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Thematic block:

PARALLEL IMPORT

Presentation title:

„THE MEANING OF „IDENTICALITY" OF PLANT PROTECTION PRODUCTS IN PARALLEL IMPORT AND PROBLEM WITH IMPORT CONTROL"

XI CEUREG Forum – Budapest, Hungary

24-25.10.2007

PARALLEL IMPORT – IDENTICALITY OF PLANT PROTECTION PRODUCTS (PPPs)

Why identicality of PPPs is crucial for the proper process of parallel import?

- **ambiguity of the word „identical”**
- **possible various interpretations by applicants and agencies allowing the products on the market**
- **possible abuse of the law leading to availability on the market of poor quality products posing a danger**
- **possibility of releasing counterfeit, unauthentic products**

EUROPEAN COMMISSION'S GUIDELINE

SANCO/223/2000 rev.9

6.12.2001

„Guideline developed within the Standing Committee on Plant Health concerning parallel trade of plant protection products within the EU and the EEA"

„the competent authority should verify, apart from the existence of a common origin, that the two plant protection products, if not identical in all respects, have at least been manufactured according to the same formulation, using the same active ingredient, and also have the same effect with due regard, in particular, to differences which may exist in conditions relating to agriculture, plant health and the environment, in particular climatic conditions, relevant to the use of the product".

EUROPEAN COMMISSION'S GUIDELINE – continued

„Identity" and „Common origin"

Plant protection products share a common origin when they (active substance and formulated product) „have been manufactured by the same company or by an associated undertaking or under licence" (paragraph 40).

EUROPEAN COMMISSION'S GUIDELINE – continued

„Identity" and „Same formulation"

The formulation type of the „reference" and the „parallel" products should be the same. As regards the type and amount of the ingredients, the batch-to-batch variations that can be expected in the manufacturing process are acceptable and should not lead to the denial of „identity".

As regards formulants, further variations should only be accepted if the two products for which „identity" is sought, continue to have the same effect with due regard to differences which may exist in conditions relating to agriculture, human and plant health and the environment, in particular climatic conditions, relevant to the use of the products.

EUROPEAN COMMISSION'S GUIDELINE – continued

„Identity" and „same active ingredient"

The active substance must have the same specifications and common origin as that already authorised in the Member States of importation.

Batch-to-batch variations in the amount, as can be expected in the manufacturing process (see FAO Guidelines and Annex VI of Directive 91/414), can be accepted.

PARALLEL IMPORT – LEGAL STATUS IN POLAND

The Act of 30th March, 2007 regarding changing the act on plant protection and some other acts (Dz. U. (legal register) of May 09, 2007):

Art. 47 a. 1. plant protection product allowed on the market of a different member state or a member country of EFTA, a party to the European Economic Area (EEA) agreement can be allowed on the market in Poland subject to a approval issued by the minister responsible for agriculture allowing the product on the market within the borders of the Republic of Poland, further called a "approval for parallel import"

2. approval for parallel market can be issued if:

1) the plant protection product is allowed on the market within the European Union or in a member state of EFTA, a party to the European Economic Area (EEA) agreement is identical to the plant protection product allowed on the market by the approval of the minister responsible for agriculture, mentioned in Art. 37, section 1.

LEGAL STATUS IN POLAND – continued

Art. 47 a. 3. the plant protection product allowed on the market in a different member state or in a member state of EFTA, a party to the European Economic Area (EEA) agreement is considered to be identical to the plant protection product allowed on the market by the approval of the minister responsible for agriculture, referred to in Art. 37, section 1, if:

1) **the product consists of the same and the same amount of active substances, other ingredients can differ slightly to a degree of not having an impact on human health, wildlife and the environment, or altering the efficacy of the product.**
2) **the product has the same formulation**

LEGAL STATUS IN POLAND – continued

3) quality requirements for the product are identical to the quality requirements of the PPP allowed on the market by the approval issued by the minister responsible for agriculture, referred to in Art. 37, section 1;
4) Physical and chemical properties of the product regarding its composition and minimum purity of the active substance are the same, taking into account the tolerances defined in regulations issued based on Art. 60.

