Council of Producers & Distributors of Agrotechnology

BECAUSE
ADVOCACY MATTERS

CPDA ADJUVANT CERTIFICATION STANDARDS

ADOPTED 9/13/2023

S = Standard

(S-1) - Product functionality claims described in labels and promotional materials must be consistent with the definitions described in the ASTM E-1519 "Standard Terminology Relating to Agricultural Tank Mix Adjuvants" and/or ASTM E-609 "Standard Terminology Relating to Pesticides."

(S-2) - New product functionality claims must be submitted to and adopted by the ASTM E-35 committee into the ASTM E-1519 or E-609 prior to use in product labels and/or promotional literature.

(S-3) - All products submitted for certification that are intended for direct application to food crops must contain only those components the U.S. Environmental Protection Agency (EPA) has approved and listed for such use in 40 CFR part 180 or by the Food and Drug Administration in 21 CFR.

(S-4) - Product labeling and packaging must be compliant with applicable U.S. Department of Transportation (DOT) regulations based on chemical, physical, and toxicological properties of the packaged product.

(S-5) - Products that contain substances in concentrations identified by the Occupational Safety and Health Administration (OSHA) as being a regulated hazardous material must disclose the presence of such substances on the Safety Data Sheet (SDS).

(S-6) - Product SDSs must be registered with a data service that is accessible 24 hours a day via a toll-free number. The service must be accessible by the U.S. Poison Control Center.

(S-7) - Product Hazard Signal Words regarding acute toxicity must be assigned based on the results of scientifically valid studies for oral toxicity, dermal toxicity, and eye irritation as required by the Occupational Safety and Health Administration's current Hazard Communication Standard (see 29 CFR § 1910.1200 and Appendices A, B, and C of that section). The required Signal Word is determined by the most severe toxicity category to which a product is assigned based on the results of applicable acute toxicity studies. (see Appendix 1 of this Schedule B).

(S-8) - All applicable Hazard Communication Standard first aid, handling, and storage requirements, as well as protective equipment recommendations, must be included on the product label. Such recommendations must be consistent with the results of the acute toxicity tests and product SDS.

(S-9) - Products specifically recommended for use with pesticides in aquatic applications must have aquatic toxicity assessment data generated in accordance with OCSPP Harmonized Test Guidelines Series 850 - Fish and Invertebrate. Label use rate recommendations must not exceed levels potentially hazardous to aquatic organisms, as determined by the assessment data.

(S-9a) – For products not intended for aquatic use, the label must indicate this with the statement or a statement similar to: "NOT FOR AQUATIC USE"

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(S-10) - Only Principal Functioning Agents that contribute to a product's claimed functionality, and which serve functions as defined in ASTM Standards E-1519 or E-609, may be claimed on product labels as part of the Principal Functioning Agent guarantee. Principal Functioning Agents must each be listed by a discreet chemical descriptor. For example, generic terms such as XYZ blend, XYZ solution, or surfactant, cannot be used as descriptors for Principal Functioning Agents.

(S-11) The top 3 Principal Functioning Agents must be listed in descending order and support the functions claimed on the label.

(S-11-a) The exception to this is when only 1 or 2 Principal Functioning Agents are required to perform the claimed functions then only 1 or 2 will be required on the label.

(S-11-b) A Statement of Certification must be completed to verify the product formulation is true and accurate to perform the claimed functions.

(S-12) - When claimed as part of the functioning agents, the percentage of surfactant must be displayed on labels if the intended functionality includes reference to a surfactant, spreader, or wetting agent. Those formulation components claimed as surfactants must be water dispersible substances that reduce the surface tension of water to 45 dynes/cm or less at 0.5% w/w (ASTM method D-1331). Formulation components are defined as individual raw ingredients in their stand-alone form, and not as blends.

(S-12-1) Claims not supported by the top 3 Principal Functioning Agents may also be made on the label by meeting the following:

(S-12-1a) List additional Principal Functioning Agents which support the additional claims and certify those components are in the formulation at a proper concentration to perform the claimed function OR

(S-12-1b) Provide supporting data utilizing ASTM approved testing methods, or other field or lab trials, which are acceptable to other regulatory agencies and verify the functions claimed are being performed by the product.

