CHEMISTRY DATA REQUIREMENT FOR PESTICIDE REGISTRATION

Formulation Unit

Technical Evaluation Section, Pesticide Control Division

Department of Agriculture, Malaysia

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- Manufacturing Licenses & Registration Certificate Of The Product In Country Of Origin.
- Description of the production
- Manufacturing limits
- Quality Control /Quality Assurance measure

MANUFACTURING LICENSES & REGISTRATION CERTIFICATE OF THE PRODUCT

The name and address of the manufacturing plant at which the pesticide will be produced shall be mention clearly.

- Item 24,Pesticides (registration) Rules 2005, Form A, Subrule 2(1)
- Only one source allowed for the purpose of new registration.

Support by relevant document:

- Manufacturing License
- Registration Certificate of the product in the country of origin.
- The translated document must be certified by the regulatory authority in the country of origin.

ITEM 24,PESTICIDES (REGISTRATION) RULES 2005, FORM A, SUBRULE 2(1)

Only one source allowed for the purpose of new registration.

24. The source of the pesticide will be obtained from the following manufacturere (s);

(a) Name : .....

Address : .....

(b) Name : .....

Address : .....

.....

(c) Name : .....

Address : .....

CERTIFICATE OF REGISTRATION

(3) Follow the approved (kind name and percentage of the ingredients) as given below: -

COMPONENT		CONTENT(% w/w)
Triclopyr Butoxy Ethyl Ester a.i.	:	96.00 Min.
Triclopyr Acid	:	1.00 Max.
Triclopyr Methyl Ester	:	1.00 Max.
2-Butoxy Ethanol	:	1.50 Max.
Water	:	0.50 Max.
	Total	100.00

(4) The product shall be packed as per packaging requirements of the importing country as per undertaking submitted to the Registration Committee.

(5) No export should take place in contravention to the provisions of the Rotterdam Convention on prior informed consent procedure for certain hazardous chemicals and pesticides in international trade.

(6) If a pesticide is banned or severely restricted in India, before exporting such pesticide, permission from Designated National Authority for Pesticide of the Country under Rotterdam Convention may be obtained.

AUTHENTICATED

7/1/14

(S.K.VIJ)
Section Officer

OFFICE OF THE REGISTRATION COMMITTEE

(DR.B.S.PHOGAT) 07/1/14
Secretary
Central Insecticides Board
and Registration Committee

Date: 07/01/2014
Copy to the Director of Agriculture, Gandhinagar (Gujarat)
Copy of the approved labels and leaflets is enclosed herewith.

(DR.B.S.PHOGAT)
Secretary
Central Insecticides Board
and Registration Committee

The Registration holder shall have to pay the revised fees for registration as per the Directions of the Writ petition No. 5302/16 between Gujarat Pesticides Samiti & Association V/s Union of India pending for final disposal in the Hon'ble High Court of Gujarat at Ahmedabad.

F. No. 3765-SE/9(3)/2013
Government of India
Ministry of Agriculture
Department of Agriculture & Cooperation
DIRECTORATE OF PLANT PROTECTION, QUARANTINE & STORAGE
CENTRAL INSECTICIDES BOARD AND REGISTRATION COMMITTEE
N.H.IV, FARIDABAD (HARYANA)-121 001

CERTIFICATE OF REGISTRATION OF INSECTICIDE UNDER SECTION 9(3) OF THE INSECTICIDES ACT, 1968.

FOR MANUFACTURE FOR EXPORT

It is to certify that the Insecticide/Weedicide/Herbicide/Fungicide **TRICLOPYR BUTOXY ETHYL ESTER TECHNICAL 96% Min.** has been registered for indigenous manufacture and export thereof only under section 9(3) of the Insecticides Act, 1968 in the name of the person/undertaking whose particulars are specified below: -

1.	Name of the Person/Undertaking and address	:	M/s Meghmani Organics Limited Plot No. 184, Phase-II, GIDC Industrial Estate Vatva, Ahmedabad- 382 445, Gujarat
2.	Address of Factory	:	1). Plot No. 22/2, GIDC Industrial Estate, Village Panoli, TA-Ankleshwar, Distt. Bharuch. 2). Plot No. 5001/B, GIDC, Ankleshwar –393 002, Dist. Bharuch, Gujarat 3). Plot No. CH-142/A, GIDC, Dahej, Vagara, Dist. Bharuch, Gujarat 4) Block No. 402-404, 452-454, Post –Chharodi, TA-SANAND, Dist. Ahmedabad- 382 170
3.	Registration No.	:	CIR (SE)-6511/2014(344)- TRICLOPYR BUTOXY ETHYL ESTER (T)-19
4.	Name of the Pesticide	:	TRICLOPYR BUTOXY ETHYL ESTER TECHNICAL 96% Min.
5.	Source of import	:	-NA-

