Digitization of Label Information

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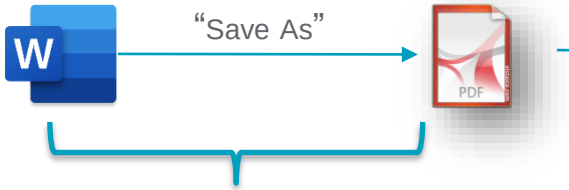
Out with the OLD……



Labels (GAP), Study Reports, Dossiers, etc.

Document Repositories (cloud, platform or local)

- Data is "hostage" to documents
- Manual transposition of data required for reuse

and in with the NEW……

Intelligent (structured) content

Manage

Storage of structured content / GAP data

Intelligent Publishing and Delivery Engine (SCA Platform)

Publish and Push

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Standardizing Label Format

- Enables use of structure content authoring
- Reduces text variability
- Enables granular capture (machine readable) of use and usage information
- Creates product end-user familiarity from consistent formatting
- Provides standard format for label preparation, amendment and review
- Enables directions for use tables for easy reading and understanding
- Enables standard text publishing rules in accordance with EPA guidelines
- Enables reuse of standard label text components across products
- Makes label information available *as data* for stakeholder access (growers, regulators, risk assessors, application equipment, FMSs, websites, eCSF, phone apps, e-catalogues, etc.)
- Enables efficient commercial label preparation (use of standard components)

Syngenta Label Reformatting
Product use directions

PEANUTS – DUAL II MAGNUM ALONE

Apply Dual II Magnum, either preplant incorporated, postplant incorporated, or preemergence, using the appropriate rate specified below. **Preplant Incorporated or Preemergence:** Follow instructions for use of Dual II Magnum alone under **Application Procedures. Postplant Incorporated:** Apply and shallowly incorporate Dual II Magnum into the soil after planting, but before peanut germination. Incorporation depth and incorporating implements must be kept above the seed, or seed will be damaged.

Apply Dual II Magnum alone, preplant incorporated, postplant incorporated, or preemergence, at a broadcast rate of 1.0-1.33 pts./A in the Southeast* and 0.8-1.33 pts./A in NM, OK, and TX.

*In the Southeast, use 1.33-2.0 pts./A and apply preemergence for partial control of Florida beggarweed.

Restrictions: (1) Dual II Magnum alone may be applied as directed after any of the following preplant incorporated herbicides when used according to their label recommendations: Balan at 3.0-4.0 qts./A; Treflan E.C. at 1.0 pt./A; Sonalan at 1.25-3.0 pts./A; Pursuit at 0.25 pt./A; or Prowl at 1.0-2.0 pts./A. (2) Do not graze or feed peanut forage or fodder to livestock for 30 days following application, and (3) Do not apply within 90 days of harvest, or illegal residues may result.

PEANUTS – DUAL II MAGNUM COMBINATIONS

TANK MIXTURE WITH BALAN L.C.

Dual II Magnum + Balan tank mixture applied preplant incorporated controls those weeds listed under **Dual II Magnum Applied Alone** and those weeds as listed on the Balan label.

Apply 1.0-1.33 pts./A of Dual II Magnum + 3.0-4.0 qts./A of Balan in a minimum of 10 gals. of spray volume per acre for ground application or in a minimum of 5.0 gals. of spray volume per acre for aerial application. Follow the recommended procedures for Balan on the Balan label for soil preparation and incorporation of this tank mix. Apply and incorporate Dual II Magnum + Balan up to 14 days prior to planting.