(S-13) - Oil-based spray adjuvant labels must describe the type(s) of oil utilized in the product in accordance with ASTM Standardized Terminology. Products using two or more types of oil must list them within the label guarantee in descending order of their compositional content.

(S-14) – Phyto-bland, paraffinic oil, and petroleum-based spray adjuvants must list the Unsulfonated Oil Residue (UR) value of the oil component on the product label.

(S-15) - The Manufacturer of certified spray adjuvants should be consistent with the industry standards for "Good Manufacturing Practices."

(S-16) - Manufacturers receiving certification for a particular product must reapply for certification if a chemical or compositional change of the product impacts one or more of the standards listed in (S-1) through (S-16). Recertification is also required if new information and/or manufacturing changes impact the principal functioning agents, toxicity, and/or safety aspects of the product.

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APPENDIX 1

Acute Oral & Dermal Hazard Classifications	Toxicity Categories				
	Category 1 (DANGER)	Category 2 (DANGER)	Category 3 (DANGER)	Category 4 (WARNING)	*Category 5 (NO SIGNAL WORD)
Oral Toxicity (mg/kg body weight)	$LD_{50} \leq 5$	$5 < LD_{50} \leq 50$	$50 < LD_{50} \leq 300$	$300 < LD_{50} \leq 2000$	$2000 < LD_{50} \leq 5000$
Dermal Toxicity (mg/kg body weight)	$LD_{50} \leq 50$	$50 < LD_{50} \leq 200$	$200 < LD_{50} \leq 1000$	$1000 < LD_{50} \leq 2000$	$2000 < LD_{50} \leq 5000$

Eye Irritation/Corrosion Hazard Classifications	Toxicity Categories				
	Category 1 (DANGER)	Category 2/2A (WARNING)	Category 2B (WARNING)	N/A	*Category 5 (NO SIGNAL WORD)
Eye Irritation/Corrosion	See Footnote 1	See Footnote 2	See Footnote 3	---------	NO EFFECT

[1]A substance is classified as Serious Eye Damage Category 1 (irreversible effects on the eye) when it produces: (a) at least in one tested animal, effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days; and/or (b) at least in 2 of 3 tested animals, a positive response of: (I) corneal opacity ≥ 3; and/or (ii) iritis > 1.5; calculated as the mean scores following grading at 24, 48, and 72 hours after installation of the substance.

[2]A substance is classified as Eye Irritant Category 2A (irritating to eyes) when it produces in at least in 2 of 3 tested animals a positive response of : (i) corneal opacity ≥ 1; and/or (ii) iritis ≥ 1; and/or (iii) conjunctival redness ≥ 2; and/or (iv) conjunctival oedema (chemosis) ≥ 2 calculated as the mean scores following grading at 24, 48, and 72 hours after installation of the substance,and which fully reverses within the observation period of normally 21 days.

[3]Within Category 2A an eye irritant is considered midly irritating to eyes (Category 2B) when the effects listed above are fully reversible within 7 days of observation.

* "Category 5" (no signal word) is only allowed when results from testing of all routes of exposure result in a category that does not require a signal word for each particular route:
Oral: Category 5 - LD50 ≤ 5000
Dermal: Category 5 - LD50 ≤ 5000
Eye Irritiation: Category 5 - no effects
Inhalation: Category 5 - Dusts & Mists LC50≤ 5.0; Vapors (mg/L) LC50≤ 20.0; Vapors (ppm/L) LC50≤ 20000
Dermal Corrosion/Irritation: Category 5 - no effects

*A product meeting all of the above Category 5 criteria is not classified as hazardous and does not require a Signal Word on the label under GHS. however, it is recommended a statement be included on a Category 5 label such as : **"Not classified as hazardous according to GHS" or "Toxicity end points for this product exceed classification under GHS and it is being labeled under previous regulations".**

Please Note: Acute Inhalation and Dermal Corrosion/Irritation toxicity studies are not required for CPDA Certification, however should either one or both of these studies be included with applicants application for CPDA Certification, the label signal word shall be determined according to the information detailed in the tables and accompaning footnotes below.