IDENTICALITY WITH RESPECT TO ACTIVE SUBSTANCES

IN GENERAL: the same specification for active substance, meaning:

- **the same chemical compound**
- **the same physical and chemical properties**
- **the same technical requirements regarding minimum purity**
- **the same composition of impurities**

⇩

the same method of active substance synthesis

(possible: different origin – from different manufacturers)

IDENTICALITY WITH RESPECT TO ACTIVE SUBSTANCES – – continued

- If there are differences found in the composition of impurities

⇩

It is necessary to issue a toxicological opinion, based on the detailed data on qualitative and quantitative composition of impurities

⇩

Positive opinion – can the product be allowed on the market?

⇩

- Detailed chemical testing of the product is necessary to determine the differences in its composition of impurities.

IDENTICALITY WITH RESPECT TO FORMULATION

- The same type of formulation (e.g.: EC, WP, SC)
- The same ingredients of formulation (co-formulates)
- The same ratio of co-formulates
- The same physical and chemical properties
- The same quality requirements

⇩

Slight differences are allowable, provided that they do not interfere with product safety and efficacy

It is necessary to analyze the identicality of formulation

U.K. RULES ON IDENTICALITY (PSD)

The Applicant Guide: Parallel Import Procedure Annex A

PSD will consider products to be different for safety and efficacy reasons where:

- **There is any difference in the nature, percentage or specification of the active substance within the formulations,**
- **There are significant differences in the nature of some co-formulants such as solvents, dispersal agents, anti-foams and preservatives,**
- **Differences in the percentage of co-formulants within the formulations are such that data would be needed to approve the imported formulation,**

U.K. RULES ON IDENTICALITY (PSD) – continued

- There are differences in the formulations that would require different hazard and/or risk phrases to be specified,
- The formulation types are different

Where the manufacturer is not the same as the reference product, PSD will need to ask the regulatory authority for details of the technical specification of the actives in the formulation. These details will be verified against those approved for the UK reference product.

ILLEGAL AND COUNTERFEIT PLANT PROTECTION PRODUCTS AND PARALLEL IMPORT

- There is a danger that within the parallel import counterfeit products may find their way into the market

FAKE PRODUCTS:

- use generic active substances with increased level of impurities (higher hygienic and toxicological risk)

  example: trifluralin: max. content of N-nitroso-di-n-propyloamine 1 mg/kg

  carbendazim – DAF (max 3 mg/kg)

  HAF (max 0.5 mg/kg)

- use of generic inert substances as formulation ingredients (higher hygienic and toxicological risk)

