40244001 C. Guyton. Rovral Residue Data for Caneberries, 1986 Field Program E-29. ASD Report No. 87-236. Study

completed 5/87.

43262501 A. Hovis. Ground Application of ROVRAL® WP

Fungicide to Raspberries to Determine the Magnitude of

Residue Present After Harvest. Rhone-Poulenc Study Number:

USA92R26. Study Completed on 6/1/94.

PERFORMING LABORATORIES:

Field: MRID 40244001: Michigan State University (Onadaga,

MI); J.E. Merrick (Wooster, OH); Oregon State University (Aurora and Corvallis, OR); and S. Johnson, Exp. Station

(Puyallup and Vancouver, WA).

MRID 43262501: Plant Sciences, Inc. (Watsonville, CA)

Analytical: MRID 40244001: Rhone-Poulenc (Monmouth

Junction, NJ).

MRID 43262501: Horizon Laboratories, Inc. (Columbia, MO).

TEST MATERIAL APPLIED TO CROP:

Iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-

1-imidazolidinecarboxamide] (CAS No. 36734-19-7).

EPA REG. NO.:

264-453 (Rovral® Fungicide).

RESIDUES MEASURED:

Iprodione

Iprodione isomer [3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide]

Iprodione metabolite [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide]

DETAILED CONSIDERATIONS

Magnitude of the Residue in/on Caneberries

Rhone-Poulenc Ag Company submitted data (1987; MRID 40244001) from 10 field trials conducted in 1986 depicting the residues of iprodione, its isomer, and its metabolite in/on the raw agricultural commodities of blackberries grown in OR(4) and raspberries grown in MI(1), OH(1), OR(2), and WA(2). Rhone-Poulenc Ag Company also submitted data (1994; MRID 43262501) from three raspberry field trials conducted in 1992 in CA(3). Data from these submissions are described and presented in this Data Evaluation Record. We note that MRID 40244001 was screened in Phase IV and was determined to be a candidate for Phase V review.

Established tolerance: The following tolerances have been established for the combined residues of iprodione, its isomer, and its metabolite in/on caneberries [40 CFR §180.399(a)]: 25.0 ppm for caneberries; 15.0 ppm for boysenberries; and 15.0 ppm for raspberries.

Use patterns: A REFS search conducted 9/27/94 identified four Rhone-Poulenc iprodione end-use products registered for use on caneberries: two 50% WP formulations (EPA Reg. No. 264-453, ROVRAL® Fungicide dated 7/7/94; and EPA Reg. No. 264-532, ROVRAL® 50 SP, dated 7/6/94), a 4 lb/gal FIC formulation (EPA Reg. No. 264-482, ROVRAL® Flowable, dated 7/7/94), and a 50% EC formulation (EPA Reg. No. 264-524, ROVRAL® WG Fungicide, dated 5/x/94; a copy of the label for this product was not available for review). A maximum of four foliar applications at 0.5-1.0 lb ai/A/application may be made per growing season using ground equipment in a minimum of 100 gal water/A. The first application is to be made at early bloom (5-10% bloom), and the second application is to be made at full bloom. Two additional applications may be made at 14-day intervals or as needed. A 0-day PHI has been established.

Discussion of the data - MRID 40244001: Ten field trials were conducted in 1986 in the test states of MI(1), OH(1), OR(6), and WA(2) depicting the magnitude of iprodione residues of concern in/on blackberries and raspberries. Blackberries and raspberries were harvested 0 days following the last of five foliar applications, with 5- to 40-day retreatment intervals, of the 50% WP formulation at 1.0 lb ai/A/application (1.25x the maximum registered seasonal rate) in 50-100 gal water/A using ground equipment (CO₂ backpack sprayer).

No information pertaining to the method of harvest was provided. Following harvest, samples were stored frozen (temperature unspecified) for 11-65 days prior to shipment via ACDS truck to the analytical laboratory (Rhone-Poulenc, Inc., Black Horse Lane, Monmouth Junction, NJ). At the laboratory, samples were stored frozen (-18 C) prior to analysis. Total storage intervals between harvest and analysis were 15-104 days.