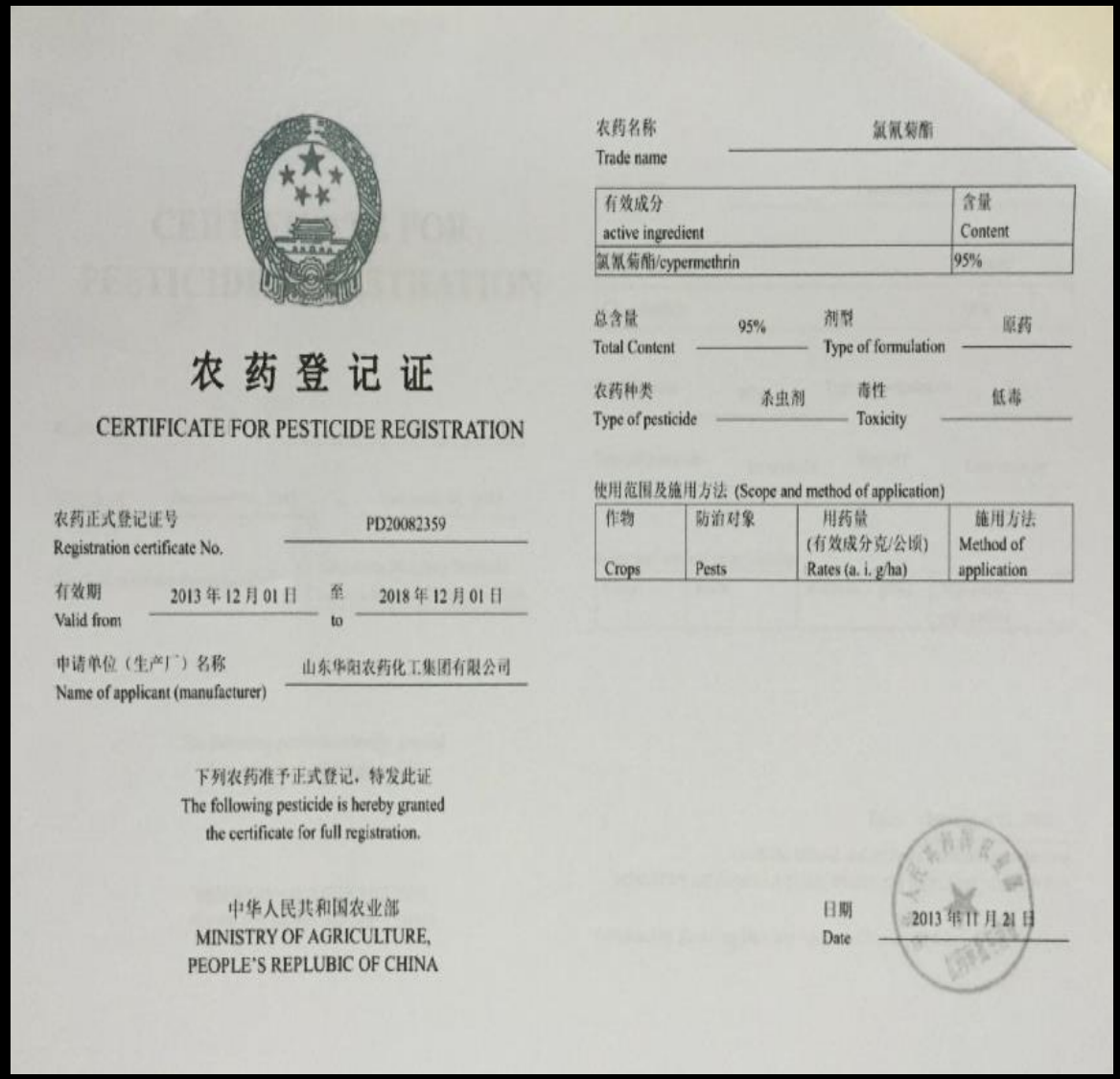
CONDITIONS:

6. (1) The Registration is subject to strict compliance of various provisions of the Insecticides Act, 1968 as amended from time to time and Rules, bye-laws framed and notification issued there under and as amended from time to time Any violations of the conditions of the Registration Certificate read with labels and leaflets and the provisions of the aforesaid Act, bylaws and Notifications will attract various penal provisions under the Insecticides Act, 1968, apart from suspension, revocation and cancellation of the registration.

(2) The entire production/imported material shall be exported.

Contd...2.

CERTIFICATE OF REGISTRATION



农 药 登 记 证

CERTIFICATE FOR PESTICIDE REGISTRATION

农药正式登记证号
Registration certificate No. PD20082359

有效期 2013 年 12 月 01 日 至 2018 年 12 月 01 日
Valid from to

申请单位（生产厂）名称
Name of applicant (manufacturer) 山东华阳农药化工集团有限公司

下列农药准予正式登记，特发此证
The following pesticide is hereby granted the certificate for full registration.

