

Evaluation Report for Category A, Subcategory 1.3 Application

Application Number: 2013-6735
Application: New Active Ingredient – Maximum Residue Limits (only)
Product: Isopyrazam Technical
Registration Number: NA
Active ingredients (a.i.): Isopyrazam
PMRA Document Number: 2568690

Background

Maximum residue limit(s) (MRLs) for isopyrazam were previously established for imported bananas.

Purpose of Application

The purpose of this application was to establish an import MRL for isopyrazam for imported peanuts and apples.

1.0 Chemistry Assessment

Please refer to the Evaluation Report under Application Number 2010-3110 for the chemistry assessment of isopyrazam.

2.0 Methods for Residue Analysis

Please refer to the Evaluation Report under Application Number 2010-3110 for the methods for residue analysis for isopyrazam.

3.0 Health Assessments

3.1 Toxicology Summary

Please refer to the Evaluation Report under Application Number 2010-3110 for toxicological information on isopyrazam.

3.2 Occupational and Residential Risk Assessment

As this is an import MRL application, no occupational or residential risk assessment was required.

3.3 Food Residues Exposure Assessment

3.3.1 Residues in Plant Foodstuffs

Please refer to the Evaluation Report under Application Number 2010-3110 for a summary of the previously reviewed data and the rationale for the regulatory decision.

The information captured herein relates to new field trial and processed commodity data provided to support the establishment of MRLs on imported apples and peanuts, and to the changes in dietary exposure due to the update of the dietary exposure assessments to include these commodities.

Apples were processed and isopyrazam residues concentrated in wet pomace (2.1x), dry pomace (4.9x) and dried apples (5.7x). Field trials conducted in Chile and Nicaragua using end-use products containing isopyrazam at slightly exaggerated rates in or on apples and peanuts are sufficient to support the proposed MRLs.

3.3.2 Dietary Risk Assessment

Acute, non-cancer chronic and cancer dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 4.02), which incorporates food consumption data from the National Health and Nutritional Examination Survey, What We Eat in America (NHANES/ WWEIA) dietary survey for the years 2005-2010 available through CDC's National Center for Health Statistics (NCHS).

3.3.2.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the basic chronic non-cancer analysis for isopyrazam: 100% crop treated, default processing factors (where available), and combined anti- + syn-isomer residues of isopyrazam in crops at MRL values. The basic non-cancer chronic dietary exposure from all supported isopyrazam-treated imported food uses (alone) for the total population, including infants and children, and all representative population subgroups is <15.0% of the acceptable daily intake (ADI). Exposure from food alone is not of health concern. The highest exposure and risk estimate is for children 1-2 years old at 14.0% (0.008320 mg/kg bw/day) of the ADI.

The refined chronic non-cancer and cancer risk assessments were conducted with the following criteria: South American supervised trial median residue (STMdRs) for bananas, apples and peanuts, experimental processing factors (where available), % crops imported from all exporting countries and 100% crops treated. The refined non-cancer chronic dietary exposure from all supported isopyrazam-treated imported food uses (alone) for the total population, including infants and children, and all representative population subgroups is ≤0.2% of the ADI. Exposure from food alone is considered acceptable. The highest exposure and risk estimate is for children 1-2 years old at 0.2% (0.000090 mg/kg bw/day) of the ADI.

The refined estimate for lifetime cancer risk from exposure to isopyrazam in food alone for the general population was 1×10^{-7} , which is not of health concern.

3.3.2.2 Acute Dietary Exposure Results and Characterization

The following assumptions were applied in the basic acute analysis for isopyrazam: 100% crop treated, default processing factors and residues in/on crops at MRL levels. The basic acute dietary exposure (food alone) for all supported isopyrazam registered commodities is estimated to be 2.5% (0.004924 mg/kg bw/day) of the ARfD for the general population. The highest exposed subpopulation is children 1-2 years of age at 16% (0.060697 mg/kg bw/day) of the ARfD, which is not of health concern.

3.3.3 Aggregate Exposure and Risk

An aggregate risk analysis for isopyrazam was not conducted as exposure is from food only and there are no residential uses in Canada. Drinking water sources are not affected as there are no registered Canadian uses.

3.3.4 Maximum Residue Limits

The recommendation for MRLs for isopyrazam was based upon the submitted field trial data from the exporting countries, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of isopyrazam [SYN534968 (*anti*) + SYN534969 (*syn*)] in/on crops and processed commodities are proposed as shown in Table 3.3.1. Residues in processed commodities not listed in Table 3.3.4 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

Table 3.3.4 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	Preharvest Interval (days)	Total Isopyrazam Residues (ppm)		Experimental Processing Factor	Recommended MRL (ppm)
			LAFT	HAFT		
Apples	448.3-462.0	13-14	0.153	0.277	No concentration in juice 5.7-fold in dried apples	0.7 in/on apples 2.0 in/on dried apples
Peanuts	385.8-398.5	7	<0.005	<0.005	--	0.01

Note: a.i. = active ingredient; ha = hectare; PHI = preharvest interval; total isopyrazam residues = sum of the SYN534968 (*anti*) + SYN534969 (*syn*) isomers; ppm = parts per million.

Please refer to the [Maximum Residue Limit Database](#) in the Pesticides and Pest Management section of Health Canada's website for the established MRLs for isopyrazam.

4.0 Environmental and Value Assessments

Environmental and value assessments were not required for this application.

5.0 Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Isopyrazam Technical, and has found the information sufficient to establish MRLs for imported peanuts and apples.

List of Abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
kg	kilogram(s)
mg	milligram(s)
MRL	maximum residue limit
NCHS	National Center for Health Statistics
RAC	raw agricultural commodities
STMdR	supervised trial median residue

References

PMRA Document Number	Reference
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1973842	2010, Isopyrazam (SYN520453) - Manufacturing Process Description and Supporting Data, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13.1, 2.13.2, 2.13.3, 2.4 CBI
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1973847	2008, Confirmation of the structure of the by-product SYN546208 for isopyrazam (SYN520453) by mass spectroscopy, DACO: 2.13.2 CBI
2051521	2011, 2.11.3-1 Manufacturing Process (Detailed) SYN520453 - ISOPYRAZAM, DACO: 2.11.3 CBI
2051522	2011, 2.11.4-1 Statement - Isopyrazam – [CBI REMOVED] Content, DACO: 2.11.4 CBI
2051524	2011, 2.13.1-1 Isopyrazam (SYN520453) Statement on Linearity for the Validation of SA-39/1, DACO: 2.13.1 CBI
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2051526	2011, 2.13.1-3 Addendum to Study TK0011956 - SYN520453 Technical Analysis of [CBI REMOVED] in Five Representative Batches, DACO: 2.13.1 CBI
2051527	1999, Validation of Analytical Method AG-1229, DACO: 2.13.1 CBI

2051528	2008, 2.13.2-1 SYN534968 AND SYN534969 Spectra FINAL REPORT, DACO: 2.13.2 CBI
2051529	2011, 2.13.2-2 Isopyrazam (SYN520452) Statement on configuration of syn- and anti-epimers, DACO: 2.13.2 CBI
2051530	2006, 2.13.2-3 Isopyrazam - Certificate of Analyses (USA and Switzerland), DACO: 2.13.2 CBI
2118654	2011, 2.11.4 – [CBI REMOVED] - Clarification, DACO: 2.11.4 CBI
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