5067 granstar 52/19-2

Sample Name:	**granstar 52/19-2**	*Injection Volume:*	**20.0**
Vial Number:	**1**	*Channel:*	**UV_VIS_1**
Sample Type:	**unknown**	*Wavelength:*	**225**
Control Program:		*Bandwidth:*	**1**
Quantif. Method:	**default**	*Dilution Factor:*	**1.0000**
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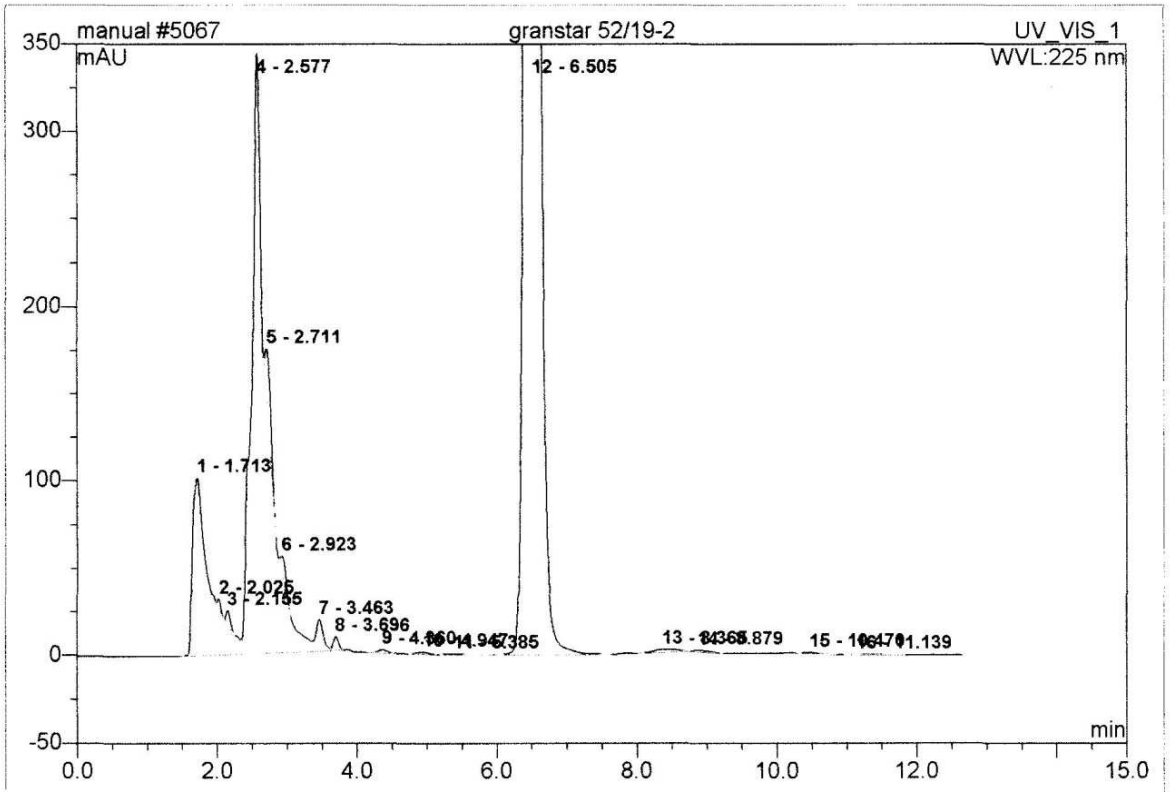
Run Time (min):	**12.65**	*Sample Amount:*	**1.0000**



5324 granstar 139/2-1

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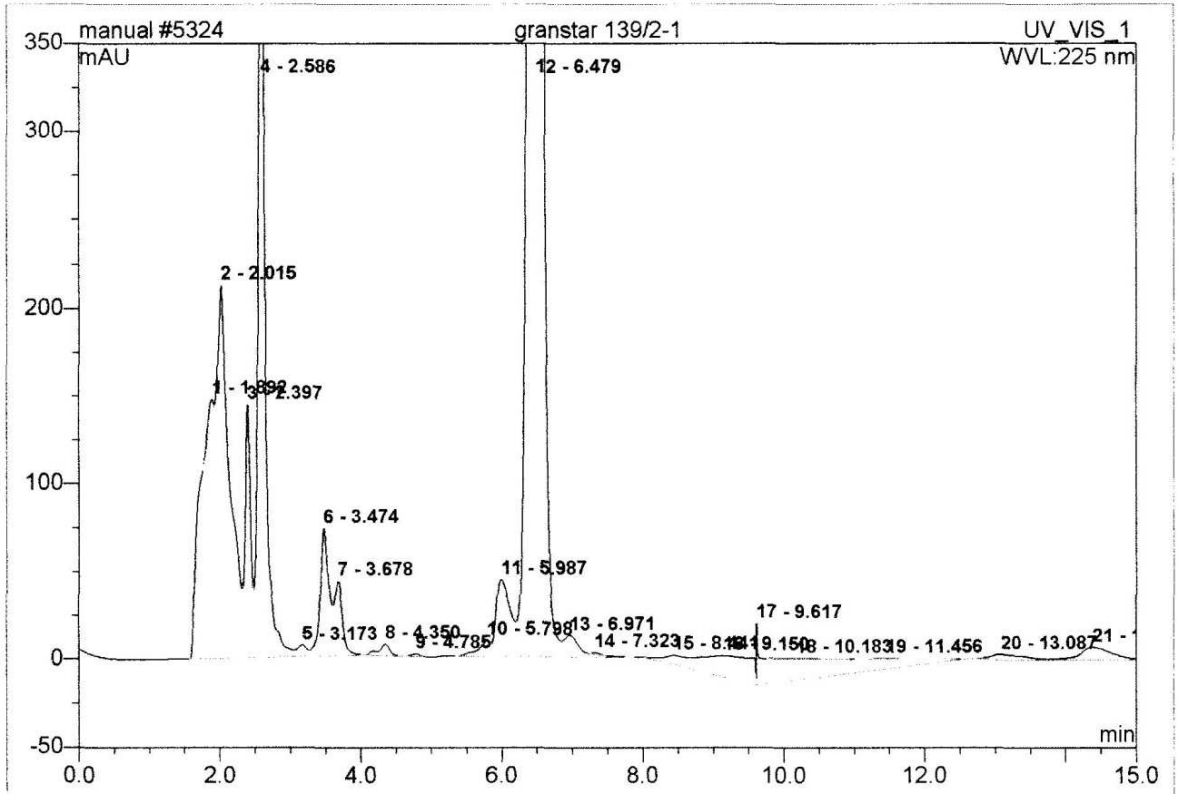