中华人民共和国农业部
MINISTRY OF AGRICULTURE, PEOPLE'S REPLUBIC OF CHINA

农药名称
Trade name 氯氰菊酯

有效成分 active ingredient	含量 Content
氯氰菊酯/cypermethrin	95%

总含量 Total Content 95%
剂型 Type of formulation 原药
农药种类 Type of pesticide 杀虫剂
毒性 Toxicity 低毒

使用范围及施用方法 (Scope and method of application)

作物 Crops	防治对象 Pests	用药量 (有效成分克/公顷) Rates (a. i. g/ha)	施用方法 Method of application

日期 Date 2013 年 11 月 21 日

DESCRIPTION OF THE PRODUCTION

Description of the raw material

- For each starting material, chemical name, CAS number, or other commercial designation of ingredient
- The purity of each starting material used to produce technical material also shall be provided
- All information that applicant knows concerning the composition, chemical and physical properties of the ingredient, including a copy of technical specifications, (SDS)

Description Of Process

- the manufacturing process starting from the starting materials, partway, by product and impurities shall be provided.
- Chemical equations for chemical reactions involved in the manufacturing process shall also be provided

Description of equipment

Flow chart of the reaction and summarizing the conditions and solvent

MANUFACTURING LIMITS

Minimum Active Ingredient (g/kg) for Technical material (TC)

Minimum and maximum Active Ingredient content (g/kg) for Technical Concentrate (TK)

Manufacturing Maximum Limits For Impurities Content (g/kg)

MANUFACTURING LIMITS

Manufacturing Maximum Limits For Impurities Proposed As Relevant At above 1g/kg, supported By Batch Analysis Data (Minimum 5 Typical Batches)

Manufacturing Maximum Limits For Impurities Proposed As Relevant At less than 1g/kg (relevant impurities), supported By Batch Analysis Data (Minimum 5 Typical Batches)

The Statistical Basic For Manufacturing Limits (Confidential Data) .

5 Batch Studies Are Required To Be Good Laboratory Practices (GLP) Studies

Unidentified and/or unaccountable fraction of TC/TK should not exceed 20g/kg

Composition of TC/TK (manufacturing limits shall be certified by the QA/QC manager)

TECHNICAL MATERIAL (TC)

TC specification has only a lower limit for active ingredient content

GLYPHOSATE ACID TECHNICAL MATERIAL

FAO Specification 284 / TC (February 2016*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (284/2000, 284/2001, 284/2012.1, 284/2012.2 & 284/2015). It should be applicable to technical materials of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the technical materials of other manufacturers. The evaluation reports (284/2000, 284/2001, 284/2012.1, 284/2012.2 & 284/2015) as PART TWO form an integral part of this publication.

1 **Description**

The material shall consist of glyphosate (acid), together with related manufacturing impurities. It shall be a white dry powder, free from visible extraneous matter and added modifying agents.

2 **Active Ingredient**

2.1 **Identity tests** (284/TC/(M)/2, CIPAC Handbook 1C, 1985, p. 2132)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 **Glyphosate acid** (AOAC 983.10, 2010) (Note 1)

The glyphosate acid content shall be declared (not less than 950 g/kg) and, when determined, the mean measured content shall not be lower than the declared minimum content.

3 **Relevant Impurities**

3.1 **Formaldehyde** (Note 2)

Maximum 1.3 g/kg

3.2 ***N*-Nitrosoglyphosate** (Note 3)

Maximum 1 mg/kg

TECHNICAL CONCENTRATE (TK)

TK specification has upper and lower limits

GLYPHOSATE ACID TECHNICAL CONCENTRATE

FAO Specification 284 / TK (February 2016*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (284/2000, 284/2001, 284/2012.1 and 284/2012.2). It should be applicable to technical concentrates of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation reports (284/2000, 284/2001, 284/2012.1, 284/2012.2 and 284/2015) as PART TWO form an integral part of this publication.

.1 **Description**

The material shall consist of glyphosate (acid) together with related manufacturing impurities. It shall be a white to greyish wet cake, free from visible extraneous matter and added modifying agents.

2 **Active Ingredient**

2.1 **Identity tests** (284/TC/(M)/2, CIPAC 1C, , p. 2132, 1985)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 **Glyphosate acid** (AOAC 983.10, 2010) (Note 1)

The glyphosate acid content shall be declared (not less than 950 g/kg on a dry weight basis) and, when determined the average measured content shall not differ from that declared by more than ± 25 g/kg.

3 **Relevant impurities**

3.1 **Formaldehyde** (Note 1)
Maximum 1.3 g/kg of the glyphosate acid content found under 2.2.

3.2 ***N*-Nitrosoglyphosate** (Note 2)
Maximum 1 mg/kg

3.3 **Loss on drying** (MT 17.4, CIPAC Handbook F, p. 57, 1995)
Sample weight: 10 g; temperature: 105°C, time: 3 hours.).
The loss on drying shall be declared and, when measured the average loss shall be not more than 200 g/kg.