Residues in/on treated and untreated blackberries and raspberries were determined using Rhone-Poulenc Method 151, a GC/ECD method in which iprodione, its isomer, and its

metabolite are separately determined. The results of the blackberry and raspberry field trials are presented in Table 1. Apparent residues of iprodione, its isomer, and its metabolite were nondetectable (<0.05 ppm each) in/on three untreated blackberry samples and six untreated raspberry samples. Detectable residues of the iprodione isomer, RP-30228, were observed in/on one sample of untreated blackberries (0.12 ppm); residues of iprodione and its metabolite were nondetectable (<0.05 ppm each) in/on this sample. The registrant stated that no explanation could be offered for the detectable residues in untreated blackberries.

Table 1. Residues of iprodione, its isomer (RP-30228), and its metabolite (RP-32490) in/on caneberries harvested 0 days following the last of five foliar applications of the 50% WP formulation at 1.0 lb ai/A (1.25x the maximum registered seasonal rate) using ground equipment.

Test	Retreatment	Storage Interval		Residue	s, ppm *	
site	Interval (days)	(days)	Iprodione	RP-30228	RP-32490	Combined
Blackber	ries			•		
OR	12-16	39	15.42	0.35	0.14	15.91
	12-15	43	5.82	0.22	0.07	6.11
	12-15	43	10.91	0.36	0.12	11.39
	7-40	15	21.87	0.74	0.20	22.81
Raspberr	ies					
MI	7-18	64:	7.27	0.26	0.10	7.63
ОН	6-14	104	1.14	0.09	< 0.05	<1.28
OR	10-28	36	4.19	0.10	0.11	4.40
	13-20	56	4.38	0.11	0.07	4.56
WA	5-14	55	11.39	0.26	0.15	11.80
	14-17	49	13.44	0.27	0.14	13.85

Each residue value represents one sample. Residue values were corrected for method recovery; insufficient raw data were provided to "uncorrect" residue values.

Discussion of the data - MRID 43262501: Three field trials were conducted in 1992 in the test state of CA depicting the magnitude of iprodione residues of concern in/on raspberries. Raspberries were harvested 0 days following the last of four foliar applications, with 14- to 21-day retreatment intervals of the 50% WP formulation (EPA Reg. No. 264-453) at 1.0 lb ai/A/application (1x the maximum registered seasonal rate) in 100 gal water/A using ground equipment (boom equipment). CBRS notes that the test substance was incorrectly identified

by EPA Reg. No. 264-482 in the submission; this Reg. No. is for ROVRAL® 4 Flowable Fungicide, a 4 lb/gal FlC formulation.

Raspberry samples were harvested by hand, placed in plastic-lined cloth bags, and stored under dry ice immediately. The samples were transferred to frozen storage within two hours of harvest. Adequate raw data pertaining to field trial information, application of the test substance, and sample-handling procedures were provided.

Intervals from sampling to shipment, extraction, and analysis were provided for each test. The harvested treated and untreated raspberry samples were stored frozen at the field facilities; although the registrant indicated that freezer temperature ranges at the field trial site were included in Appendix B of the submission, this information was not found by the study reviewer. Samples were shipped frozen via ACDS freezer truck to Rhone-Poulenc (Research Triangle Park, NC) where they were stored frozen (<-10 C). Samples were shipped to Horizon Laboratories for analysis in January 1994, where they were stored frozen at -20 to -10 C. The analytical laboratory noted that samples had been homogenized with dry ice at Rhone-Poulenc prior to shipment; however, no data were provided concerning the dates of sample homogenization at Rhone-Poulenc. The intervals between harvest and residue analysis were 504-516 days (~17 months); samples were analyzed within 1 day of extraction.

Residues in/on treated and untreated raspberries were determined using a GC/ECD method in which iprodione, its isomer, and its metabolite are derivatized to a common moiety. The results of the raspberry field trials are presented in Table 2. Apparent iprodione residues of concern were nondetectable (<0.05 ppm) in/on three untreated raspberry samples.

Table 2. Iprodione residues of concern found in/on raspberries harvested 0 days following four foliar applications of the 50% WP formulation at 1.0 lb ai/A (1x the maximum registered seasonal rate) using ground equipment.

Trial, Site	Number of Samples	Retreatment Interval (days)	Residues • (ppm Iprodione Equivalents)
CA, 92-063	3	14-17	3.6, 4.4, 4.5
CA, 92-064	3	15-21	1.7, 3.1, 3.8
CA, 92-065	3	14-15	5.2, 5.6, 5.7

Residue values were not corrected for concurrent method recovery.