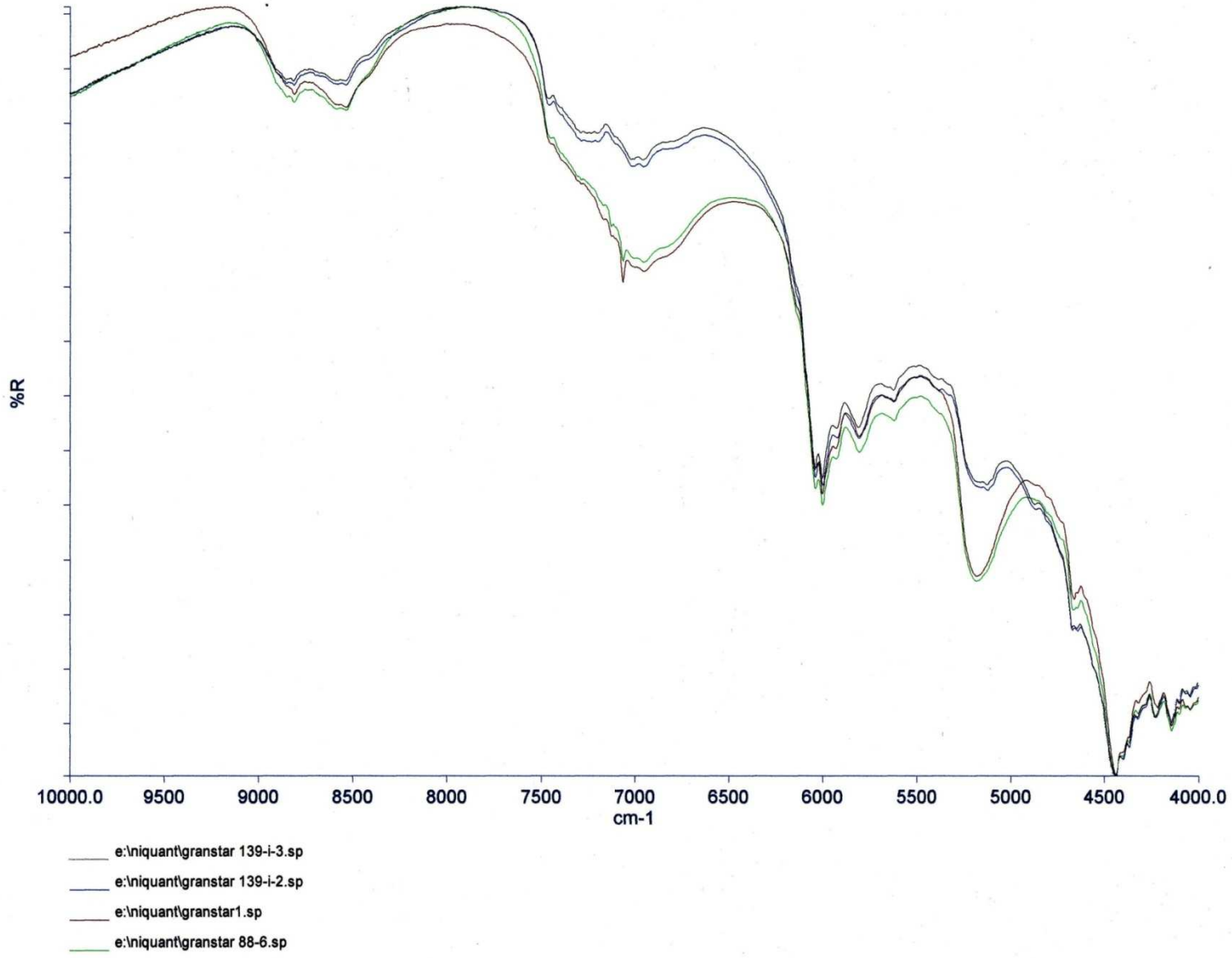
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