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Acute Inhalation Hazard Classifications	Toxicity Categories				
	Category 1 (DANGER)	Category 2 (DANGER)	Category 3 (DANGER)	Category 4 (WARNING)	*Category 5 (NO SIGNAL WORD)
Dust and Mists (mg/L)	≤0.05	>0.05 LC_{50} ≤0.5	>0.5 LC_{50} ≤1.0	>1.0 LC_{50} ≤5.0	See Footnote 4
Vapors (mg/L)	≤0.5	>0.5 LC_{50} ≤2.0	>2.0 LC_{50} ≤10.0	>10.0 LC_{50} ≤20.0	See Footnote 4
Vapors (ppm/L)	≤100	>100 LC_{50} ≤500	>500 LC_{50} ≤2500	>2500 LC_{50} ≤20000	See Footnote 4

[4]Criteria for Category 5 are intended to enable the identification of substances which are of relative low acute toxicity hazard but which under certain circumstances may present a danger to vulnerable populations. These substances are anticipated to have an oral or dermal LD_{50} in the range of 2000 - 5000 mg/kg body weight and equivalent doses for inhalation. The specific criteria for Category 5 are:

i) The test item is classified in this category if reliable evidence is already available that indicates the LC_{50} to be in the range of Category 5 values or other animal studies or toxic effects in humans indicate a concern for human health of an acute nature.

ii) The test item is classified in this category through extrapolation, estimation or measurement of data, if assignment to a more hazardous category is not warranted, and

-Reliable information is available indicating significant toxic effects in human; or

- Any mortality is observed when tested up to Category 4 values by oral, inhalation or dermal routes; or

- Where expert judgement confirms significant clinical signs of toxicity, when tested up to Category 4 values, except for diarrhoea, piloerection, or an ungroomed appearance; or

- Where expert judgement confirms reliable information indicating the potential for significant acute effects from other animal studies.

Dermal Corrosion/Irritation Hazard Classifications	Toxicity Categories				
	Category 1 (DANGER)	Category 1A, 1B, 1C (DANGER)	Category 2 (WARNING)	Category 3 & 4 (N/A)	*Category 5 (NO SIGNAL WORD)
Dermal Corrosion/Irritation	Destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one test animal after exposure ≤ 1h	See Footnote 5	See Footnote 6	---------	NO EFFECT

[5]The Corrosion/Dermal Category 1 may be further divided into three sub-categories (1A, 1B, and 1C) which can be used by those authorities requiring more than one designation for corrosivity.Corrosive test item should be classified in category 1 where sub-categorization is not required by a competent authority or where data are not sufficient for sub-categorization. When data are sufficient and where required by a competent authority test item may be classified in one of the three sub-categories (1A, 1B, 1C) in accordance with the criteria as per the table below.

Sub-Category 1A	Corrosive responses in at least one animal following exposure ≤ 3 min during and observation peroid ≤ 1h
Sub-Category 1B	Corrosive responses in at least one animal following exposure > 3 min and ≤ 1 h and observations ≤ 14 days
Sub-Category 1C	Corrosive responses in at least one animal following exposure > 1h min and ≤ 4 h and observations ≤ 14 days

[6]**Category 2: Dermal Corrosion/Irritation is the production of reversible damage to the skin following the application of a test substance for up to 4 hours with results as follows:**

(1) Mean score of ≥ 2.3 and ≤ 4.0 for erythema/eschar or for oedema in at least 2 of 3 tested animals from grading at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or

(2) Inflammationthat persist to the end of the observation period normally 14 day in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyper plasia, and scaling; or

(3) In some cases where there is pronounced variability of response among animals, with very difinite positive effects related to chemicals exposure in a single animal but less than the criteria above.