ITEM 23,PESTICIDES (REGISTRATION) RULES 2005, FORM A, SUBRULE 2(1)

Technical Material

(Total (%w/w) declared : (A + B)

Active ingredient content (%w/w) declared in label : (A)

23. For every constituent in the formulation, provide the following information in the table:

(a) Active Ingredient (common name)	Chemical abstracts service (CAS) Number, if any	Purpose in formulation	Percent of the source product in formulation (%w/w or g/l)	Percent by weight of the active ingredient in formulation (%w/w)
				(A)
(b) Inert ingredient (common name)	Chemical abstracts service (CAS) Number, if any	Purpose in formulation	Percent of the source product in formulation (%w/w or g/l)	Percent by weight of the active ingredient in formulation (%w/w)
				(B)
			Total (%w/w)	**(A + B)**

Active Ingredient	• Provide the common name of pesticide as listed in schedule 1 • Minimum Active Ingredient (g/kg) and %w/w
Inert ingredient	• Provide the chemical name of each impurities in the TC/TK. • Manufacturing Maximum Limits For Impurities Content (g/kg) and (%w/w)
Purpose in formulation	• Impurities as a result of manufacture • Stabilizer / additive
Percent of the source product in formulation (%w/w or g/l)	• -
Total (%w/w)	• (A + B)

Percent by weight of the active ingredient in formulation (%w/w)

- Specify the weight percentage of active ingredient in your TC/TK.
- Minimum Active Ingredient (g/kg) and %w/w
- Concentration of active ingredient declared in the labels.

Percent by weight of the inert ingredient in formulation (%w/w)

- Manufacturing Maximum Limits For Impurities Content (g/kg) and (%w/w)

ITEM 24,PESTICIDES (REGISTRATION) RULES 2005, FORM A, SUBRULE 2(1)

Technical Concentrate (TK)

Total (%w/w) declared = (C + D)

Active ingredient content (%w/w) declared in label : (C)

23. For every constituent in the formulation, provide the following information in the table:

(a) Active Ingredient (common name)	Chemical abstracts service (CAS) Number, if any	Purpose in formulation	Percent of the source product in formulation (%w/w or g/l)	Percent by weight of the active ingredient in formulation (%w/w)
			(A)	(C)
(b) Inert ingredient (common name)	Chemical abstracts service (CAS) Number, if any	Purpose in formulation	Percent of the source product in formulation (%w/w or g/l)	Percent by weight of the active ingredient in formulation (%w/w)
			(B)	**(D)**
			Total (%w/w)	**(C + D)**

Active Ingredient	• Provide the common name of pesticide as listed in schedule 1 • The % w/w purity of technical materials used shall be indicated.
Inert ingredient	• Provide the chemical name of each chemical in the impurities and stabilizer/additive/solvent used in the Technical Concentrate (TK) • The % w/w purity of stabilizer/additive/solvent used shall be indicated.
Purpose in formulation	• Specify the purpose of each ingredient both active and inert. • Impurities as a result of manufacture • Stabilizer / additive

Percent of the source product in formulation (%w/w or g/l)	• **Specify the quantity of each component as actually introduced into the formulation. Units (e.g. %w/w or g/L) should be expressed as used in the formulation. If the quantity is a liquid measure , enter the volume and the specific gravity (express by g/L)**
Total (%w/w)	• **(A + B)**
Percent by weight of the active ingredient in formulation (%w/w)	• **Specify the weight percentage of active ingredient in your technical concentrate (TK)** • **Concentration of active ingredient declared in the labels.**
Percent by weight of the inert ingredient in formulation (%w/w)	• **Specify the quantity of each component (solvent/stabilizer/additive) as actually introduced into the formulation.**

The composition declared in item 23,Pesticides (registration) Rules 2005, Form A, Subrule 2(1)
, shall supported by chemical composition materials (TC and or TK endorsed by QA/QC manager

Chemical composition materials (TC and or TK)

1. Date:
2. Product Name:
3. Name and Adress of manufacturing plant including ZIP Code:

Manufacturing process, maximum limits for impurities ≥ 1 g/kg, 5 batch analysis data	Mass balances were [nn.n – nnn.n] % and percentages of unknowns were [n.n – n.n] %.
Declared minimum [a.i.] content	[nnn] g/kg and %w/w
Relevant impurities ≥ 1 g/kg and maximum limits for them	[nnn] g/kg and %w/w
Relevant impurities < 1 g/kg and maximum limits for them:	[nnn] g/kg and %w/w
Stabilisers or other additives and maximum limits for them:	[insert data and additional rows, or enter None, as appropriate].

Notes.

- Insert additional rows for other salt, ester, etc., TCs or TKs.
- If isomer ratio is a key property, insert an additional row for the data.