Original label = 83 pages

Revised label format = 63 pages

9.6 **Peanut**

9.6.1 Preplant Incorporated, Postplant Incorporated, Preemergence or Lay-by Applications

Crops (including cultivars, varieties, and/or hybrids)		
Peanut		
Application Timing	**Rate (pt/A)**	**Use Directions**
Preplant Incorporated **Postplant Incorporated**	Use the following rates for the specific geography *Southeast:* Apply 1.0 - 1.33 pt/A *NM, OK and TX:* Apply 0.8 - 1.33 pt/A Within the rate range, use lower rates on soils relatively coarse textured and higher rates on fine textured soils.	**For Preplant Incorporation:** Apply within 14 days before planting. Apply to the soil and incorporate into the top 2 inches of soil before planting using an implement capable of providing uniform incorporation. Use preplant incorporated application if furrow irrigation is used or when a period of dry weather after application is expected. If peanuts will be planted on beds, apply and incorporate after bed formation. **For Postplant Incorporation:** Apply and shallowly incorporate into the soil after planting but before peanut germination. Incorporation depth and incorporating implements must be kept above the seed, or seed will be damaged.
Preemergence **Lay-By**	Use the following rates for the specific geography *Southeast:* Apply 1.0 - 1.33 pt/A Apply 1.33 - 2.0 pt/A preemergence for partial control of Florida beggarweed. *NM, OK and TX:* Apply 0.8 - 1.33 pt/A Within the rate range, use lower rates on soils relatively coarse textured and higher rates on fine textured soils.	**Preemergence Application:** Apply after planting but before crop emergence. If applying at planting, apply behind the planter. **Lay-By Application:** Apply to the soil immediately after the last cultivation.
For Weed Control: • Refer to **Section 8.0** for list of weeds controlled or partially controlled.		
Tank Mix Options: • Refer to **Section 9.6.2** for tank mix application options.		
Resistance Management: • Refer to **Section 3.1**.		
Precaution: • Dual II Magnum will not control emerged weeds. Control emerged weeds with an appropriate registered foliar herbicide or by mechanical means.		
USE RESTRICTIONS		
1) Refer to **Section 7.1** for additional product use restrictions. 2) **Maximum Single Application Rate:** 2.0 pt/A 3) **Minimum Application Interval:** Not Applicable 4) **Maximum Annual Rate:** 2.0 pt/A/year a. **DO NOT** exceed 1.91 lb ai/A/year of *S*-metolachlor-containing products. 5) **DO NOT** graze or feed peanut forage or fodder to livestock for 30 days following application. 6) **Preharvest Interval (PHI):** 90 days		

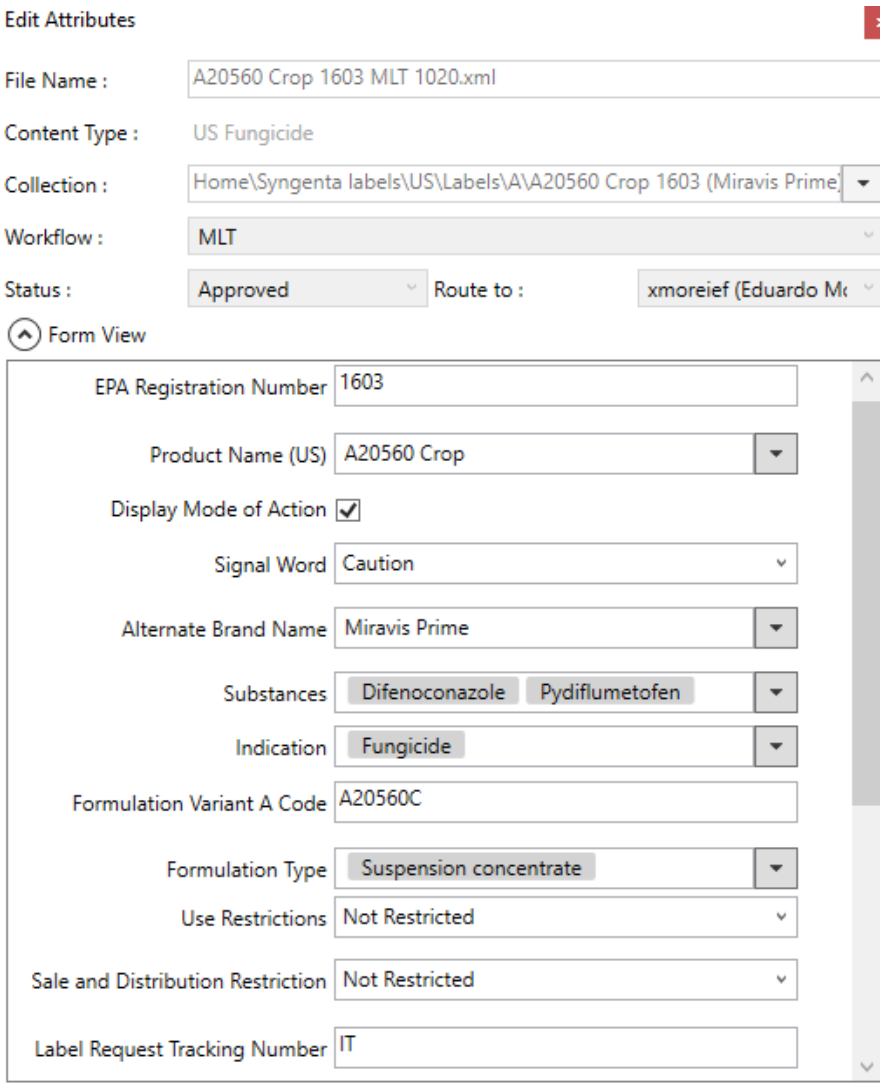
Structured Content Authoring (SCA) Process