No production statistics for blackberries or raspberries are available from the 1992 USDA Agricultural Statistics. Blackberry field trials were conducted in Region 12 which represents 73% of U.S. blackberry production; raspberry trials were conducted in Regions 5 and 12, which together represent 89% of U.S. raspberry production ("EPA Guidance on Number and

Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances," E. Saito and E. Zager, 6/2/94).

Summary of studies: The blackberry data (MRID 40244001) from field trials conducted in 1986 indicate that the combined residues of iprodione, its isomer, and its metabolite will not exceed the established tolerance (25.0 ppm for caneberries) in/on blackberries harvested 0 days following the last of five foliar applications of the 50% WP formulation at 1.0 lb ai/A/application (1.25x the maximum registered seasonal rate) using ground equipment. The combined residues (corrected for method recoveries) in/on blackberries treated with the described treatment regime were 6.11-22.81 ppm; insufficient raw data were provided to "uncorrect" residue values.

The raspberry data (MRIDs 40244001 and 43262501) from separate field trials conducted 1986 and 1992, respectively, indicate that the combined residues will not exceed the established tolerance of 15.0 ppm in/on raspberries harvested 0 days following the last of four (1992 trials) or five (1986 trials) foliar applications of the 50% WP formulation at 1.0 lb ai/A/application (1x or 1.25x the maximum registered seasonal rate). The combined residues in/on raspberries treated with the described treatment regime were <1.28-13.85 ppm in/on samples collected from the 1986 trials and 1.7-5.7 ppm in/on samples collected from the 1992 trials. Residue values from the 1986 field trials were corrected by the registrant for concurrent method recoveries whereas the values reported from the 1992 trials were not corrected for method recoveries. The registrant attributed the higher residue levels observed in the 1986 trials to the additional application of iprodione and to the use of a backpack sprayer for iprodione application.

We note that residues in/on raspberries and boysenberries are presently covered by two tolerances, caneberries at 25 ppm and individual tolerances at 15 ppm. Issues pertaining to tolerance reassessment with respect to caneberries will be addressed when the reregistration eligibility decisions for iprodione are made.

Residue Analytical Methods

Caneberry samples from the 1986 field trials (1987; MRID 40244001) were analyzed for residues of iprodione, its isomer, and its metabolite by Rhone-Poulenc (Monmouth Junction, NJ) using a GC/electron capture detection (ECD) method, Rhone-Poulenc Method No. 151. The limit of quantitation was 0.05 ppm for each analyte. Rhone-Poulenc Method No. 151 has been submitted for inclusion in PAM Vol. II (PP#1G3998, J. Garbus, 6/8/92 and 12/15/92; PP#3F2810, R. Perfetti, 3/21/82).

Blackberry and raspberry samples were homogenized with acetone and filtered. The acetone was removed from the filtrate by rotary evaporation, and a solution of 1% sodium sulfate was added. The extract was partitioned three times with ethyl acetate:dichloromethane (10:90, v:v) and the organic phases were combined. The solvent was then removed by rotary evaporation and the residue was dissolved in ethyl acetate:toluene (3:1, v:v) for

cleanup by GPC using a Bio-Beads column. The eluate was evaporated to dryness under vacuum and the residue was dissolved in ethyl acetate:hexane (3:97, v:v). The extract was then cleaned up on a Florisil column; iprodione and its isomer were eluted with ethyl acetate:hexane (15:85, v:v), and iprodione metabolite was eluted with ethyl acetate:hexane (1:1, v:v). The eluates were evaporated to dryness by rotary evaporation and then dissolved in hexane (iprodione and its isomer) and benzene (iprodione metabolite) prior to analysis by GC/ECD.

Concurrent method recoveries were determined by Rhone-Poulenc to establish the suitability of the method for residue data collection purposes. These data are presented in Table 3.

Table 3. Concurrent method recoveries of iprodione, its isomer (RP-30228), and its metabolite (RP-32490) from untreated samples of caneberries fortified with each analyte and analyzed using Rhone-Poulenc Method No. 151 (MRID 40244001).

	F:		% Recovery *	
Commodity	Fortification Level (ppm)	Iprodione	RP-30228	RP-32490
Blackberries	0.5		98.9, 120.1	105.8, 110.4
	1.0	90.0, 144.5	-	-
•	5.0	84.5, 102.3		-
Raspberries	0.2		108.5	120.4
	1.0		101.7, 103.2, 109.5	105.7, 108.7, 122.6
	2.0	117.1		
	5.0	101.0, 109.7		<u> </u>
	10.0	97.3, 126.8	-	
	20.0	96.7	-	-

Each recovery value represents one sample.