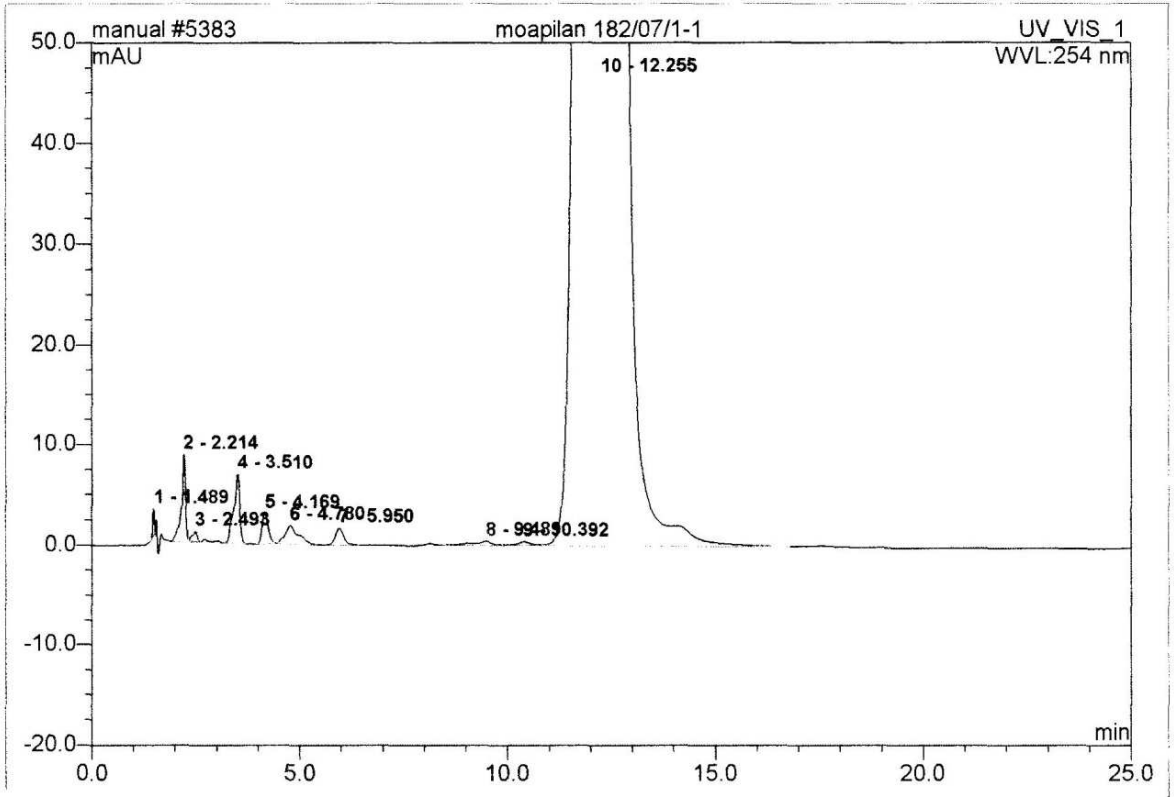
5383 moapilan 182/07/1-1