Formulation/CSF
Product Name
Reg. Number
Label preparation workflow

Templates

Components

Master and Production Labels



Standardized Text Components

Authoring template

FIRST AID

First Aid Exposure

If swallowed

Call a poison control center or doctor immediately for treatment advice.

Have person sip a glass of water if able to swallow.

Do not induce vomiting unless told to do so by the poison control center or doctor.

Do not give anything by mouth to an unconscious person.

First Aid Exposure

If in eyes

Hold eye open and rinse slowly and gently with water for 15-20 minutes.

Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

Call a poison control center or doctor for treatment advice.

First Aid Exposure

If on skin or clothing

Take off contaminated clothing.

Rinse skin immediately with plenty of water for 15-20 minutes.

Call a poison control center or doctor for treatment advice.

First Aid Exposure

If inhaled

Move person to fresh air.

If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIAN

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

HOT LINE NUMBER

For 24-Hour Medical Emergency Assistance (Human or Animal)

Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident)

Call

1-800-888-8372

Published Label

1.0 FIRST AID

FIRST AID	
If swallowed	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If in eyes	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If inhaled	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
NOTE TO PHYSICIAN	
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal) Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**	

PRECAUTIONARY STATEMENTS

Granular capture of use and usage information

Authoring template

Brassica Head and Stem Vegetables, Crop Group 5-16

Crops (Including cultivars, varieties, and/or hybrids of these)

Broccoli Brussels sprouts	Cabbage	Cabbage, Chinese (napa)	Cauliflower

Rate Group (Row)

Target Pest

Beet armyworm Cabbage webworm Corn earworm Cross-striped cabbageworm Diamondback moth Fall armyworm Imported cabbageworm

Rate (oz/A)

2.4 - 4.8

[Target Pest]

Cabbage looper

Soybean looper

[Target Pest]

Suppression Only:

Liriomyza leafminers (*Liriomyza trifolii* and *Liriomyza sativae*)

[Rate]

3.2 - 4.8

Application Timing

Apply when larvae are first observed. Application may be repeated to maintain control.

Use Directions

Apply this product diluted in a minimum volume of 10 gal/A by ground. If the crop canopy is dense or the

Published Label

7.2 *Brassica* Head and Stem Vegetables, Crop Group 5-16

Crops (Including cultivars, varieties, and/or hybrids of these)			
Broccoli Brussels sprouts	Cabbage	Cabbage, Chinese (napa)	Cauliflower
Target Pest	**Rate (oz/A)**	**Application Timing**	**Use Directions**
Beet armyworm Cabbage webworm Corn earworm Cross-striped cabbageworm Diamondback moth Fall armyworm Imported cabbageworm	2.4 - 4.8	Apply when larvae are first observed. Application may be repeated to maintain control.	Apply this product diluted in a minimum volume of 10 gal/A by ground. If the crop canopy is dense or the
Cabbage looper Soybean looper	3.2 - 4.8		
Suppression Only: *Liriomyza* leafminers (*Liriomyza trifolii* and *Liriomyza sativae*)			

Label Digitization

Drivers

1) *The need to improve the regulatory submission, review and approval process for labels.*

2) *The need to capture label information, particularly use and usage information, in a digital, machine readable format for downstream applications and databases.*

Desired Outcomes

- *An agreed common format for regulated pesticide labels* to enable structured content authoring, reuse of label content and digitization of use and usage information.