Raspberry samples from the 1992 field trials (1994; MRID 43262501) were analyzed for residues of iprodione, its isomer, and its metabolite by Horizon Laboratories (Columbia, MO) using a GC/electron capture detection (ECD) method in which the analytes are hydrolyzed to a common moiety, 3,5-dichloroaniline (DCA), and then derivatized prior to analysis. The limit of quantitation was 0.05 ppm; the registrant estimated the limit of detection limit to be 0.004 ppm. The method included in this submission is entitled "Method for the Analysis of Rovral®-Related Residues: Common Moiety Method (Version 2.0 for Raspberries)."

Raspberry samples which had been ground with dry ice were combined with 3 N aqueous KOH and heated at 100 C over night to hydrolyze iprodione residues of concern to 3,5-dichloroaniline. The hydrolyzed samples were combined with water and distilled, and the distillate was partitioned with water and dichloromethane. Following phase separation, the dichloromethane fraction was collected and iprodione residues were derivatized to N-(3,5-dichlorophenyl)-2-chloropropylamide (DCPA) by the addition of 2-chloropropionyl chloride. The extract was rotary-evaporated to dryness, taken up in cyclohexane, and evaporated to dryness again. The dried residue was dissolved in 6% diethyl ether in hexane and purified on a Florisil column. DCPA was eluted from the column with 15% diethyl ether in hexane. The eluant was rotary-evaporated to dryness, dissolved in ethyl acetate, and analyzed by GC/ECD. Residues were reported as iprodione equivalents.

Method validation and concurrent method recoveries were conducted by Horizon Laboratories to determine the suitability of this method for residue data collection purposes. In the method validation study, untreated control samples of raspberries from the 92-063 field trial were fortified with iprodione, its isomer (RP-30228), and its metabolite (RP-32490) each at 0.05 ppm, 0.50 ppm, and 5.00 ppm. Data concerning apparent residues in unfortified samples were not included in the submission. Representative chromatograms, sample calculations, and standard curves were provided. Method recovery data are presented in Table 4. Concurrent method recoveries (in iprodione equivalents) were 88.5%, 94.2%, and 98.2% from three untreated raspberry samples fortified with iprodione at 0.05 ppm, 5.00 ppm, and 10.00 ppm, respectively.

Table 4. Method recoveries of iprodione, its isomer (RP-30228), and its metabolite (RP-32490) from untreated samples of raspberries fortified with each analyte and analyzed using the common moiety GC/ECD method (MRID 43262501).

Fortification Level (ppm)		% Recovery *	
	Iprodione	RP-30228	RP-32490
0.05	83.0, 98.1	88.3, 97.1	92.9, 102.3
0.50	97.2, 99.0	89.7, 90.4	96.6, 100.6
5.00	95.3, 100.6	93.5, 94.7	94.4, 95.6

Each recovery value represents one sample.

The submitted method validation and concurrent method recovery data indicate that the GC/ECD methods, Rhone-Poulenc Method No. 151 and the common moiety method, are adequate for residue data collection of iprodione residues of concern in/on caneberries.

Storage Stability Data

All samples from the submitted field trials were stored frozen prior to residue analysis. The maximum storage interval prior to residue analysis of caneberries collected from the respective field trials was 514 days (~17 months). Data depicting the frozen storage stability of iprodione, its isomer, and its metabolite in/on small fruits and berries (blueberries, grapes, and strawberries) are currently under review (MRID 43273401, CBRS No. 14162, D206161). These data indicate that fortified iprodione residues of concern are stable for up to 12 months under frozen storage conditions.

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The second secon		10520		-	raspberries	Dem.y	•	•		ground	100.00	14-15	4 .				ó				S	٧.		-	02/11/94

IOTES: Vest a yest that was conducted

NA = Not applicable

RP - 2028 = Inrodone isomer: RP - 22480 = Inrodone ma

– 50228 = (prodone teomer; FP – 52460 ≈ (prodone metabolite. Julia value from Sed brids conducted in 1988 were conscied for method recovery; the registrant did not state which recovery val

Residue values from Beld tries conducted in 1992 were not corrected for π = Site 92 – 063, $^{\pm\pi}$ = site 92 – 064, $^{\pm\pi}$ = site 92 – 065.

' = SNs 92 - O53, "" = sNs 52 - O54, "" = sNs 52 - O55. 966 teles used CO2 backpack sprayers, 1992 tips used boom equip