Sample Name:	**moapilan 182/07/1-1**	*Injection Volume:*	**20.0**
Vial Number:	**1**	*Channel:*	**UV_VIS_1**
Sample Type:	**unknown**	*Wavelength:*	**254**
Control Program:		*Bandwidth:*	**1**
Quantif. Method:	**default**	*Dilution Factor:*	**1.0000**
Recording Time:	**6/26/07 12:48**	*Sample Weight:*	**1.0000**
Run Time (min):	**57.47**	*Sample Amount:*	**1.0000**



5384 mospilan 27/07-1

Sample Name:	**mospilan 27/07-1**	*Injection Volume:*	**20.0**
Vial Number:	**1**	*Channel:*	**UV_VIS_1**
Sample Type:	**unknown**	*Wavelength:*	**254**
Control Program:		*Bandwidth:*	**1**
Quantif. Method:	**default**	*Dilution Factor:*	**1.0000**
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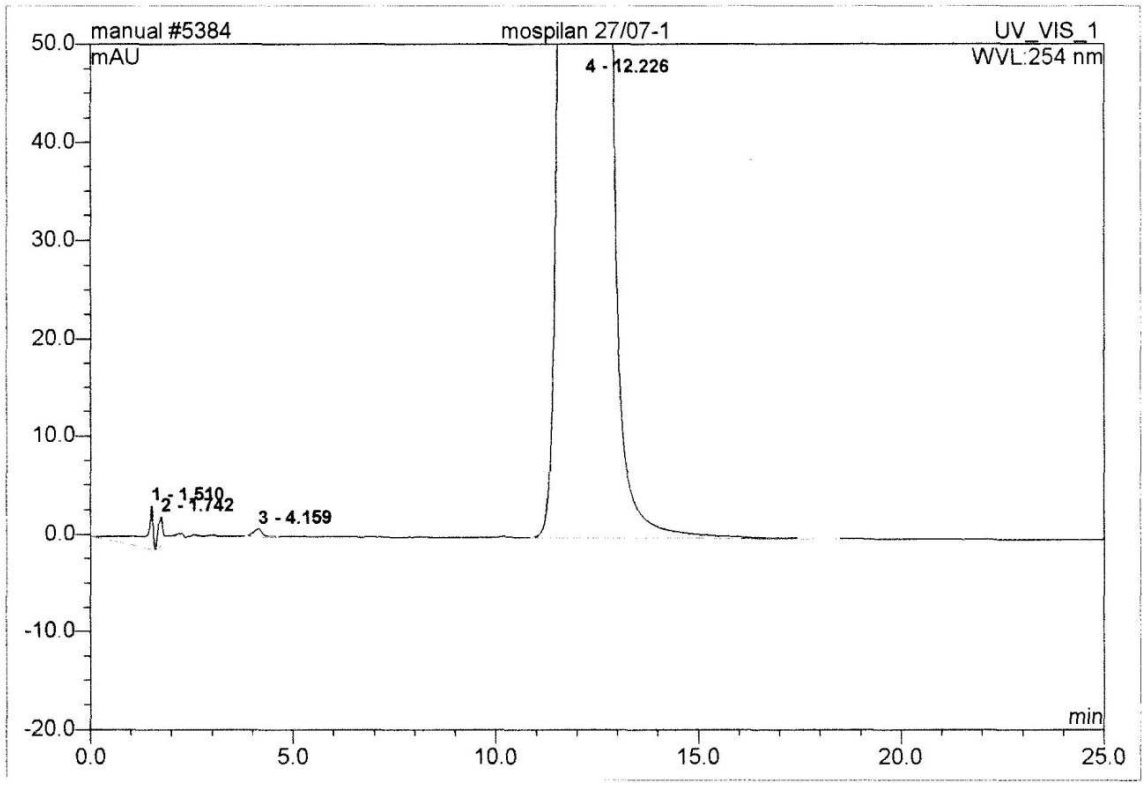
Run Time (min):	**34.02**	*Sample Amount:*	**1.0000**