1.Date	• Complete the item for identification
2. Product Name	• Specify the complete name of this pesticide product as it will appear on the label. This name must be the same as that which appears on the application form.
3. Name and Adress of manufacturer including ZIP Code	• Specify the name of the producer and the address of the site where this product will be produced

QUALITY CONTROL/QUALITY ASSURANCE MEASURE

- Quality Control of raw materials and ingredients
- Effective process control
- quality control methods shall be stated clearly
- Using Valid, reliable methodology

2. BATCH ANALYSES REPORT

BATCH ANALYSIS REPORT

- Conducted on TK/TC . Represent batches produces over the relatively short time period.
- Confirmed the Active Ingredient content
- Including the relevant impurities
- Including the physical and physical testing
- Test method supporting the report must clearly defined, well validated, reproducible and robust

BATCH ANALYSIS REPORT

5 batch studies are required to be Good Laboratory Practices (GLP) studies.

Typically the unidentified and/or unaccountable fraction of TC/TK should not exceed 20g/kg

Use as a supporting data to establish the specification

High standard Deviation (SD) might not lead to reasonable results.

3. SPECIFICATION

Composition of the pesticide (including impurities, by-products, related products, stating their concentrations)

- Minimum content of active ingredient, state in g/kg or % w/w
- Maximum content of significant and relevant impurities, state in g/kg or % w/w

Specific properties/Test related to use

ACTIVE INGREDIENT:

At least two identity tests are required for the active ingredient

- Where the active ingredient is in the form of a salt (etc.) and the counter ion (etc.) is not identified by the test for the active component, a separate identity test may be required for the counter ion (etc.)
- For salt, if an active ingredient identity test is based on IR, a band specific to the salt may be sufficient.

If the mixture is not defined by an ISO common name,the specifications for technical and formulated products will normally include a clause for isomer ratio.

- eg. Permethrin 60:40 and Permethrin 75:25
- analytical method to determine isomer ratio must be peer validated, as a minimum.

4. PHYSICAL AND CHEMICAL PROPERTIES

REQUIRED TO BE GOOD LABORATORY PRACTICES (GLP) STUDIES

i. *Studies and data on the physical and chemical properties of a pure active ingredient are required only where its composition is presumed to be different from the composition of the pure reference material (e.g. different or variable ratio of isomers).*

i. *Studies and data for solubility in organic solvents at room temperature are required for pure or technical grade active ingredient*

Appearance (physical state, colour and odour)

Melting/decomposition/boiling point, vapour pressure (at stated temperature), solubility in water and in organic solvent (at stated temperature)

Partition coefficient between water and organic solvent, density , hydrolysis rate, photolysis, absorption spectra (UV,IR, MS or NMR

5. STORAGE STABILITY

STORAGE STABILITY TEST (TK)

1. Accelerated Storage Test Procedures is performed usually at 54 ± 2º C for 14 days or at 45 ± 2º C for 6 weeks or at 40 ± 2º C for 8 weeks or at 35 ± 2ºC at 12 weeks or at ambient temperature (warehouse/laboratory ambient temperature) for 2 years.

2. Active Ingredient and relevant physical and chemical properties testing for Storage stability studies are required to be performed in Good Laboratory Practices (GLP) certified test facilities or in ISO accredited laboratories.

Parameter of analyses

- Active Ingredient, relevant impurities and relevant physical and chemical properties testing based on type of formulation according to Manual on Development and Use of FAO and WHO Specifications for Pesticides

Sample

- Samples shall be analyzed before and after testing using the same batch.
- taken from a batch that has passed quality control analysis.
- 2 samples must be prepared. One of the samples is treated in the oven, and the other one is a control sample which must be analyzed concurrently after the test

The packaging used

- based upon that in which the product is sold.
- observation of the effect on the packaging used must be reported.

Laboratory Facility

- Active Ingredient and relevant physical and chemical properties testing for storage stability studies are required to be performed in Good Laboratory practice (GLP) or ISO 17025

6. METHOD OF ANALYSES

Validated methods for determining the content of active ingredient and, relevant impurities.

Validation data shall be provided to confirm that the analytical procedures used give reliable and accurate results.

The type of validation data , typically includes demonstration of linearity over a suitable concentration range, repeatability, reproducibility, specificity, robustness, precision and accuracy.

Analytical methods described in official and recognized publications (CIPAC handbooks ,AOAC manual for pesticide products) are regarded as validated and do not require revalidation.

However, the suitability of these methods should be verified under actual conditions of use; that is, the specificity and accuracy of the method should be demonstrated for the published method when applied to the relevant sample matrix and laboratory conditions.

CHEMISTRY DATA REQUIREMENT

NEW REGISTRATION FOR FORMULATED PRODUCT

DATA REQUIREMENT FOR CHEMICAL PESTICIDE REGISTRATION (FORMULATED PRODUCT)

Part A- Requirement On Technical Active Ingredient

- Identity
- Physical and Chemical Properties
- Manufacturing Process
- Identity and amount of isomers, impurities and other by products, including the possible range
- 5 batch analysis
- Safety data Sheet (SDS)

Part B- Requirement On The Formulation

- Physical and Chemical Properties
- Specification (MS / FAO/WHO specification or others)
- Manufacturing process and quality control
- Storage stability test
- Specific properties depending on formulation type
- Known compatibility with other pesticides
- Packaging
- 5 Batch analysis
- Safety data Sheet (SDS)

Data for Technical Grade of Active Ingredient (TGAI) is required on cases where **TGAI is not registered with Pesticide Board** but **its formulated product (ready-made) is directly imported and is intended to be registered**. In this case, the registrant must declare the source of the technical grade active ingredient and provide a letter of undertakings/authorization;

- That it is the sole source

- That if an alternative source is subsequently utilized, prior approval must be obtained from the Board.

