CIRCULATED PHASE-2 REVIEW DOCUMENT (GENERATED)

BY SUNEETI TUTEJA ON 16-11-2021 11:27:12

1) Sectional Committee No. & Title:	FAD 1 - Pesticides
2) IS No:	IS 8074 : 1990
3) Title:	Monocrotophos SL - Specification (Second Revision)
4) Date of Previous Review:	March, 2022

Review Analysis:

5.1) Status of standard(s), if any from which assistance had been drawn in the formulation of this IS.

1. Standard (No.)	2. Standard (Title)	3. Whether the standard has since been revised	4. Major changes	5. Action proposed
IS 1070 : 1977	Water for general laboratory use (second revision)	3rd revision in 1992 Reagent Grade water-Specifications (Third revision)	Limits for three grades of water depending on their end use have been specified and the characteristics have also been suitably modified.	(Page 2, Clause 7.3, 2nd line) – Replace the phrase ' (See IS 1070 : 1977)' by '(See IS 1070 : 1992). Incorporate the same change in Annex A (Clause 2).
IS 10627 : 1983	Methods for sampling of pesticidal formulations.	No Revision	NIL	NIL
IS 8025 : 1990	Monocrotophos. technical	IS 8025 : 1990 Monocrotophos,technical specification (Second Revision)	NIL	NIL
IS 6940 : 1982	Methods of test for pesticides and their formulation	IS 6940 : 1982 Methods of test for pesticides and their formulations (First Revision)	Clause 13.5.4 has been substituted by Electrometric Procedure for Determination of Acidity or Alkalinity.	NIL
IS 1448 (part 20) : 1982	Determination of flash point by Abel apparatus	IS 1448 : Part 20 : 2019 Methods of Test for Petroleum and its Products P : 20 Determination of Flash Point — Abel Closed-Cup Method (Third Revision)	Alignment with the latest version of ISO 13736 : 2013.	(Page 1, Clause 3.2.3, 2nd line) – Replace the phrase 'IS 1448 (part 20) : 1982' by 'IS 1448 (part 20) : 2019'.

5.2) Status of standard referred in the standard.

1. Referred standards (No.)	2. Referred standards (Title)	3. Since revised standard number of the corresponding standard	4. Changes in the referred Standards since last review of standard	5. Changes in the referred standard which are affecting the standard under review	6. Action proposed
		No	o entry made in this table		

	(No.)		2. Standard (Tit	le)	that relev	ovisions could be vant while ewing the	4. Action	proposed
Internationa Pesticide Ma Highly Hazaı WHO/HTM/N	nagement, rdous Pestic	Guidelines on ides	Pesticide Manag Highly Hazardou	de of Conduct on ement, Guidelines on Is Pesticides WHOPES/2016.03	Claus	se 6	to toxicolo parameter	of clause related ogy and safety rs of the product 074 : 1990.
4) Technical	l comments	on the standard	l received, if any.					
1. Source		2. Clause of IS		3. Comment		4. Action p	proposed	
			No en	itry made in this table				
5) Informat	ion availab	le on relevant te	chnical developme	ents				
1. Source	2. Develo	opment					3. Relevant clause of the IS under review that is likely to be impacted (Clause & IS No.)	4. Action proposed
BIS Licensee	following reasons: i) More accurate precise method ii) Easy for handling iii) Eliminates methodical error (Personnel error) iv) Deals with common instrument (HPLC method) v) Validated and accepted globally (CIPAC Method 1990, Monocrotophos panel of PAC- GB)3.3.1, IS 8074 : 1990HPLC method (CIPAC method) of Monocroto content as alternative			Monocrotophos content as				
General	during its concern r	application. But	, on the other hand o its high toxicity. A	os and they feel the factor they are concerned and lso, they believe that reg	accept	the safety	All clauses	As per recomendation

Research Papers	MCP (Monocrotophos) and lead might have affected the development of cerebrum and cerebellum via thyroid disruption leading to developmental neurotoxicity. (Kumar BK, Reddy AG, Krishna AV, Quadri SSYH, Kumar PS (2016) Developmental neurotoxicity of monocrotophos and lead is linked to thyroid disruption, Veterinary World 9(2): 133- 141.)	Clause 3, IS 8074 : 1990	Inclusion of safety/toxicity requirement clause for compliance of the product with the specified toxicity limits a per WHO/FAO/FSSA
Research Papers	To prevent future problems with HHPs, the registration system for pesticides may need to be revised. This may involve: • Defining protection goals and unacceptable risks in the pesticide legislation. • Strengthening of registration procedures and in particular the assessment of risk. • Adding registration considerations based on the HHP criteria. This could, for example, include not registering products that fall under GHS Category I, or adding restrictions or conditions of approval that ensure products whose handling and application require the use of PPE that is uncomfortable, expensive or not readily available, are not accessible to small scale users and farm workers in hot climates. • Requiring the periodical review of registered pesticides and initiating a registration review where monitoring, field surveillance, new scientific information, or new information from comparable countries indicates high risks, e.g. because of relatively high numbers of adverse incidents. • Pro-actively favouring registration of products that pose less risk where such alternatives are viable and available. In this respect, particular attention should be given to encouraging the use of biological control. (International Code of Conduct on Pesticide Management, Guidelines on Highly Hazardous Pesticides, WHO/HTM/NTD/WHOPES/2016.03)	Clause 3, IS 8074 : 1990 Clause 3.3, IS 8074 : 1990	Inclusion of safety/toxicity requirement clause for compliance of the product with the specified toxicity limits a per WHO/FAO/FSSA Inclusion of PH (Pre harvest interval) testing parameter to estimate the level of residua toxicity.
Research Papers	An acceptable daily intake (ADI) of 0.0006 mg/kg bw was allocated in 1993 and confirmed in 1995. This ADI was established on the basis of a 28-day human volunteer study with an NOAEL for erythrocyte acetylcholinesterase of 0.006 mg/kg bw/d and using a 10-fold safety factor. An acute reference dose (ARfD) of 0.002 mg/kg bw was established by JMPR in 1995.	Clause 3, Is 8074 : 1990	Inclusion of safety/toxicity requirement clause for compliance of the product with the specified toxicity limits a per WHO/FAO/FSSA
Central Ministry	Monocrotophos is banned in 112 countries, Not approved in EU vide Legisl. 2002/2076/EC; Details of country (As per PAN data) EU, UK, Brazil, China, Indonesia, Myanmar, Pakistan, Thailand etc. Alternatives are available for use. It is toxic to honey bees and aquatic organisms. Therefore, import, manufacture, sale, transport, distribution and its use shall be prohibited in agriculture.	IS 8074 : 1990	Possibility of withdrawal upon complete implementation of ban.