5383 mospilan 182/07/1-1

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Vial Number:	**1**	*Channel:*	**UV_VIS_1**
Sample Type:	**unknown**	*Wavelength:*	**254**
Control Program:		*Bandwidth:*	**1**
Quantif. Method:	**default**	*Dilution Factor:*	**1.0000**
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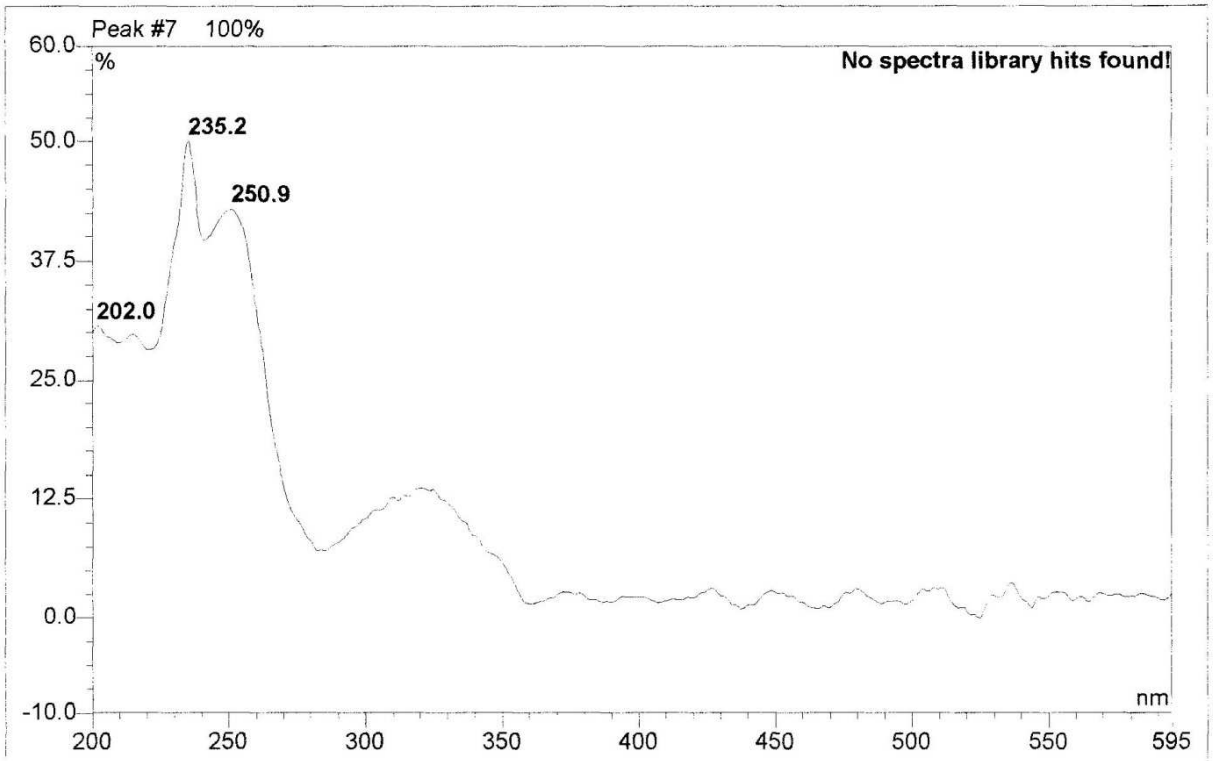
Run Time (min):	**57.47**	*Sample Amount:*	**1.0000**