Manufacturing source

Manufacturing Process/ Formulating Process

Physical and Chemical Properties

Specification

Batch Analyses Report

Storage Stability Testing

Method Of Analyses

MANUFACTURING LICENSES & REGISTRATION CERTIFICATE OF THE PRODUCT

The details on the manufacturing source (name and address) of TGAI and product must be mentioned clearly.

- Item 24,Pesticides (registration) Rules 2005, Form A, Subrule 2(1).
- Only one (1) source for TGAI and product allowed during the process of new registration.

Support by relevant document:

- Manufacturing License
- Registration Certificate of the TGAI and product in the country of origin.
- The translated document must be certified by the regulatory authority in the country of origin.

CERTIFICATE OF REGISTRATION

Ministry of Agriculture of The People's Republic of China

Document No.: 07040020160420-182

Certificate for Veterinary Product Registration

In accordance with the related regulations of "Veterinary Management Regulation" and "Veterinary Product Approval Number Administrative Measures", this product has met the related requirements through examination and been authorized to be produced in China.

Company Name: Elanco (Shanghai) Animal Health Co., Ltd.

Manufacturing Address: 1 Changzhong Road, Wusi, Fengxian District, Shanghai

General Name: Cyromazine

Trade Name: N/A

Content specification: It contains not less than 98.0% of C6H10N6, calculated on the dried basis.

License No.: S.Y.Z.(2016)090012077

Period of Validity: June 22, 2016 - June 21, 2021

Issuing Date: June 22, 2016

中华人民共和国农业部
兽药产品批准文号批件

批件号：07040020160420-182

企业名称：礼来（上海）动物保健有限公司

生产地址：上海市奉贤区五四场中路1号

根据《兽药管理条例》、《兽药产品批准文号管理办法》等有关规定，该产品经审查符合要求，准予生产。

通用名称：环丙氨嗪

商品名称：无

兽药产品批准文号：兽药字(2016)090012077

含量规格：按无水物计算，含C6H10N6不得少于98.0%

有效期：2016-06-22至2021-06-21

发证日期：2016-06-22

中华人民共和国农业部 兽药审批专用章

2. MANUFACTURING PROCESS/FORMULATING PROCESS

MANUFACTURING PROCESS/ FORMULATING PROCESS (CHEMICAL PESTICIDE)- TC/TK

- Manufacturing Licenses & Registration Certificate Of The Product In Country Of Origin.
- Description of the production
- Manufacturing limits
- Quality Control /Quality Assurance measure

MANUFACTURING LICENSES & REGISTRATION CERTIFICATE OF THE PRODUCT

The name and address of the manufacturing plant at which the TGAI and pesticide will be produced shall be mention clearly.

- **Item 24,Pesticides (registration) Rules 2005, Form A, Subrule 2(1)**

Support by relevant document:

- **Manufacturing License**
- **Registration Certificate of the product in the country of origin.**
- **The translated document must be certified by the regulatory authority in the country of origin and by their embassy.**

ITEM 24,PESTICIDES (REGISTRATION) RULES 2005, FORM A, SUBRULE 2(1)

Only one source of TGAI declared with only one source for formulated declared during the application of new registration.

24. The source of the pesticide will be obtained from the following manufacturere (s);

(a) Name : .....

Address : .....

(b) Name : .....

Address : .....

.....

(c) Name : .....

Address : .....

DESCRIPTION OF THE PRODUCTION

Description of equipment

Flow chart of the reaction

Quality Control/Quality Assurance Measure

- **QC of the raw materials and ingredient**
- **Effective process controls**
- **Using valid, reliable methology**

DESCRIPTION OF THE PRODUCTION

Flow chart of the reaction

Quality Control/Quality Assurance Measure

- QC of the raw materials and ingredient
- Effective process controls
- Using valid, reliable method

MANUFACTURING LIMITS

The identity of every ingredient in the formulated product shall be stated and its concentration given in g/kg for solid formulation or g/L for liquid formulation as per recommended by FAO/WHO and in %w/w.

An upper and lower limit for each active ingredient in line with the Malaysian Regulation and FAO/WHO tolerances.

Proposed target limits for the inert ingredients in the product including range of variability for those inert ingredients which vary from batch to batch due to adjustment of the corresponding physical parameter

MANUFACTURING LIMITS

Certificate of composition (manufacturing limits shall be certified by the QA manager)

Product composition must stated clearly:

- Item 23,Pesticides (registration) Rules 2005, Form A, Subrule 2(1).