Laboratory	Inclusion of clause for safety requirements or toxicology requirements based on/mentioning the followings: i) Evaluation of PHI of each active ingredient(pesticides) of product in 2-3 no. of Agricultural crops ii) Dissipation studies of active ingredient in monocrotophos iii) Active ingredient toxicity co-relations with maximum residue limits	i) Clause 3, IS 8074 : 1990 ii) Clause	Inclusion of safety/toxicity requirement clause for
	of FAO/WHO/CODEX to address risk assessment.	3.3, IS 8074 :	compliance of the product
		1990 iii)	with the
		Clause 5,	specified
		IS 8074 :	toxicity limits as
		1990	per
			WHO/FAO/FSSAI
			Inclusion of PHI
			(Pre harvest
			interval) testing
			parameter to
			estimate the
			level of residual
			toxicity.

5.6) Issues arising out of changes in any related IS or due to formulation of new Indian Standard.

1. Related IS (revised or new)	2. Related IS Title	3. Provision in the IS under review that would be impacted & the clause no. or addition of new clause/provision	4. Changes that may be necessary in the Standards under review	5. Action proposed
IS 8074 : 1990	Monocrotophos SL - Specification (Second Revision)	Respective clauses as per recomendation	Respective clauses as per recomendation	As per recomendation

5.7) Any consequential changes to be considered in other IS.

1. Related IS to get impacted	2. Related IS Title	3. Requirements to be impacted	
IS 8025 : 1990	Monocrotophos,technical specification (Second Revision)	Annexure B, IS 8025 : 1990 – Method of estimation of Monocrotophos. Addition of HPLC method (CIPAC method) for estimation of Monocrotophos content as alternative methodology	
) Any other ol	bservation:	i) As per Directorate of Plant Protection, Quarantine and Storage (GOI) monochrotophos has been included in the list of pesticides, which are banned, refused registration, and restricted in use as of 31.10.2019. ii) A WHO sponsored	

study carried out in India from July 1999 to June 2000 in Andhra Pradesh, Haryana, Punjab and Karnataka shows that among 1531 pesticide poisoning cases, 609 cases were due to organophosphorus pesticides. Where monochrotophos was found in 86 cases. iii) As per WHO, monochrotophos SL comes under class Ib. SO, WHO recommends that handling and application of monochrotophos should be entrusted only to competently supervised and well trained applicators. In case of India, the applicators are farmers. iv) Accumulation of monochrotophos in living tissues poses harmful threat to humans and adverse effects on non-target living systems present in the environment. It causes histopathological, acute, genotoxic, cardiotoxicity, hyperglycaemic and stressogenic efects to diferent living organisms. v) Monochrotophos has been included in the PIC-decision guidance document for a banned and severely restricted chemicals in February 2005. vi) The reference annexure have to be updated as per the revised standard year and titles.

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7.1) ARP Report		<u>ARP IS 8074 1990.pdf</u>
7.2) Draft Document		working draft_IS 8074.pdf
8) Recommendations - On the basis of the analysis of the info available as mentioned above consideration of sectional committee is solicited on the following aspects of the IS under review:	807 of r cert rele star 807 toxi inco Inco (tes The refe par 199	he possibility of ban on monocrotophos can not be ruled out. Hence the IS 4 : 1990 has to be withdrawn in the case of complete ban. But, due to lack esearch data to prove its toxicity, monocrotophos might be banned on tain plants or not banned at all, in that case IS 8074 : 1990 will still be evant and we need stricter guidelines and technical revisions in the indard. ii) Considering the toxicity issue of monocrotophos, Clause 3 of IS 4 :1990 may include the compliance of the product with the specified icity limits as per WHO/FAO/FSSAI. Other clause related changes may be proporated as per changes in cross reference standards in Table no.1. iii) dusion of HPLC method of estimating monocrotophos in clause 3.3.1 sting method for estimation of monocrotophos) along with IS 8025 :1990. e HPLC method has to be incorporated in IS 8025 : 1990 and to be given due erence in IS 8074 : 1990. iv) Inclusion of PHI (Pre harvest interval) testing ameter to estimate the level of residual toxicity in Clause 3.3 of IS 8074 : 0. v) Hence, considering all these changes in the clauses of IS 8074 : 1990, standard needs to be revised.

ACTION LOG

COMMUNICATION

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https://www.services.bis.gov.in:8071/php/BIS_2.0/Reaffirmation/ProcessAction.php?ID=MTUxMzg=