5385 mospilan 27/07-1

Sample Name:	**mospilan 27/07-1**	*Injection Volume:*	**20.0**
Vial Number:	**1**	*Channel:*	**UV_VIS_1**
Sample Type:	**unknown**	*Wavelength:*	**254**
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Quantif. Method:	**default**	*Dilution Factor:*	**1.0000**
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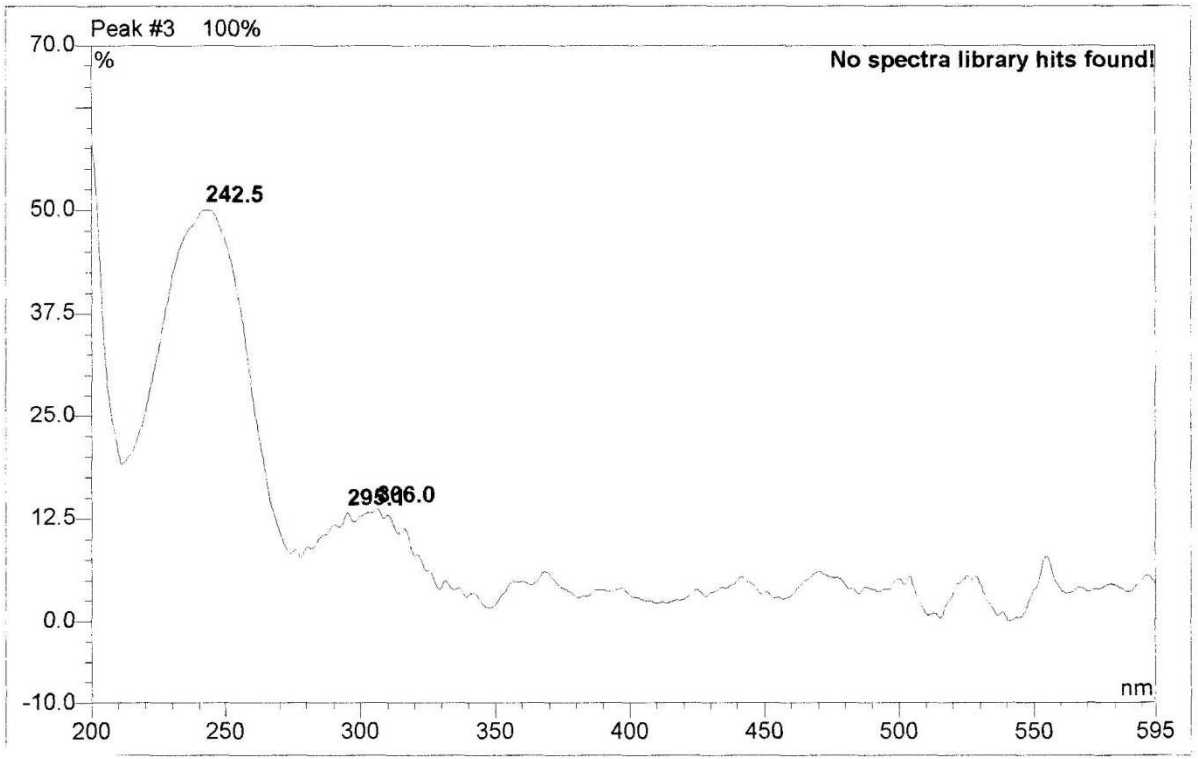

CONCLUSIONS

- There is a need for uniform interpretation of the identicality of plant protection products.
- There is a need to establish a control system for both the process of allowing the products on the market and after it has been allowed (control of samples from the market).
- The type and scope of control must allow for a detailed analysis of composition.
- It is necessary to exchange data among the countries on the irregularities detected in the process of parallel import.