ITEM 23,PESTICIDES (REGISTRATION) RULES 2005, FORM A, SUBRULE 2(1)

Active ingredient content declared in label = (C)

23. For every constituent in the formulation, provide the following information in the table:

(a) Active Ingredient (common name)	Chemical abstracts service (CAS) Number, if any	Purpose in formulation	Percent of the source product in formulation (%w/w or g/l)	Percent by weight of the active ingredient in formulation (%w/w)
			(A)	(C)
(b) Inert ingredient (common name)	Chemical abstracts service (CAS) Number, if any	Purpose in formulation	Percent of the source product in formulation (%w/w or g/l)	Percent by weight of the active ingredient in formulation (%w/w)
			(B)	
			Total (%w/w)	**(A + B)**

Active Ingredient	• Provide the common name of pesticide as listed in schedule 1 • The % w/w purity of technical materials used shall be indicated.
Inert ingredient	• Provide the chemical name of each chemical in the inert ingredient used in the formulation • The % w/w purity inert ingredient used shall be indicated.
Purpose in formulation	• Specify the purpose of each ingredient both active and inert. (For example, disinfectant, synergist surfactant, defoamer, surfactant)

Percent of the source product in formulation (%w/w or g/l)	• **Specify the quantity of each component as actually introduced into the formulation. Units (e.g. %w/w or g/L) should be expressed as used in the formulation. If the quantity is a liquid measure , enter the volume and the specific gravity (express by g/L)**
Total (%w/w)	• **(A + B)**
Percent by weight of the active ingredient in formulation (%w/w)	• **Specify the weight percentage of active ingredient in your formulation.** • **Concentration of active ingredient declared in the labels.**
Percent by weight of the inert ingredient in formulation (%w/w)	• **Specify the quantity of each component as actually introduced into the formulation.**

COMPOSITION OF THE FORMULATED PRODUCT

composition shall endorsed by QA/QC Manager as a supported document to the composition claimed by registrant in Item 23,Pesticides (registration) Rules 2005, Form A, Subrule 2(1)

Certificate Of Composition

1. Date:
2. Product Name:
3. Name and Adress of manufacturer including ZIP code:
4. Country where the product formulated:
5. Specific Gravity (for liquid)
6. pH

(7) Active Ingredient (Common Name)	(9) Chemical Abstracts Service (CAS)	(10) Supplier Name and Adress	(11) Purpose in Formulation	(12) Percent of Source product in Formulation (%w/w or g/l)	(13 a) Percent by weight of active ingredient in formulation (%w/w)	(14) Manufacturing Certified limits (%w/w) Upper limit	Lower limit
				(A)	**(C)**		
(8) Inert Ingredient (Common Name)	(9) Chemical Abstracts Service (CAS)	(10) Supplier Name and Adress	Purpose in Formulation	(12) Percent of Source product in Formulation (%w/w or g/l)	13 (b) Percent by weight of active ingredient in formulation (%w/w)		
				(B)	**(D)**		
Total (%w/w)					**(A + B) or (C + D)**		

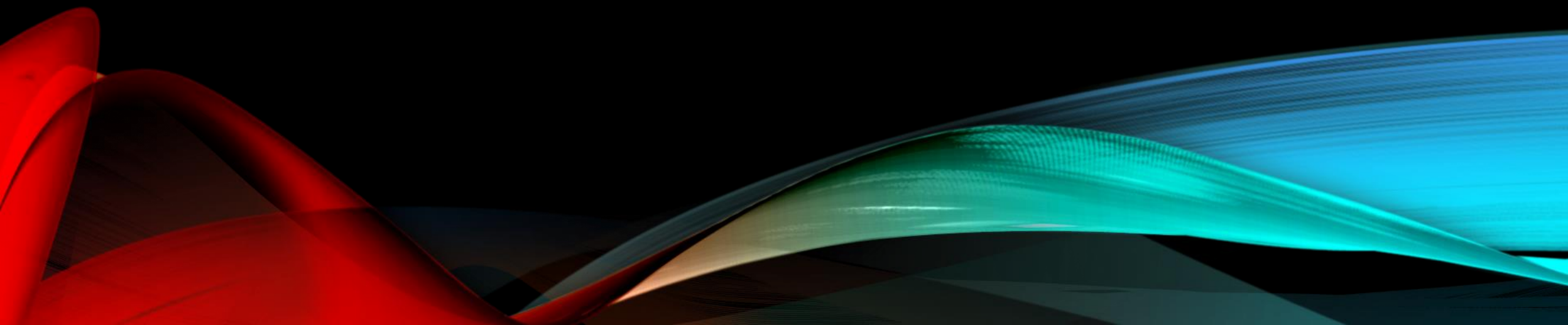
1.Date	• Complete the item for identification
2. Product Name	• Specify the complete name of this pesticide product as it will appear on the label. This name must be the same as that which appears on the application form.
3. Name and Address of manufacturer including ZIP Code, country where the product formulated, Sg, PH	• Specify the name of the producer and the address of the site where this product will be produced