- *Establishment of common data standards, structure/content models and vocabulary for all stakeholders*

- *Capture of label information at the correct level of detail*

- *Jointly developed solutions to* enable stakeholders to save resources

Application Equipment Manufacturers

US EPA OPPEL & PPLS, PPDC? AAPCO?

APVMA

PMRA Electronic Standardized Pesticide Label (ESPL)

Health Canada

AgGateway

NA/EU Closed Loop Spray Product Project

OECD EGEEPD

eLabel Data Standard

(eLDS)

OECD

ECHA EUROPEAN CHEMICALS AGENCY

IUCLID 6

CLE DIGITAL LABEL COMPLIANCE (DLC)

CropLife EUROPE

HESI

CROP LIFE INTERNAT'I

CropLife INTERNATIONAL

EU Commission

PPAMS

European Commission

?

Other players?

<dita>

(document standards)

UNITED NATIONS

GHS

Cristal

European Crop Protection

and CLE

EU Commission

DG GRO F2

European Commission

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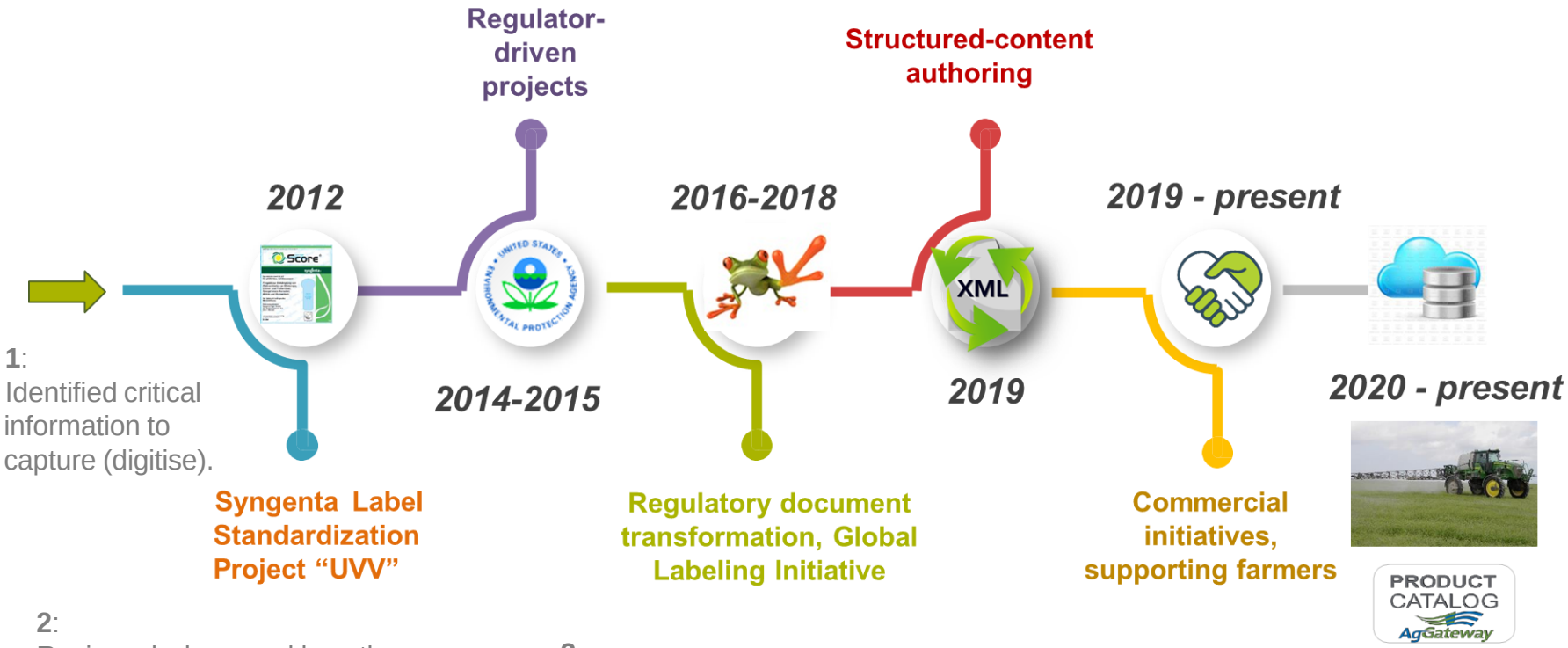
Thank You!