4. Active Ingredient	• Provide the common name of pesticide as listed in schedule 1 • The % w/w purity of technical materials used shall be indicated.
5. Inert Ingredient	• Provide the chemical name of each chemical in the inert ingredient used in the formulation • The % w/w purity inert ingredient used shall be indicated
6. Purpose in formulation	• Specify the purpose of each ingredient both active and inert. (For example, disinfectant, synergist surfactant, defoamer, surfactant)

Percent of the source product in formulation (%w/w or g/l)	• **Specify the quantity of each component as actually introduced into the formulation. Units (e.g. %w/w or g/L) should be expressed as used in the formulation. If the quantity is a liquid measure , enter the volume and the specific gravity (express by g/L)**
Total (%w/w)	• **(A + B)**
Percent by weight of the active ingredient in formulation (%w/w)	• **Specify the weight percentage of active ingredient in your formulation.** • **Concentration of active ingredient declared in the labels.**
Percent by weight of the inert ingredient in formulation (%w/w)	• **Specify the quantity of each component as actually introduced into the formulation.**

Manufacturing Certified Limit	• **These limits are to be set based on representative sampling and chemical analysis (i.e., quality control) of the product.**
Upper Limit:	• **Specify the maximum percentage of each active ingredient, intentionally added inert ingredient, and any impurities greater than 0.1%w/w to he permitted in the product.**
Lower Limit	• **Specify the minimum percentage of each active ingredient and intentionally added inert ingredient to the permitted in the product**

3. PHYSICAL AND CHEMICAL PROPERTIES



- Appearance
- Physical state, colour, (for all formulation)
- Corrosiveness
- Flammability
- Explosivity
- Known compatibility with other chemicals (only to be performed when tank mix is recommended on the label)
- Oxidation/reduction :chemical incompatibility (only to be performed when tank mix is recommended on the label)

Rate of release, or release/retention index, of active ingredient (for slow- release granules (CG), slow-release capsule suspensions (CS), long lasting insecticidal nets (LN).

“Free” active ingredient (For slow release granules (e.g. encapsulated granules, CG) and slow release capsule suspensions (CS).

By- products of manufacture or storage (all specifications where relevant impurities may be associated with active ingredient

4. SPECIFICATION

SPECIFICATION

1.Composition of the pesticide (including inerts ingredients stating their concentrations)

- State in g/kg or g/L or % or w/w
- Maximum content of relevant impurities, state in g/kg or % w/w
- By products of manufacture (if applicable)

2. Specific properties/Test related to use

3. Necessary method of analysis.

5. BATCH ANALYSES REPORT

BATCH ANALYSIS REPORT

- Conducted on formulated product . Represent batches produces over the relatively short time period.
- Confirmed the Active Ingredient content
- Including the relevant impurities
- Including the physical and physical testing
- Test method supporting the report must clearly defined, well validated.
- Use as a supporting data to establish the specification
- High standard Deviation (SD) might not lead to reasonable results.

5. STORAGE STABILITY

TEST

- TESTS TO BE CONDUCTED Of THE PRODUCT WILL MOST LIKELY COMPLY WITH THE SHELF LIFE/EXPIRY DATE SPESIFICATION OF 2 YEAR
- TESTS TO BE CONDUCTED FOR THE PRODUCT THAT COMPLY THE SHELF LIFE LESS THAN 2 YEARS
- TESTS TO BE CONDUCTED FOR THE PRODUCTS THAT COMPLY THE SHELF LIFE MORE THAN 2 YEARS

Parameter of analyses

- Active Ingredient and relevant physical and chemical properties testing based on type of formulation according to Manual on Development and Use of FAO and WHO Specifications for Pesticides

Sample

- Samples shall be analyzed before and after testing using the same batch.
- taken from a batch that has passed quality control analysis.
- 2 samples must be prepared. One of the samples is treated in the oven, and the other one is a control sample which must be analyzed concurrently after the test

The packaging used

- based upon that in which the product is sold.
- observation of the effect on the packaging used must be reported.

Laboratory Facility

- Active Ingredient and relevant physical and chemical properties testing for storage stability studies are required to be performed in Good Laboratory practice (GLP) or ISO 17025

6. METHOD OF ANALYSES

Validated methods for determining the content of active ingredient and, relevant impurities.

Validation data shall be provided to confirm that the analytical procedures used give reliable and accurate results.

The type of validation data , typically includes demonstration of linearity over a suitable concentration range, repeatability, reproducibility, specificity, robustness, precision and accuracy.

Analytical methods described in official and recognized publications, such as CIPAC handbooks and the AOAC manual for pesticide products are regarded as validated and do not require revalidation. However, the suitability of these methods should be verified under actual conditions of use; that is, the specificity and accuracy of the method should be demonstrated for the published method when applied to the relevant sample matrix and laboratory conditions.

Validation of methods used to determine physical parameters will not be required, provided that CIPAC or equivalent accepted methods are used.

QUESTION PLS