Appendix – Back up slides

The Syngenta Label Digitization Journey: things we learned along the way



1:
Identified critical information to capture (digitise).

2:
Reviewed where and how the critical information was presented in the then-current labels.
Single country focus.

3:
Extended the analysis and review to global focus: all countries and labels; processes, governance, label structure, regulatory requirements.

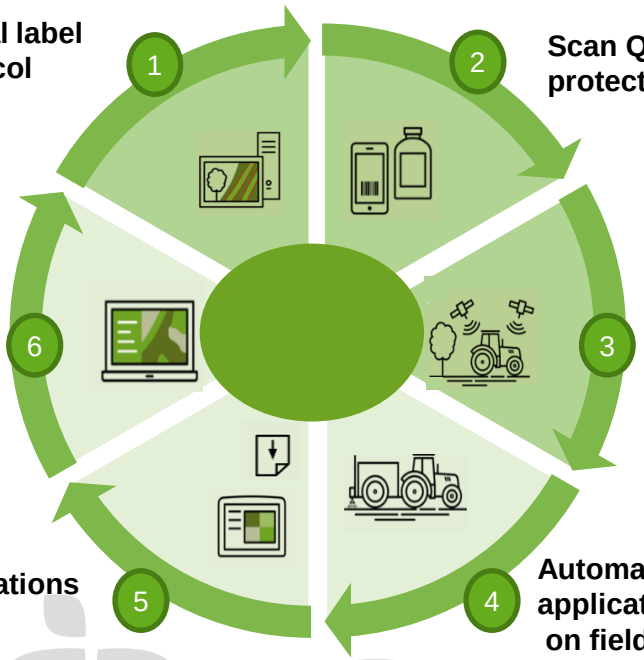
4:
Piloted structured-content label authoring platform implemented with 6 countries.

5:
Platform extended:
- data pipelines to digital apps,
- GAP/directions-for-use information model,
- detailed input UI for use info. Interoperable/reusable information!

Digital Label Compliance

Digital Label Compliance (DLC) aims to de-risk growers and reduce complexity in dealing with the handling and application of Plant Protection Products by increasing label comprehension *via* digital, machine-readable labels. The automated application of Plant Protection Products according to the digital label considering the geolocation and conditions of a grower's field and the subsequent recording of spray operations is maintaining a high-level of protection for human health and the environment while de-risking growers.

The Digital Label Compliance concept is a six-step process:



1. **Registered digital label incl. spray protocol and IPM**
2. **Scan QR code on crop protection label**
3. **Aggregate registered spray protocol conditions with field specific data**
4. **Automatic application on field**
5. **Document on-field operations**
6. **Improve farming Operations incl. compliance with IPM**

Scope:

- Cross-industry concept open to all relevant stakeholders
- All Plant Protection Products
- All EU Member States
- All farmers including high-tech adopters with digital ag and precision application equipment and low-tech adopters without these technologies
- Pre-competitive - legal compliance
- Elements of CP application in relation to Integrated Pest Management (IPM)

Potential future scope:

- Advanced IPM recommendations

Crop Life International

Crop Life International promotes a harmonized approach (common format for dealing with label information, harmonized label elements).

- Jointly developing and/or building on existing solutions avoids the need to “reinvent the wheel”, enabling regulators and industry alike to save resources, for example to
  - Increase efficiency
  - Ease compliance

- Reduced heterogeneity leading to reduced complexity for
  - Manufacturers of plant protection products
  - Providers of machinery and farm management systems
  - Farmers

- Removing unnecessary complexity from food supply chains

Suggestions have been made concerning potential EGEEPD workplan (see appendix slide)

Structured Content Authoring (SCA)
MS Word add-on for user familiarity

Authoring template

Published Label

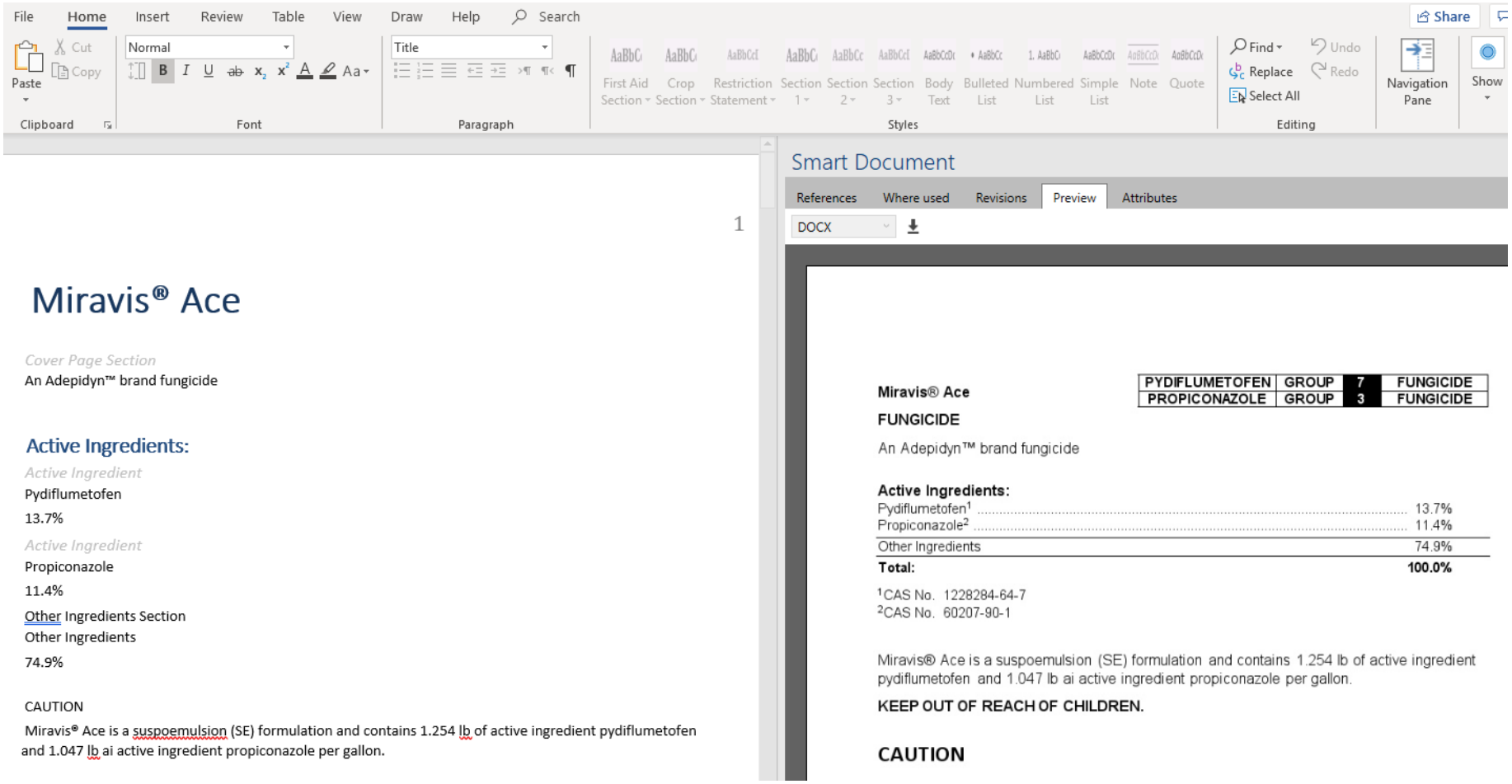


Table of Contents

Section numbering automated ensuring cross references updates

TABLE OF CONTENTS

Cross-references and placeholders – content reuse

Authoring template

PRODUCT INFORMATION

Product Name (US) is only allowed for use in soybeans resistant to mesotrione. It may be applied preplant, preplant incorporated, or preemergence for control of many annual grass and broadleaf weeds. It will provide control of weeds resistant to ALS inhibitors (Group 2), PPO inhibitors (Group 14), and glyphosate (Group 9).

Product Name (US) is a combination of the herbicides s-metolachlor and mesotrione. See WEEDS CONTROLLED OR PARTIALLY CONTROLLED BY Product Name (US) for list of weeds controlled or partially controlled by Product Name (US). This product should be used in combination with other herbicides as part of a weed management program for full season weed control and resistance management. A postemergence application of an herbicide with a different target site of action registered for use in soybeans will maximize weed control and delay development of herbicide resistance.

Published Label

3.0 PRODUCT INFORMATION

A22089 is only allowed for use in soybeans resistant to mesotrione. It may be applied preplant, preplant incorporated, or preemergence for control of many annual grass and broadleaf weeds. It will provide control of weeds resistant to ALS inhibitors (Group 2), PPO inhibitors (Group 14), and glyphosate (Group 9).

A22089 is a combination of the herbicides s-metolachlor and mesotrione. See Section **8.0** for list of weeds controlled or partially controlled by A22089. This product should be used in combination with other herbicides as part of a weed management program for full season weed control and resistance management. A postemergence application of an herbicide with a different target site of action registered for use in soybeans will maximize weed control and delay development of herbicide resistance.

Capture of Product Name (A22089) as metadata enables automated population of this information in the published label.

Component references

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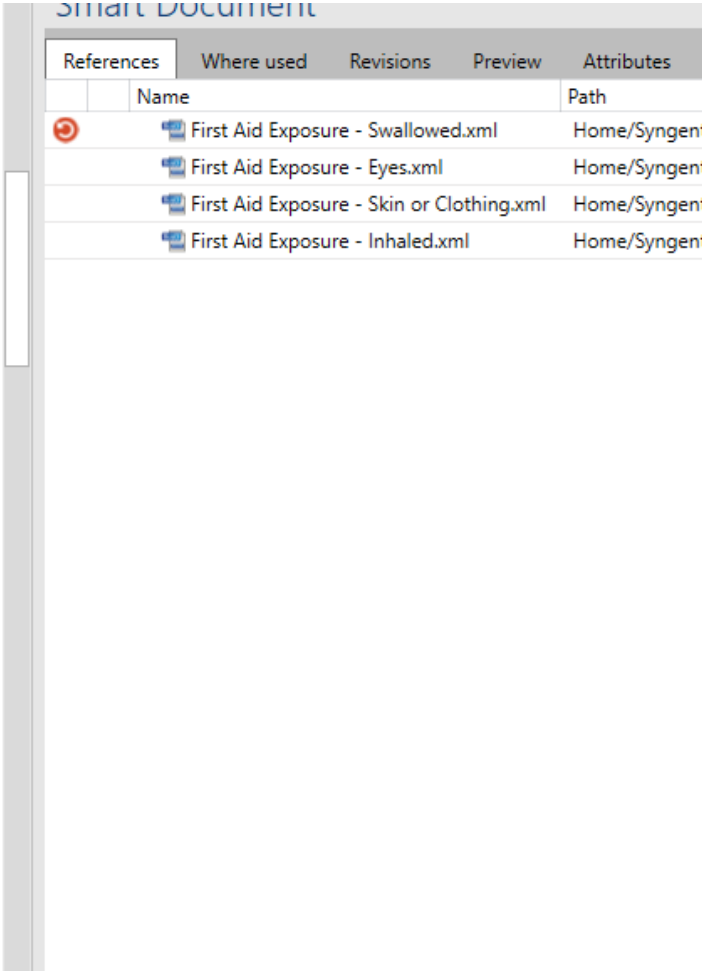

Intelligent Content & Publishing Engines

Existing Syngenta Labels

Reformat Labels to Standard Format agreed by US EPA

Submit Reformatted Labels to US EPA for approval

Approved Syngenta Labels (Standardized Format)

Convert

Syngenta Labels as Structured Content (XML)

Manage

Storage of Label Components and Data (XML)

Publish

User Defined Publishing (MS Word, PDF, Web Apps, EPA OPPEL, WDL, etc.)

Links to drones, apps, databases, websites, etc.

Value Proposition: Label Digitization

Co-developing label standards creates efficiencies and results in cost savings across agencies, industry and stakeholders while enabling:

- More efficient regulatory submission, review and approval of product labels
- Digital capture of worst-case use and usage parameters required for regulatory risk assessment activities
- Digital capture of actual usage information to refine risk assessment
- Improved stewardship and compliance through easier access to key label information – ‘smart’ stewardship support, fewer incidents, automated real-time capture of application information
- Product application by automated equipment in the field using digitized parameters

- Standardization of label formats, vocabulary and content is key to enabling digitization of label information for downstream applications by regulators, growers and industry partners
- Unifying label standards across the regulatory landscape would result in a consistent, uniform label standard to which industry and industry stakeholders would have to adhere